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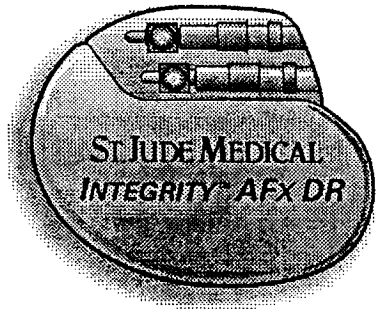

INTEGRITY™ AFx DR
Model 5346

Dual Chamber Pulse Generator
with AUTOCAPTURE™ Pacing System

User's Manual

USER'S MANUAL

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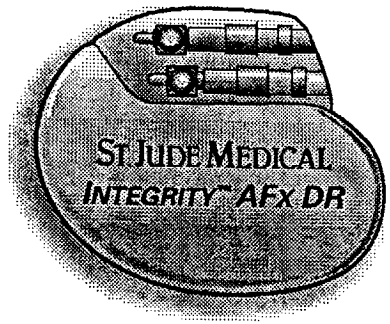

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User's Manual

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

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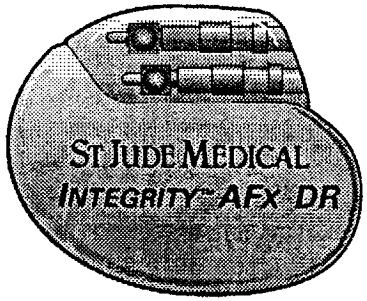

Figure 1. Integrity AFx DR Model 5346

DESCRIPTION

The Integrity™ AFx DR Model 5346 dual-chamber pulse generator is an implantable, multi-programmable, mode-switching pacing device.

These devices are equipped with a number of automatic rate-adjusting algorithms, patient safety features, and an extensive offering of diagnostic tools and tests, including:

- the AutoCapture™ Pacing System, which automatically sets the ventricular pulse amplitude and regularly adjusts the setting according to the patient's measured capture threshold
- Dynamic Atrial Overdrive™ (DAO), a unique automatically-adjusting pacing algorithm intended to suppress atrial arrhythmias
- an advanced hysteresis response which provides the user a means to periodically search for intrinsic rate and to respond to a sudden drop in the intrinsic rate with user-programmable *Intervention Rate* and *Duration*
- noninvasive EP testing (NIPS) without the need for an external stimulator

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- the Omnisense™ accelerometer activity sensor which provides rate-modulated pacing.

More information on the programming of these and other features can be found in the Bradycardia Reference Manual.

The device's lead connector is IS-1/VS-1compatible. A single setscrew for each lead secures the pin within the connector.

Integrity pulse generators can be programmed with the Model 3510/3500 Programming System equipped with Model 3307 software or higher.

Note

The AutoCapture Pacing System requires a compatible low polarization lead. For more information, see the Bradycardia Reference Manual.

INDICATIONS AND USAGE

Implantation of the Integrity pulse generator is indicated in the following permanent conditions, when associated with symptoms including, but not limited to:

- syncope
- presyncope
- fatigue
- disorientation
- or any combination of those symptoms.

Rate-Modulated Pacing is indicated for patients with chronotropic incompetence,[1] and for those who would benefit from increased stimulation rates concurrent with physical activity.

Dual-Chamber Pacing is indicated for those patients exhibiting:

- sick sinus syndrome
- chronic, symptomatic second- and third-degree AV block
- recurrent Adams-Stokes syndrome

1. Chronotropic incompetence has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 70% of the age-predicted maximum heart rate or 120 ppm during exercise testing, whichever is less, where the age-predicted heart rate is calculated as 197 – (0.56 x age). Gwinn N, Leman R, Kratz J, *et al.* Chronotropic incompetence: A common and progressive finding in pacemaker patients. *American Heart Journal* 1992; 123:1216-19.

- symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out

Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems.

Ventricular Pacing is indicated for patients with significant bradycardia and:

- normal sinus rhythm with only rare episodes of A-V block or sinus arrest
- chronic atrial fibrillation
- severe physical disability.

Dynamic Atrial Overdrive is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

For specific indications associated with individual modes, refer to "Operating Modes" on page 22.

CONTRAINDICATIONS

Implanted cardioverter-defibrillator (ICD). Because Integrity pulse generators will be automatically programmed to a unipolar pulse configuration if the device initiates Backup VVI pacing, the Integrity is contraindicated in patients with an implanted cardioverter-defibrillator (ICD).

Rate-Modulated Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate *Maximum Sensor Rate* should be selected based on assessment of the highest stimulation rate tolerated by the patient.

Dynamic Atrial Overdrive stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation.

Dual-Chamber Pacing, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients.

Single-Chamber Ventricular Demand Pacing is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction, or suffer a drop in arterial blood pressure with the onset of ventricular pacing.

Single-Chamber Atrial Pacing is relatively contraindicated in patients who have demonstrated compromise of AV conduction.

For specific contraindications associated with individual modes, refer to "Operating Modes" on page 22.

WARNINGS

To prevent permanent damage to the pulse generator and tissue damage at the electrode/tissue interface:

- ***Electrosurgery.*** Do not use electrosurgical devices in the vicinity of an implanted pulse generator. If electrocautery is necessary, use a bipolar cauterizer or place the indifferent electrode as far from the pulse generator as possible.
- ***Lithotripsy.*** Do not focus a lithotripsy beam within six inches of the pulse generator. Program the pulse generator to *Sensor* Off prior to lithotripsy to prevent inappropriate increases in pacing rate. A thorough assessment of pulse generator function with special attention to the sensor should be performed following exposure to lithotripsy.
- ***Therapeutic Radiation.*** Do not use ionizing radiation in the vicinity of an implanted pulse generator. Radiation therapy may damage the electronic circuitry of the pulse generator.
- ***Ultrasound Treatment.*** Do not use therapeutic ultrasound within six inches of the pulse generator.

Perform a thorough assessment of pulse generator function following exposure to any of the above.

Backup VVI Operation. The device will be reprogrammed to Backup VVI settings (Table 1) if the microprocessor and/or device software ceases to function.

These default settings cannot be changed.

Parameter	Value
Mode	VVI
Base Rate	67.5 ppm
Pulse Configuration	Unipolar
Sense Configuration	Unipolar Tip
Pulse Amplitude	4.0 V minimum
Pulse Width	0.6 ms
Refractory Period	320 ms
Sensitivity	2.0 mV

Table 1. Backup VVI Settings

When a device in Backup VVI is interrogated by the Model 3510/3500 programmer, a message will be displayed on the programmer screen that the unit is operating in Backup VVI. Follow the on-screen instructions or contact your St. Jude Medical representative immediately.

Recommended Replacement Time (RRT). At RRT, the nominal life of the pulse generator is three months. When the pacemaker exhibits signs of RRT, described on page 39, it should be replaced expeditiously.

Patient follow-up visits should be scheduled at an appropriate frequency so that RRT can be detected well before EOL.

Noninvasive EP Testing (NIPS). Life-threatening ventricular tachycardia or fibrillation may occur during NIPS, therefore: (1) closely monitor the patient, and (2) make defibrillation and resuscitation equipment, and trained personnel, readily available during testing. Only physicians trained in tachycardia induction and reversion protocols should use NIPS. For more information on NIPS, see the Bradycardia Reference Manual.

Ventricular Support Pacing during NIPS testing is delivered in the VOO mode. The specific indications and contraindications for VOO mode can be found on page 25.

PRECAUTIONS

- For single use only.

Sterilization

- Do not implant or resterilize a pulse generator that has been contaminated by contact with body fluids.
- Do not resterilize the pulse generator more than once.
- Do not implant a pulse generator from a damaged package without resterilizing it.
- To sterilize the pulse generator, use ethylene oxide gas at temperatures not exceeding 50° C (122° F), according to the sterilizer manufacturer's instructions. Allow proper aeration per local and national ordinances.[2]
- Do not sterilize the pulse generator with an autoclave, steam, gamma radiation, or ultrasonics.

2. See also AAMI GVR-1987, *Good Hospital Practice: Ethylene Oxide Gas – Ventilation Recommendations and Safe Use.*

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- Resterilization of a pulse generator does not change the "use before" date established at the time of manufacture.

Storage and Handling

- ***Mechanical Shock.*** Integrity pulse generators are ruggedly constructed. However, if you suspect the pulse generator has been damaged, do not implant it; return it to the manufacturer.
- ***Temperature.*** Do not subject the pulse generator to temperatures above 50° C (122° F) or below –5° C (23° F). Exposure to temperatures below 0° C may cause false RRT indications. Following exposure to extreme temperatures, warm the device to room temperature. If RRT indications are still present, return the pulse generator to the manufacturer.
- ***Incineration.*** Do not incinerate the pulse generator.

Preparation for Implantation

- ***Package Label.*** Before opening the sterile package, carefully read the label and verify that the package contains the desired pulse generator.
- ***Verifying Operation.*** Before opening the sterile package, verify that the pulse generator is operating properly by interrogating it in the package. Remove the magnet and position the Model 3510/3500 programmer telemetry wand over the package and select "Interrogate." Then, select the "Meas. Data/Diagnostics" tab. The unit's Measured Data should indicate normal voltage and battery status, and the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 13 on page 42.
- ***Package Integrity.*** Ensure that the package has not been opened or in any way compromised. If damage is suspected, return it to the manufacturer.
- ***"Use Before" Date.*** Do not implant the pulse generator after the "use before" date printed on the label.
- ***Opening the Package.*** If interrogation of the device in its sterile packaging indicates normal functioning, remove it from the package. The package's outer tray can be opened in non-sterile surroundings. However, when opening the inner tray, complete sterile technique must be observed (Figure 2).

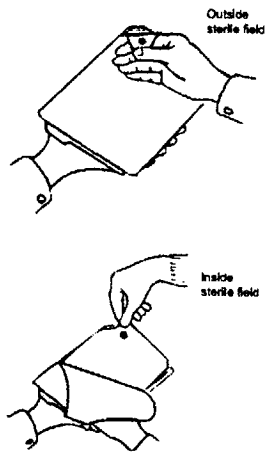

Figure 2. Opening the Sterile Package

Pre-Implant Testing

- ***Pacing System Analyzer.*** Before implantation, the clinician may wish to test the device using a pacing system analyzer (PSA) with recently calibrated sensitivity and output settings. When the probe is attached to the pulse generator's connector, the programmed parameters should be identical to the Shipped Settings listed on the package label and in Table 13 on page 42.
- ***Adaptor Probes.*** Use only 3.2 mm IS-1 or VS•1 PSA cable adaptor probes when testing the pulse generator. Other probes may damage the connector.
- ***Compatible Pacing Leads.*** Prior to implantation, make sure the pacing leads fit easily and snugly into the pulse generator's header.
- ***Capture/Sensing Thresholds.*** Capture and sensing thresholds should be determined with a PSA before implanting the pulse generator. Connect the negative (black) PSA terminal to the portion of the lead terminal pin corresponding to the tip electrode. The positive (red) terminal should be connected to the ring electrode portion of the lead pin for bipolar leads or to an indifferent electrode. For more information on conducting capture and sensing threshold tests, please consult the PSA technical manual.

Implantation

- ***Case Markings.*** Examine the markings on the pacemaker case and verify proper atrial and ventricular connection.

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- ***Setscrew.*** Exercise caution when turning the setscrew, which may be backed out of the connector if turned counter-clockwise for more than two rotations.

Programming

- ***Programmer.*** The Integrity can be interrogated and programmed with the Model 3510/3500 programmer with Model 3307 software or higher version. For a list of programmable parameters and their programmable values, see Table 14 on page 47.
- ***Setting Lead Type.*** When the user interrogates the device for the first time, the programmer will prompt the user to set the *Lead Type*. Because some parameters are conditioned on the *Lead Type (e.g., Pulse Configuration)*, the user should set this parameter when the device is implanted.
- ***Emergency VVI.*** When programming the device to Emergency VVI settings, press the programmer's *Emergency VVI* button only once. For a complete list of emergency settings, see Table 13 on page 42.
- ***ODO, OVO, and OAO Modes*** are not recommended for patients who would be adversely affected by even a short cessation of device function.
- ***Pulse Amplitude.*** If the AutoCapture Pacing System is not in use, or if the lead is implanted in the atrium, determine the capture threshold before programming the *Pulse Amplitude*. Program *Pulse Amplitude* to yield a suitable safety margin for reliable, long-term capture. Reassess capture thresholds periodically.
- ***High-Output Settings.*** Programming high-output settings with a high *Base Rate* may shorten the time to RRT.
- ***Runaway Protection.*** Hardware circuitry in the Integrity prevents the device from stimulating at rates higher than 190 ppm (± 10 ppm).
- ***Ventricular AutoCapture.*** Before setting *Ventricular AutoCapture* On, ensure that the lead is compatible by conducting a Ventricular Evoked Response Sensitivity Test.

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Environmental and Medical Therapy Hazards

Integrity pulse generators are equipped with special shielding and filters which significantly reduce the adverse effects of electromagnetic interference (EMI) on the operation of the device.

Patients should be directed to exercise reasonable caution in avoidance of strong electric or magnetic fields. If the device inhibits or reverts to asynchronous operation while in the presence of electromagnetic interference (EMI), the patient should move away from the EMI source or turn the source off.

Advise patients to seek medical guidance before entering environments which could adversely affect the operation of the pulse generator, including areas protected by a warning notice preventing entry by pacemaker patients.

Medical Procedures and Environments

In general, pacemaker patients should not be exposed to hospital equipment that produces high electromagnetic field strength signals, such as diathermy machines and electrosurgical units.

- ***External Defibrillation.*** The electronic circuitry in Integrity DR pulse generators provides protection from defibrillation discharges. Nevertheless, do not place defibrillator paddles directly over the pulse generator or pacing lead. Following defibrillation, ensure that the pacemaker is operating correctly.
- ***Magnetic Resonance Imaging (MRI).*** Before and after the patient is exposed to MRI, conduct a detailed assessment of the stimulation device. The extremely strong magnetic fields generated during MRI may cause the device to temporarily stimulate in an asynchronous mode (VOO, DOO, or AOO) if *Magnet Response* is set to a option other than Off. If a patient must undergo MRI, before the procedure, program the pulse generator to *Sensor* Off and *Magnet Response* Off.
- ***Ionizing Radiation.*** Therapeutic ionizing radiation (e.g., used in linear accelerators and cobalt machines) can permanently damage the pulse generator's circuitry. The effect of ionizing radiation is cumulative; the potential for damage to the pulse generator is proportional to the patient's total radiation dosage. If the patient must be exposed to ionizing radiation, protect the pulse generator during the procedure with local radiation shielding. If tissue near the implant site must be irradiated, it may be

necessary to move the pulse generator to another area. Before and after exposure to radiation, evaluate the pulse generator operation to identify any adverse consequences.

- ***Transcutaneous Electrical Nerve Stimulation (TENS).*** To reduce the possibility of interference with pacemaker function, place the TENS electrodes close to one another and as far from the pulse generator as possible. Before allowing unrestricted use of TENS in a home or other setting, screen the patient in a monitored environment for possible interaction.
- ***Therapeutic Diathermy.*** Avoid using diathermy equipment, including therapeutic ultrasound, in the vicinity of the pacemaker.
- ***Electrosurgical Cautery*** can 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. A bipolar cauterizer may minimize these effects. Following electrocautery, conduct a thorough assessment of the pulse generator.

PATIENT ENVIRONMENT

- ***High-Voltage*** transmission lines and equipment, arc or resistance welders, induction furnaces, and similar equipment may generate substantial EMI fields which may interfere with device operation.
- ***Communication Equipment,*** such as microwave transmitters,[3] linear power amplifiers, or high-power amateur transmitters may generate sufficient EMI to interfere with device operation. Advise patients to move away from this equipment to resume normal pacemaker operation.
- ***Home Appliances*** which are in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. Electric vibrators, razors, and handtools held directly over the device may disturb its operation.
- ***Twiddler's Syndrome.*** Caution patients against manipulating the implanted pulse generator since it may result in lead damage or lead displacement.
- ***Patient Activities.*** Any activities which involve repetitive impacts or jarring (such as horseback riding, jackhammer use, etc.) may increase the

3. Home appliance microwave ovens do not interfere with pulse generator operation.

pacing rate when the pulse generator's *Sensor* is programmed On. Caution patients against such activity and program *Sensor* parameters with these activities in mind.

- ***Theft Detection Systems.*** Theft detection systems, such as those often located at the entrances and exits of stores and public libraries may disturb pacemaker function only if the patient pauses in the path of the beam.

- ***No Pacer Symbol.*** Caution pacemaker patients to avoid areas marked with the No Pacer symbol.

Figure 3. No Pacer Symbol

- ***Cellular Phones.*** A St. Jude Medical-designed protective filter in the Integrity prevents cellular phone-generated electromagnetic signals from interfering with the operation of the device.[4]

4. Carrillo R, Williams DB, Traad EA, Schor JS. Electromagnetic filters impeded adverse interference of pacemakers by digital cellular telephones. *JACC* 1996; 27(2A):15A Abstract 901-22.

Figure 4. Cellular Tested Symbol

Clinical tests performed by the manufacturer and five independent organizations[5] have documented that devices with this filter are not affected by any known analog cellular phone systems or any of the digital phone technologies listed in Table 2. No special precautions are required for patients using cellular phones.

For more information, you or your patient may wish to contact Technical Service (page 56).

5. Center for Devices and Radiological Health, FDA, Rockville MD; Medical Devices Bureau of Health, Ottawa, Ontario, Canada; Mount Sinai Medical Center of Greater Miami, Miami Beach FL; Center for Study of Wireless Electromagnetic Compatibility, University of Oklahoma, Norman OK; Qualcomm, Inc., San Diego, CA.

Type	Description
NADC (TDMA 50)	North American Digital Communications (Time Division Multiple Access 50 Hz)
U.S. (TDMA 11)	Time Division Multiple Access 11 Hz
CDMA	Code Division Multiplex Access
PCS (GSM 1.9 GHz)	Personal Communication Systems (GSM 1.9 GHz)

Table 2. Digital Phones Standards Tested

Explantation

- Do not reuse explanted pulse generators and leads.
- Clean explanted equipment with +1% sodium hypochlorite, rinse with water, dry.
- Return the explanted device to the manufacturer.
- Explant the pulse generator before cremation of a deceased patient.
- Hex wrenches are provided for disconnecting a previously implanted pulse generator from the indwelling pacing leads. See "Package Contents" on page 35.

Adverse Events

The clinical study evaluating the Dynamic Atrial Overdrive (DAO) algorithm involved 399 patients. For the total study population, the mean patient implant duration was 399.4 ± 216.6 days (range of 36 to 901 days). For the DAO ON group, the patient cumulative implant duration was 83,318 days with a mean implant duration of 410.4 ± 226.8 days (range of 47 to 901 days). The cumulative patient implant duration for the DAO OFF group was 76,047 days with a mean implant duration of 388.0 ± 205.5 days (range of 36 to 901 days). A total of 17 deaths were reported during the course of the study in this population. Six (6) of these patients were randomized to DAO OFF and 11 patients were randomized to DAO ON. Investigators judged that none of the deaths were device-related. Table 3 on page 13 summarizes the deaths reported during the study.

Observed Adverse Events

An Adverse Event was defined as any unfavorable clinical event, which impacted or, had the potential to impact the health or safety of a Clinical Study participant caused by, or associated with, a study device or intervention. An adverse event can occur during

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exposure to the procedure, exposure to the device, and/or, at implant (including, but not limited to, adverse events related or potentially related to any device utilized, including accessories, regardless of manufacturer).

These reported events were reviewed by the Adverse Event Committee members and were then classified as an Adverse Event or an Other Reported Event. Adverse events were classified as a complication, an observation, an other reported event or a patient death. A complication was defined as any adverse event resulting in an injury or an invasive intervention (e.g. lead repositioning after lead dislodgment) which would not have occurred in the absence of the implanted device and/or system components. An observation was defined as any adverse event that is not associated with injury to the patient or an invasive intervention (e.g. DAO algorithm is programmed OFF because the patient could not tolerate high rate pacing) which would not have occurred in the absence of the implanted device and/or system components. An other reported event was defined as any other clinical event that was reported by the investigator, which was not caused by, or associated with the study device.

Table 4 on page 14 summarizes the adverse events reported and classified as complications during the study.

Table 5 on page 15 summarizes the adverse events reported and classified as observations during the study.

A total of 114 events were classified as Other Reported Events. Other Reported Events of interest in this patient population are listed in Table 6 on page 16.

Cause of Death	DAO OFF	DAO ON	TOTAL
Congestive Heart Failure	3	3	6
Cerebral Vascular Accident	1	0	1
Cardiopulmonary Arrest	0	1	1
Chronic Obstructive Pulmonary Disease	0	1	1
Complication of Pericardiocentesis	1	0	1
Coronary Artery Disease	0	1	1
Pancreatic Cancer	0	1	1
Renal Shutdown	0	1	1
Respiratory Failure	0	1	1
Shock with Undetermined Etiology	0	1	1
Unknown	1	1	2
Total	6	11	17

Table 3. Patient Deaths

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Type of Complication	Number of Patients* (% of total)		Number of Events		Events per device-year†		Events per patient-month‡	
	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON
Lead Dislodgment (Ventricular)	4 (2.04)	4 (1.97)	4	4	0.019	0.018	0.0016	0.0015
Lead Dislodgment (Atrial)	3 (1.53)	2 (0.98)	3	2	0.014	0.009	0.0012	0.0007
Pneumothorax	2 (1.02)	1 (0.49)	2	1	0.010	0.004	0.0008	0.0004
Myocardial Perforation	0	2 (0.98)	0	2	-	0.009	-	0.0007
Lead Dislodgement (Atrial and Ventricular)	1 (0.51)	1 (0.49)	1	1	0.005	0.004	0.0004	0.0004
System Infection	0	1 (0.49)	0	1	-	0.004	-	0.0004
Cardiac Tamponade	0	1 (0.49)	0	1	-	0.004	-	0.0004
System Replacement	0	1 (0.49)	0	1	-	0.004	-	0.0004
Total	10 (5.1)	13 (6.4)	10	13	0.048	0.057	0.0040	0.0048

Table 4. Complications (Footnotes appear on page 16)

Type of Observation	Number of Patients* (% of total)		Number of Events		Events per device-year†		Events per patient-month†	
	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON
Chest Pains	0	1 (0.49)	0	1	-	0.004	-	0.0004
Hematoma	2 (1.02)	1 (0.49)	2	1	0.010	0.004	0.0008	0.0004
Infection	1 (0.51)	0	1	0	0.005	-	0.0004	-
Intermittent Loss of Capture (Atrial)	2 (1.02)	0	2	0	0.010	-	0.0008	-
Intermittent Loss of Sensing (Atrial)	0	4 (1.97)	0	4	-	0.018	-	0.0015
Palpitations with High Rate Pacing**	0	5 (2.46)	0	5	-	0.022	-	0.0018
Lead Dislodgment (Ventricular)	0	1 (0.49)	0	1	-	0.004	-	0.0004
Lead Fracture	1 (0.51)	0	1	0	0.005	-	0.0004	-
Pacemaker Mediated Tachycardia (PMT)	2 (1.02)	1 (0.49)	2	1	0.010	0.004	0.0008	0.0004
Painful Incision Site	0	1 (0.49)	0	1	-	0.004	-	0.0004
Pericardial Effusion	1 (0.51)	0	1	0	0.005	-	0.0004	-
Presyncope	1 (0.51)	1 (0.49)	1	1	0.005	0.004	0.0004	0.0004
Reprogramming	2 (1.02)	2 (0.98)	2	2	0.010	0.009	0.0008	0.0007
Telemetry Error	0	1 (0.49)	0	1	-	0.004	-	0.0004
Unconfirmed Programmed Parameter Change	0	1 (0.49)	0	1	-	0.004	-	0.0004
Total	12 (6.12)	19 (9.33)	12	19	0.058	0.083	0.0048	0.0069

Table 5. Observations *(Footnotes appear on page 16)*

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Type of Event	Number of Patients* (% of total)		Number of Events		Events per device-year†		Events per patient-month‡	
	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON	DAO OFF	DAO ON
Ablation (Atrial Flutter)	2 (1.02)	2 (0.98)	2	2	0.010	0.009	0.0008	0.0007
Ablation (AV Node)	4 (2.04)	6 (2.95)	4	7	0.019	0.031	0.0016	0.0026
Ablation (Maze Procedure)	1 (0.51)	0	1	0	0.005	-	0.0004	-
Atrial Fibrillation	1 (0.51)	2 (0.98)	1	2	0.005	0.009	0.0004	0.0007
Cardioversion	18(9.18)	13(6.40)	18	13	0.086	0.057	0.0072	0.0048
Cerebral Vascular Accident (CVA)	0	1 (0.49)	0	1	-	0.004	-	0.0004
Chronic Atrial Fibrillation	2 (1.02)	4 (1.97)	2	4	0.010	0.018	0.0008	0.0015
Hospitalization (Atrial Fibrillation)	2 (1.02)	1 (0.49)	2	1	0.010	0.004	0.0008	0.0004
Total	30 (15.3)	29 (14.26)	30	30	0.144	0.131	0.0120	0.0110

Table 6. Other Reported Events

* All patients implanted (400 pulse generators in 399 patients). A total of 196 devices in 196 patients were in the DAO OFF group and 204 devices in 203 patients were in the DAO ON group. Cumulative implant duration is 76,047 device days for the DAO OFF group and 83,310 device days for the DAO ON group.

† This rate is obtained by dividing the number of adverse events by the total device cumulative implant duration in years (208.34 years for the DAO OFF group and 228.24 years for the DAO ON group).

‡ This rate is obtained by dividing the number of adverse events by the total patient cumulative implant duration in months (2498.26 months for the DAO OFF group and 2737.12 months for the DAO ON group).

** Resolved in two patients with adjustment of the overdrive pacing settings, while three patients had overdrive pacing turned off without attempting to adjust the parameter settings.

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Potential Adverse Events

The following are potential complications associated with the use of any pacing system:

- Air embolism
- Body rejection phenomena
- Cardiac tamponade or perforation
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program a pulse generator because of programmer malfunction
- Infection
- Interruption of desired pulse generator function due to electrical interference
- Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation)
- Loss of normal pacemaker function due to battery failure or component malfunction
- Pacemaker migration, pocket erosion, or hematoma
- Pectoral muscle stimulation
- Phrenic nerve or diaphragmatic stimulation.

The following, in addition to the above, are potential complications/observations associated with the use of rate-modulated or overdrive pacing systems:

- Inappropriate, rapid pacing rates due to sensor failure or to the detection of signals other than patient activity
- Loss of activity-response due to sensor failure
- Palpitations with high-rate pacing.

Clinical Studies

Patients enrolled in the ADOPT-A study were implanted with either a Trilogy® DR+ /DAO 2360L /2364L or an Integrity AFx DR 5346 device. The DAO (Dynamic Atrial Overdrive) algorithm was incorporated in all 3 models. The DAO algorithm is designed to provide atrial pacing (atrial overdrive pacing) a majority of the time and bases the pacing rate on the detection of intrinsic atrial activity (or on sensor indicated rate).

A total of 39 clinical centers worldwide have participated in the ADOPT-A study. Of these clinical centers, there are 28 U.S. centers, 8 Canadian Centers and 3 U.K. centers. A total of 399 patients have been implanted since August 14, 1998.

Patient Population

The primary objective of this randomized, controlled, single-blinded study is to investigate whether DDDR pacing at 60 ppm with the Dynamic Atrial Overdrive (DAO) pacing algorithm can prevent episodes of symptomatic atrial fibrillation more effectively than DDDR pacing at 60 ppm in patients with symptomatic paroxysmal or persistent atrial fibrillation and sinus node dysfunction with one or more 1991 ACC/AHA Class 1 bradycardia pacing indications. The secondary objectives include number of symptomatic AF episodes, patient health-related quality of life, cardioversions, and hospitalizations.

The overall study population consisted of 399 patients. Table 7 below describes the patient characteristics. Of the 399 patients, 196 patients were randomized to the DAO OFF control group and 203 patients were randomized to the DAO ON control group. There were no statistically significant differences in gender, age, ejection fraction, NYHA class, antiarrhythmic drug use, or pre-implant symptomatic AF episode frequency between the DAO ON and DAO OFF groups.

In addition to the required sinus node dysfunction indication, other indications were also reported. Table 8 on page 19 lists the additional reported indications for implant

	DAO OFF (n=196)	DAO ON (n=203)
Mean Age	71.22 ± 9.81	71.31 ±9.97
Male	50%	51%
Female	50%	49%
Mean Left Ventricular Ejection Fraction	57% ±12	56% ±13
Mean Symptomatic Atrial Fibrillation Episodes Prior to Implant (6 Months)	7.89 ±4.24	8.14 ±4.19

Table 7. Patient Characteristics

Indication	No. of Patients: DAO OFF (%)	No. of Patients: DAO ON (%)
Second Degree AV Block	7 (3.6%)	10 (4.9%)
Third Degree AV Block (Complete)	3 (1.5%)	8 (3.9)
Bifascicular or Trifascicular	2 (1.0%)	2 (0.9%)
Hypersensitive Carotid Sinus Syndrome or Neurovascular Syndrome	3 (1.5%)	0 (0.0%)

Table 8. Additional Indications for Pacemaker Implant

Methods/Results

Prior to discharge, all patients were provided with a cardiac event recorder and instructed to its use whenever they felt symptomatic. Patients were asked to carry this recorder with them until the 6-month follow-up evaluation at which time it should be returned to the investigational center. Patients were instructed to transmit all ECG episodes recorded by the device by telephone to a central receiving center. All transmitted ECGs were analyzed by two electrophysiologists to classify the rhythm and assess the existence of Atrial Fibrillation (AF) according to a specific ECG classification system.

An AF day was defined as a day on which a patient transmitted a recording documenting AF, as classified by the reviewing electrophysiologists. If multiple recordings documenting AF were transmitted on a given day by an individual patient, that day was still considered as one AF day.

For the study population, AF burden is defined as the total number of AF days divided by the cumulative follow-up days of the population over the study period.

AF Burden Reduction. The percentage of atrial pacing in the DAO ON group was 92.9% compared to 67.9% in the DAO OFF group ($p<0.0001$). Antiarrhythmic drug use during the follow-up period for the large majority of patients did not change. For the minority of patients with antiarrhythmic drug changes (i.e., new drug added, change in dosage and/or drug discontinued), there was no statistically significant difference between the DAO

OFF and DAO ON groups. Of all the symptomatic atrial tachyarrhythmias observed during the study, 90.4% were classified as Atrial Fibrillation episodes.

Of the 399 patients, a total of 288 (158 in the DAO OFF group and 130 in the DAO ON group) were included in the efficacy analysis. Patients were prospectively excluded for lack of follow-up duration (n=55), DAO parameter misprogramming at implant (n=22), missing baseline ECG/data (n=8) or unsuccessful atrial lead implant (n=1). In addition, the first 25 enrolled patients were excluded as investigator requested changes were made to the protocol precluding pooling of the data.

Figure 5 shows the distribution of AF Burden over time and Table 9 shows the AF Burden Reduction. The DAO ON group had 22,526 days of total cumulative follow-up time with a total of 421 AF days, while the DAO OFF group has 27,359 days of cumulative follow-up time with a total of 682 AF days. The AF burden for DAO ON and DAO OFF groups are 1.869% and 2.493% respectively.

As shown in Figure 5 and Table 9, there was a statistically significant and consistently decreasing AF burden observed over time between DAO ON vs. DAO OFF group ($p<0.05$).

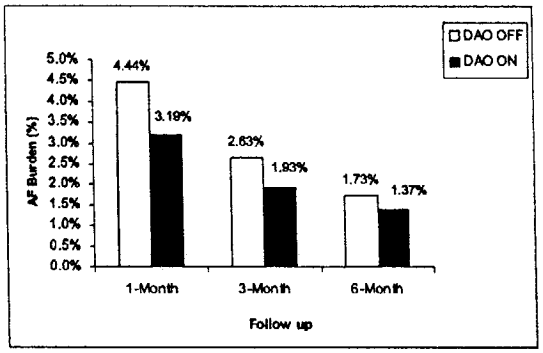

Figure 5. Distribution of AF Burden.

	DAO OFF	DAO ON
Total Patients	158	130
Patients with AF Days	81	73
Total of AF Days	682	421
Total Follow-Up Duration (days)	27,359	22,526
AF Burden	2.493%	1.869%

Table 9. AF Burden Reduction

Secondary objective results are further described below:

- ***Symptomatic AF Episodes.*** There is a statistically significant reduction in the number of symptomatic AF episodes 6 months post implant compared to 6 months prior to implant in both the DAO ON (3.2 ± 8.6 vs. 8.4 ± 4.2) and DAO OFF (4.3 ± 11.5 vs. 8.1 ± 4.2) groups ($p < 0.0001$).
- ***Patient Health Related Quality of Life.*** Using the SF-36 Quality of Life instrument as a qualitative measure of the patients' well being, there is a statistically significant improvement in the standardized physical component (PCS) scores within the DAO ON group ($p=0.013$). In the standardized mental component (MCS) scores, there is a statistically significant improvement within both the DAO OFF and the DAO ON groups ($p<0.001$). Additionally, in the Social Functioning (SF) sub-scale, there is a statistically higher improvement in the DAO ON group when comparing between groups ($p=0.003$).
- ***Hospitalizations.*** The DAO ON group has a 6.3% reduction of hospitalization days when compared to the DAO OFF group, although the difference was not statistically significant.
- ***Cardioversions.*** The DAO ON group has a 62.7% reduction of cardioversions when compared to the DAO OFF group.

Summary

The results of analyses demonstrate that the AF burden was significantly reduced when the Dynamic Atrial Overdrive (DAO) algorithm was programmed ON when compared to the DAO OFF group. The positive results suggest that the Dynamic Atrial Overdrive (DAO) pacing algorithm has proved to be safe and effective during the course of the study.

OPERATING MODES

Integrity pulse generators are dual-chamber devices that may be programmed to the following pacing therapy modes, depending upon the chamber to be paced.

Single-Chamber Modes

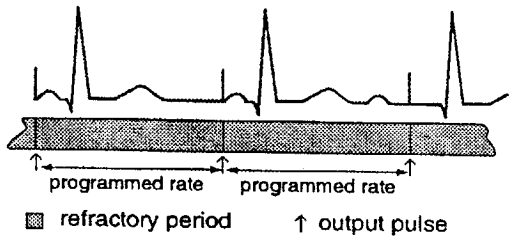

Figure 6. AOO Mode

AOO

(Atrial Asynchronous Pacing)

In AOO mode, atrial pacing is provided at the programmed rate regardless of intrinsic rhythm (Figure 6).

Indications. AOO is indicated when there is a need for atrial pacing and in the presence of significant electromagnetic or electromyogenic noise which could inappropriately inhibit the pulse generator.

Contraindications. AOO mode is contraindicated in the presence of competitive intrinsic cardiac rhythm or AV conduction disorders.

CAUTION

AOO(R) mode is intended for temporary use. Long-term use may result in competitive pacing in the atrium.

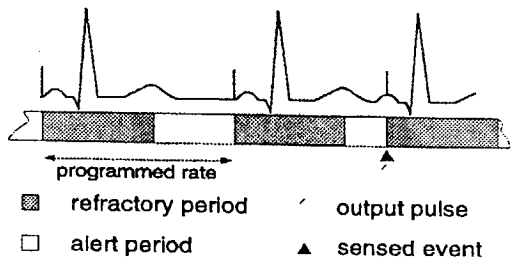

Figure 7. AAT Mode

AAT

(Atrial Stimulation, Sensing, and Triggering)

The AAT mode paces the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period causes the pacemaker to deliver an output pulse synchronously with the detected atrial event (Figure 7).

Indications. AAT pacing is primarily intended for temporary use in the evaluation of arrhythmias through chest wall electrical stimulation.

Triggered pacing modes, such as AAT, may be useful in avoiding inappropriate inhibition of the pulse generator due to electromagnetic or electromyogenic interference. A triggered mode will pace on detection of such signals, instead of being inhibited by them.

Contraindications. AAT pacing is contraindicated in the presence of AV conduction disorder, atrial fibrillation, or atrial flutter.

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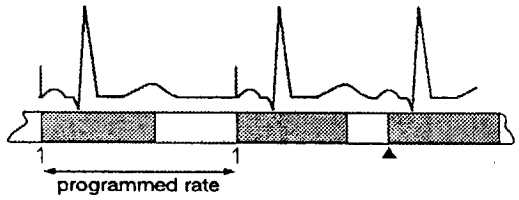

Figure 8. AAI Mode

AAI

(Atrial Stimulation, Sensing, and Inhibition)

The AAI mode paces the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period will inhibit the output pulse and reset pacemaker timing to the beginning of the refractory period (Figure 8).

Indications. AAI pacing is indicated for symptomatic bradycardia caused by sinus node dysfunction.

Contraindications. AAI pacing is contraindicated in the presence of AV conduction disorders, chronic atrial fibrillation, or atrial flutter.

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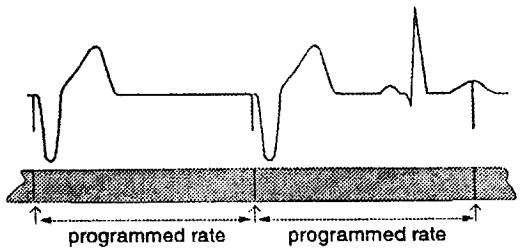

Figure 9. VOO Mode

VOO

(Ventricular Asynchronous Pacing)

The VOO mode paces the ventricle at the programmed rate, regardless of the intrinsic rhythm (Figure 9).

Indications. VOO pacing may be indicated for patients who need continual ventricular pacing and who are subject to electromagnetic interference or electromyogenic noise which could inappropriately inhibit the pulse generator.

Contraindications. VOO pacing is contraindicated in the presence of competitive intrinsic cardiac rhythm and in patients who have or are likely to experience pacemaker syndrome during single-chamber ventricular pacing.

CAUTION

VOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, inducing potentially dangerous ventricular tachyarrhythmias.

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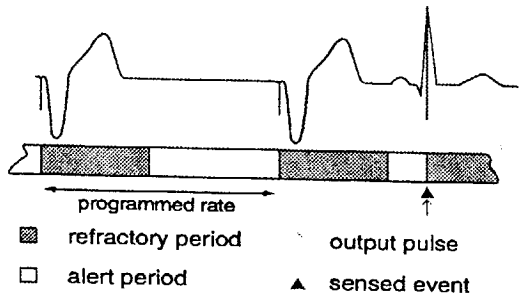

Figure 10. VVT Mode

VVT

(Ventricular Stimulation, Sensing, and Triggering)

The VVT mode paces the ventricle at the programmed rate in the absence of intrinsic ventricular activity. Intrinsic ventricular activity during the alert period causes the pacemaker to deliver an output pulse synchronously with the detected ventricular event (Figure 10).

Indications. VVT pacing is intended for temporary diagnostic use in the evaluation and management of arrhythmias performed by triggering the pulse generator output through chest wall stimulation.

Triggered pacing modes, such as VVT, may be useful in avoiding inappropriate inhibition of the pulse generator due to electromagnetic or electromyogenic interference. A triggered mode will pace on detection of such signals, instead of being inhibited by them.

Contraindications. VVT pacing is contraindicated in the presence of pacemaker syndrome.

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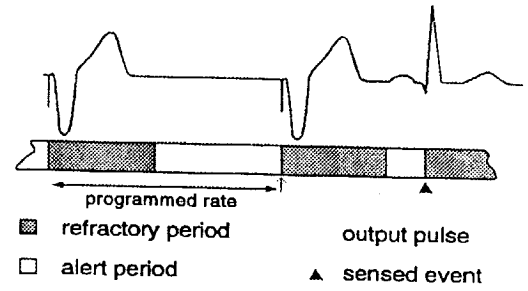

Figure 11. VVI Mode

VVI

(Ventricular Stimulation, Sensing, and Inhibition)

The VVI mode paces the ventricle at the programmed rate in the absence of intrinsic activity. Intrinsic activity during the alert period will inhibit the output pulse by resetting the pacemaker timing to the beginning of the refractory period (Figure 11).

Indications. VVI pacing is indicated for symptomatic bradycardia of any aetiology. This includes, but is not limited to, AV block or sinus node dysfunction and the various manifestations of sinus node dysfunction, including sinus node arrest, sinus bradycardia, and brady-tachy syndrome.

Contraindications. VVI pacing is contraindicated in the presence of pacemaker syndrome.

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Dual-Chamber Modes

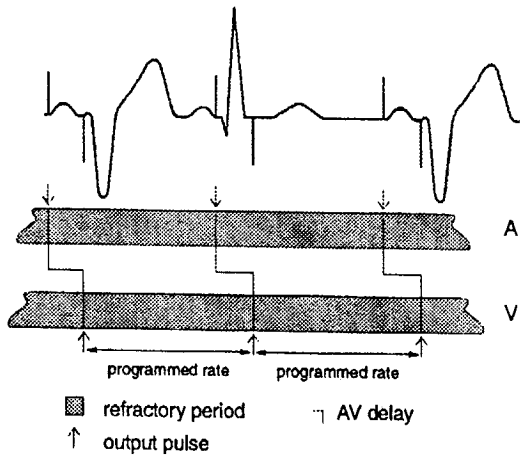

Figure 12. DOO Mode

DOO

(Dual-Chamber Asynchronous Pacing)

DOO mode paces both chambers at the programmed *Base Rate* and *AV Delay*, regardless of intrinsic activity (Figure 12).

Indications. DOO mode is indicated when there is a need for dual-chamber pacing along with the likelihood of significant electromagnetic or electromyogenic noise which could inappropriately inhibit or trigger the pacemaker.

Contraindications. DOO mode is contraindicated in the presence of competitive intrinsic cardiac rhythm.

CAUTION

DOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, including potentially dangerous tachyarrhythmias.

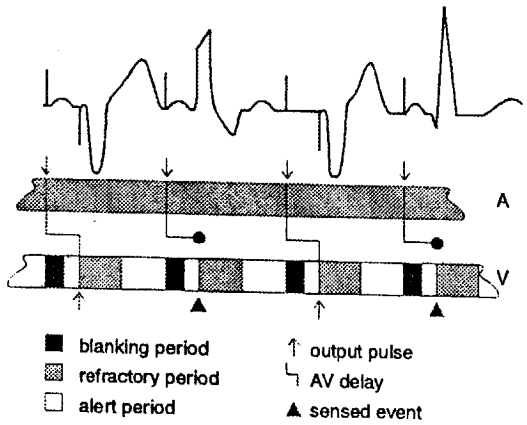

Figure 13. DVI Mode

DVI

(Dual-Chamber Stimulation; Ventricular Sensing, Inhibition and Tracking)

DVI mode paces both chambers but senses only in the ventricle. In the absence of intrinsic ventricular activity, both chambers are paced at the programmed *Base Rate* and *AV Delay*. When a ventricular event is detected during the atrial escape interval (AEI), all pulse generator output is inhibited and the timing cycle of the AEI is re-started. If no intrinsic ventricular event is sensed during the AEI or *AV Delay*, the AEI times out, and an atrial output pulse is delivered (Figure 13).

A native ventricular event during either the AEI or the *AV Delay* will inhibit the ventricular output and reset the timing cycle of the AEI. If no sensed ventricular event occurs within the *AV Delay*, it times out, at which point a ventricular output is delivered.

Indications. DVI pacing is indicated in situations where dual-chamber pacing is required and there is a specific reason that atrial sensing is not desired.

Contraindications. DVI pacing is contraindicated in the presence of competitive intrinsic atrial rhythms, or silent atria.

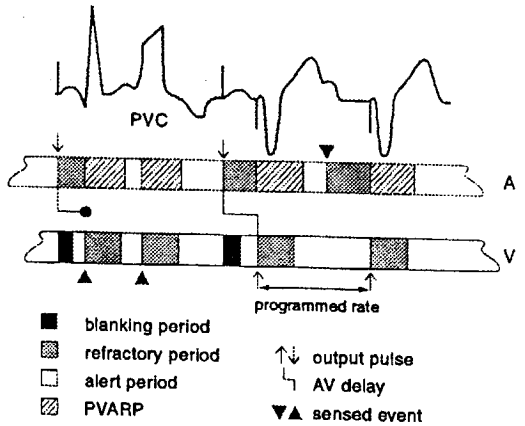

Figure 14. DDI Mode

DDI

(Dual-Chamber Stimulation; Ventricular Sensing, Inhibition and Tracking)

In DDI mode, the pulse generator paces and senses in both chambers. Intrinsic atrial activity during the atrial alert period will inhibit the atrial output pulse and prevent competitive atrial pacing. This sensing will not affect pacemaker timing and, in the absence of intrinsic ventricular activity, a ventricular output pulse will be provided at the end of the programmed rate (V-to-V) interval (Figure 14).

As with DVI mode, AV sequential pacing at the programmed rate is provided in the absence of intrinsic activity. Additionally, intrinsic ventricular activity occurring during the ventricular alert period of the AEI or *AV Delay* will inhibit the pacemaker and reset the timing as previously described.

Indications. DDI pacing is indicated in situations where dual-chamber pacing is required, the avoidance of competitive atrial pacing is desired, and there is a specific reason that atrial tracking is not required or desired (such as intermittent atrial tachyarrhythmia).

Contraindications. DDI pacing is contraindicated in high-grade AV block with normal sinus node function, chronic atrial fibrillation or flutter, and silent atria.

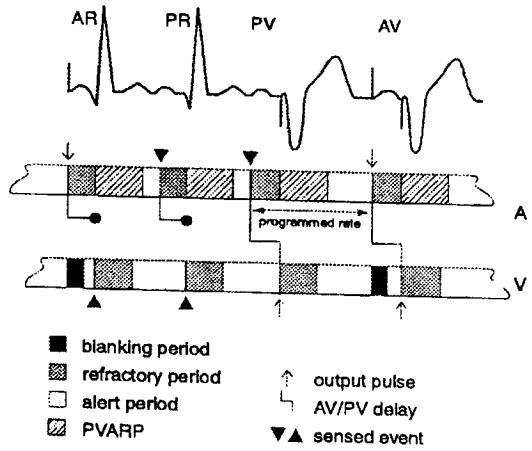

Figure 15. DDD Mode

DDD

(Dual-Chamber Stimulation, Sensing, and Inhibition; Atrial Tracking)

DDD mode allows pacing and sensing in both chambers; intrinsic activity inhibits the output in the respective chamber and intrinsic atrial events are tracked in the ventricle. In the absence of intrinsic activity, both chambers are paced at the programmed *Base Rate* and *AV Delay* (Figure 15).

When an intrinsic atrial event is sensed during the AEI, the atrial output pulse is inhibited, and the timing cycle for the *PV Delay* begins. If no intrinsic atrial event is sensed, an atrial pulse is delivered at the end of the AEI and the timing cycle for the *AV Delay* begins.

In the presence of atrial pacing, rate acceleration does not occur if an intrinsic ventricular event is sensed during the AV/PV Delay, although ventricular output is inhibited. If no ventricular event is sensed in *AV/PV Delay*, it times out, a ventricular pulse is delivered, and the timing cycle for the AEI begins.

Intrinsic ventricular activity sensed during the ventricular alert period of the AEI will inhibit both atrial and ventricular output pulses and recycle the timing cycles on both channels to the beginning of the AEI.

Note

In DDDR mode, during activity, the pulse generator's A-A interval is adjusted to reflect the sensor-indicated pacing rate determined for each pacing cycle.

Indications. DDD pacing is indicated in the presence of AV conduction disorders with normal or abnormal sinus node function.

Contraindications. DDD pacing is contraindicated in the presence of frequent or persistent atrial tachyarrhythmias or silent atria. However, the Integrity's Auto Mode Switch feature can automatically switch the device to DDI pacing in the presence of atrial tachyarrhythmias. Intact retrograde conduction, though not a contraindication, requires the careful programming of an appropriate Post-Ventricular Atrial Refractory Period (PVARP) value.

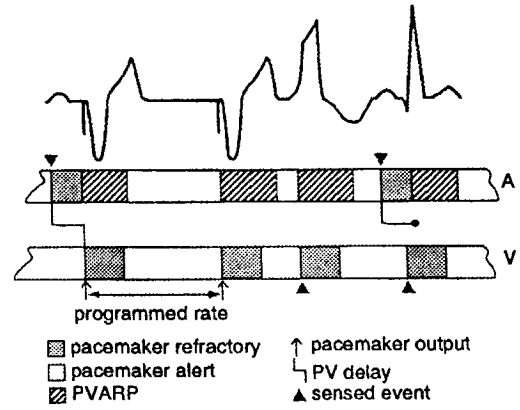

Figure 16. VDD Mode

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VDD

(Ventricular Stimulation; Dual-Chamber Sensing and Inhibition; Atrial Tracking)

VDD mode provides ventricular pacing synchronized to intrinsic atrial activity. The pulse generator can sense in both chambers but pace only in the ventricle (Figure 16 on page 32).

In the absence of intrinsic atrial and ventricular activity, the pulse generator paces the ventricle (VVI pacing). Native ventricular activity will inhibit the pulse generator.

The mode features preferential P-wave sensing, which maintains an atrial alert even when the other timing cycles would have precluded one. The device will always preserve an atrial alert window equal to the *PV Delay* + 25 ms. Should the other timing cycles infringe on this atrial alert window, the PVARP will be shortened as required to maintain this atrial alert window.

A sensed atrial event occurring during a window at the end of the V to V interval will initiate the *PV Delay* and extend the V to V interval. Although the VDD mode may prolong the V to V interval, it maintains AV synchrony. It is therefore possible for the pacemaker to track a sinus rhythm which is lower than the programmed *Base Rate*.

Indications. AV block with normal sinus function.

Contraindications. Sinus node dysfunction, chronic atrial flutter or fibrillation, inadequate atrial sensing, or silent atria.

ODO, OVO, and OAO Modes

In these modes, pacing is turned off while the device continues to sense intrinsic activity and record the events in the pulse generator memory. These modes are useful primarily for temporary diagnostic evaluation of underlying rhythm and when a record of the activity is needed. However, when these modes are programmed, the Model 3510/3500 programmer does not display markers or heart rate.

These modes are not available when *Sensor* is programmed On or Passive, and the *Sensor* cannot be programmed On or Passive when these modes are programmed.

As with all modes, programming a different mode will clear diagnostic data.

CAUTION

ODO, OVO, or OAO modes are not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of pacemaker function.

Rate-Modulated Modes

The function of rate-modulated modes (*Sensor* On) is to alter the pacing rate to match activity changes in accordance with programmed parameters. Rate-response can be enabled with any pacing mode.

Indications. These are the same as modes without rate modulation except that rate-modulated modes are further indicated when an increase in pacing rate with activity is desired.

Contraindications. These are the same as modes without rate modulation, except that rate-modulated modes are also contraindicated when pacing rates above the programmed *Base Rate* may not be well tolerated.

Diagnostic Data, Tests, and Tools

The Integrity pulse generator collects and retains a variety of diagnostic data that can be viewed and printed with the Model 3510/3500 programmer. These include:

- Measured Rate
- Event Histogram
- Heart Rate Histogram
- Auto Mode Switch Histogram (Peak Filtered Rate and Duration)
- Sensor-indicated Rate Histogram
- Event Record
- Event Snapshots
- Measured Data: Magnet Rate; Pulse Amplitude, Current, Energy, and Charge; Lead Impedance; Battery Voltage, Battery Current, and Battery Impedance
- Device identification with model name and number, unit serial number, lead information, and battery identification
- Date last programmed

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- A portion of the device memory to store important Patient Information, including Implant Date.

The Integrity AFx DR also offers features to facilitate follow-up, including:

- Battery Test, which allows assessment of the battery status with application of a magnet
- Noninvasive electrophysiologic lab tests (NIPS or EP Lab)
- P-wave and R-wave measurements, which automatically measure the amplitude of intrinsic P-waves or R-waves, then recommend a setting for *Sensitivity* that includes a suggested safety margin
- Semi-automatic capture and sensing threshold tests
- Simultaneous display of ECGs and Intracardiac Electrograms (IEGM) with annotated markers and Electronic Calipers™
- Temporary programming of all parameters for diagnostic purposes
- Auto-Set and Prediction Model procedures, which facilitate activity sensor programming.

For more information, see the Bradycardia Reference Manual.

IMPLANTATION AND LEAD CONNECTION

Package Contents

The Integrity pulse generator is shipped in a sterile box containing:

- Integrity pulse generator
- Connector kit containing:
  - White #2 torque wrench
  - 3 additional hex wrenches (sizes 2, 4, 6) for disconnecting implanted leads
- Registration form
- Credit policy form
- User's Manual
- Patient Manual.

Lead Connection

Integrity AFx DR Model 5346 is equipped with a connector that accepts unipolar or bipolar VS•1 or IS-1 3.2 mm leads.

Note

For the AutoCapture Pacing System to function, the pulse generator must be connected to a ventricular bipolar, low polarization pacing lead. See the Bradycardia Reference Manual.

The pulse generator has a single setscrew for each lead. The setscrew makes contact with the lead connector pin (cathode) securing the lead within the pacemaker connector while an annular spring makes contact with the proximal ring (anode).

To connect the Integrity pulse generator to the leads:

1. Remove blood and body fluids from the terminal pins of the implanted lead.
2. Use the white-handle #2 torque wrench to retract both setscrews in the device connector so that the pacing lead terminal pins can be fully inserted.

CAUTION

Exercise caution when turning the setscrew, which may be backed out of the connector if turned counter-clockwise for more than two rotations.

3. Check the markings on the pulse generator case and verify proper atrial and ventricular connection.
4. Insert the lead firmly into the connector until the lead pin is immobile and visible in the viewport at the opposite end of the connector.
5. Insert the white-handle #2 torque wrench through the aperture on the header and into the setscrew on the side of the connector.
6. Turn the wrench clockwise until it clicks. The wrench is torque-limited and will not allow excessive tightening.
7. Repeat Steps 4 through 6 for the second lead.
8. Tug gently on the leads to ensure they are secured in the connector.
9. After the device has been implanted, interrogate the device and set the *Lead Type* to the correct setting. *Lead Type* is accessed by selecting the [Patient Data] tab on the Programmed Parameters screen. *Lead Type* settings are described in the Bradycardia Reference Manual.

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A suture hole is provided in the header which can be used to secure the pulse generator inside the subcutaneous pocket in order to minimize possible migration.

Device Registration and Identification

Device Registration. An Implantable Device Registration Form is enclosed with each pulse generator to serve as a permanent record of information pertaining to the implanted device. The completed original should be returned to the manufacturer in the postage-paid, addressed envelope provided. Copies of the registration form are provided for the hospital, the implanting physician, and the follow-up physician.

Patient Identification Card. A temporary Patient Identification Card is part of the registration form. This card should be filled out and given to the patient before discharge from the hospital. A permanent card will be sent to the patient approximately 30 days after receipt of the Implantable Device Registration from the physician or hospital.

X-Ray Identification

St. Jude Medical pulse generators have a radiopaque identifier, visible on conventional X-ray film, which consists of the Pacesetter logo and a two-letter model code (Figure 17 on page 37).

The code for all Integrity pulse generator models is:

V
T

The model number of each pulse generator is stored in the device's memory and is automatically displayed on the programmer screen when the device is interrogated.

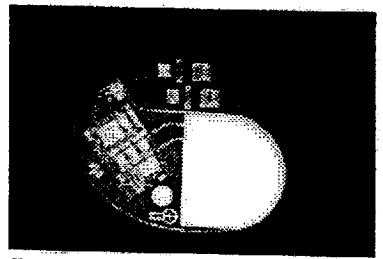

Figure 17. X- Ray Image of Integrity AFx DR

Determining Device Longevity

Many individual factors affect pulse generator service life, such as programmed parameters, percentage of time paced, internal impedance, etc. The projected longevity data in Tables 10 and 11 are based on accelerated battery test data under certain conditions and do not account for such factors as sensor-driven pacing rate changes, effects of rate-limiting algorithms, the patient's medical condition, or effects of a specific pacing prescription. Furthermore, these data are based on battery life projections, which are approximations. RRT precedes EOL by a wide margin of safety, seldom less than three months under normal circumstances.

The test data were calculated with *Sensor* set to Passive[6] and *Pulse Width* set to 0.4 ms. The data in Table 10 were also obtained with *Ventricular AutoCapture* On.

6. Current drains for the *Sensor* Passive (VVI, DDD pacing) and *Sensor* On (VVIR, DDDR) settings are similar.

Pacing at 60 ppm	BOL to RRT in Years		RRT to EOL in Months	
	Mean	Range	Mean	Range
2.5 V Atrium; 1.0 V Ventr., 500Ω	10.1	8.7 – 11.6	4.0	3.6 – 4.5
2.5 V Atrium; 1.0 V Ventr., 750Ω	10.8	9.8 – 11.8	4.0	3.6 – 4.5
2.5 V Atrium; 1.0 V Ventr., 1000Ω	11.1	10.0 – 12.3	4.0	3.7 – 4.4

Table 10. Projected Time from BOL to EOL (100% DDD Pacing, AutoCapture On)

Pacing at 60 ppm	BOL to RRT in Years	RRT to EOL in Months
2.5 V; 500Ω in atrium, 500Ω in ventricle	8.6	5.5
3.5 V; 500Ω in atrium, 500Ω in ventricle	6.3	4.6
2.5 V; 500Ω in atrium, 750Ω in ventricle	8.9	5.2
3.5 V; 500Ω in atrium, 750Ω in ventricle	7.3	4.4
2.5 V; 1000Ω in atrium, 1000Ω in ventricle	9.8	4.5
3.5 V; 1000Ω in atrium, 1000Ω in ventricle	7.8	4.7

Table 11. Projected Time from BOL to EOL (100% DDD Pacing, AutoCapture Off)

Recommended Replacement Time

RRT is the point at which battery voltage has dropped to the lowest capacity to maintain adequate pulse generator operation for a nominal period of three months before EOL.

When the pulse generator reaches RRT, a number of indicators alert the clinician to this condition:

- Pacing intervals increase by 100 ms over the *Base Rate* to reduce current drain (Table 12 on page 40 shows the difference between the programmed *Base Rate* and actual pacing rates at RRT)
- The programmer displays a message that the pacemaker has detected RRT and prompts the user to clear RRT or continue

- The *Magnet Response* is automatically programmed to Battery Test[7], and the Magnet Rate will be 86.3 ppm or less
- Battery voltage drops to 2.5 V or less
- *Sensor* is programmed to Off
- *Shortest AV/PV Delay* is programmed to 70 ms
- *Ventricular AutoCapture* is programmed to Off (*Ventricular Pulse Amplitude* is reset to twice the average of the last four capture threshold measurements up to a limit of 5.0 V)
- The following features no longer operate at RRT:
  - *Rest Rate*
  - *Dynamic Atrial Overdrive (DAO)*
  - all diagnostic data collection[8]
  - NIPS and EP Lab.

For more information, consult the Bradycardia Reference Manual.

7. Unless *Magnet Response* is Off, then it is not changed at RRT.
8. With the exception of average measured battery voltage and current.

CAUTION

- *Programming to high output settings with a high Base Rate may cause the pulse generator to reach RRT prematurely.*
- *If the programmer displays an RRT warning message, the clinician should fully evaluate the pulse generator.*

Programmed Rate	Actual Rate at RRT
45	41.9
50	46.2
55	50.4
60	54.5
65	58.6
70	62.7
75	66.7

Table 12. Programmed Pacing Rate (ppm) versus Actual Pacing Rate (ppm) at RRT

Programmed Rate	Actual Rate at RRT
80	70.6
85	74.4
90	78.3
95	82.0
100	85.7
105	89.4
110	93.0
115	96.5
120	100.0
125	103.4
130	106.8
135	110.2
145	116.8
150	120.0

Table 12. Programmed Pacing Rate (ppm) versus Actual Pacing Rate (ppm) at RRT (Continued)

Programmed Rate	Actual Rate at RRT
155	123.2
160	126.3
165	129.4
170	132.5

Table 12. Programmed Pacing Rate (ppm) versus Actual Pacing Rate (ppm) at RRT (Continued)

WARNING

At RRT, the nominal life of the pulse generator is seldom less than three months. The pacemaker should be replaced immediately.

End-of-Life

When the output pulse amplitude drops to 50 percent of its programmed value, the pulse generator has reached EOL. Typically, this occurs when the battery voltage has fallen to approximately 2.2 V.

At EOL, the *Magnet Response*/Battery Test will reveal a Magnet Rate of 68 ppm or less.

Recommended Replacement Time

TECHNICAL DATA

Shipped, Emergency VVI, and Standard Settings

A dash (—) indicates that the parameter is not available in the current configuration. A nominal setting is the value that will be instituted when the parameter is first programmed or autoprogrammed. Indented parameters are those that appear only when the previous unindented parameter has been programmed On.

Parameter	Shipped Settings	Emergency VVI Settings	Standard/Nominal Settings
Mode	DDD	VVI	DDD
Base Rate	60 ppm	70 ppm	60 ppm
Hysteresis Rate	Off	Off	Off
Search Interval	—	—	Off
Cycle Count	—	—	1
Intervention Rate	—	—	Off
Intervention Duration	—	—	1 min
Recovery Time	—	—	Medium

Table 13. Shipped, Emergency VVI, and Standard Settings for Integrity AFx DR Model 5346
(Table footnotes appear on page 46)

Parameter	Shipped Settings	Emergency VVI Settings	Standard/Nominal Settings
Rest Rate	Off	Off	Off
Maximum Tracking Rate	110 ppm	--	110 ppm
AV Delay	170 ms	--	170 ms
PV Delay	150 ms	--	150 ms
Rate Responsive AV/PV Delay	Off	--	Off
Shortest AV/PV Delay	70 ms	--	70 ms
Ventricular Refractory	250 ms	325 ms	250 ms
Atrial Refractory (PVARP)	275 ms	--	275 ms
V. AutoCapture	Off	Off	Off
Backup Pulse Configuration	--	--	Unipolar
E/R Sensitivity	--	--	49.7 mV
V. Pulse Amplitude	3.5 V	5.0 V	3.5 V
V. Pulse Width	0.4 ms	0.6 ms	0.4 ms

Table 13. Shipped, Emergency VVI, and Standard Settings for Integrity AFx DR Model 5346
(Table footnotes appear on page 46)

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Parameter	Shipped Settings	Emergency VVI Settings	Standard/Nominal Settings
V. Sensitivity	2.0 mV	2.0 mV	2.0 mV
V. Pulse Configuration	See Package Label	Unipolar*	Unipolar
V. Sense Configuration	See Package Label	Unipolar Tip*	Unipolar Tip
A. Pulse Amplitude	3.5 V	—	3.5 V
A. Pulse Width	0.4 ms	—	0.4 ms
A. Sensitivity	1.0 mV	—	1.0 mV
A. Pulse Configuration	See Package Label	—	Unipolar
A. Sense Configuration	See Package Label	—	Unipolar Tip
Magnet Response	Battery Test	Battery Test	Battery Test
AutoIntrinsic Conduction Search	Off	—	Off
Negative AV/PV Hysteresis/Search	Off	—	Off
Auto Mode Switch	Off	—	Off
Atrial Tachycardia Detection Rate	—	—	225 ppm

Table 13. Shipped, Emergency VVI, and Standard Settings for Integrity AFx DR Model 5346
(Table footnotes appear on page 46)

Parameter	Shipped Settings	Emergency VVI Settings	Standard/Nominal Settings
AMS Base Rate	—	—	60 ppm
Dynamic Atrial Overdrive	Off	—	Off
Lower Rate Overdrive	—	—	10 ppm
Upper Rate Overdrive	—	—	5 ppm
No. of Overdrive Pacing Cycles	—	—	15
DAO Rate Recovery	—	—	8;12
Post Ventricular Atrial Blanking	100 ms	—	100 ms
Ventricular Safety Standby	On	—	On
Ventricular Blanking	12 ms	—	12 ms
PVC Options	+PVARP on PVC	—	+PVARP on PVC
PMT Options	Off	—	Off
PMT Detection Rate	—	—	110 ppm
Sensor	Off	Off	Off

Table 13. Shipped, Emergency VVI, and Standard Settings for Integrity AFx DR Model 5346
(Table footnotes appear on page 46)

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Parameter	Shipped Settings	Emergency VVI Settings	Standard/Nominal Settings
Maximum Sensor Rate	110 ppm	—	110 ppm
Threshold	AUTO (+ 0.0)	—	AUTO (+ 0.0)
Slope	8	—	8
Reaction Time	Fast	—	Fast
Recovery Time	Medium	—	Medium
Atrial Lead Type	Uncoded	No Change	No Change
Ventricular Lead Type	Uncoded	No Change	No Change

Table 13. Shipped, Emergency VVI, and Standard Settings for Integrity AFx DR Model 5346
(Table footnotes appear on page 46)

* If *Lead Type* is programmed to "Bipolar Only," the Emergency VVI setting will be bipolar.

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Programmable Parameters, Settings, and Tolerances

Parameter	Settings	Units	Tolerance
Mode	AOO(R); AAI (R); AAT(R); OAO; VOO(R); VVI(R); VVT(R); VDD(R); OVO; DOO(R); DVI(R); DDI(R); DDD(R); ODO	n/a	n/a
Base Rate	30*; 40 – 130 in steps of 5; 140 – 170 in steps of 10	ppm	±16 ms
Hysteresis Rate†	Off; 30 – 130 in steps of 5; 140; 150	ppm	± 8 ms
Search Interval	Off; 5; 10; 15; 30	ppm	± 8 ms
Cycle Count	1 – 16	n/a	n/a
Intervention Rate	Off; 60; Intrinsic+0; Intrinsic+10; Intrinsic+20; Intrinsic+30; 80 – 120 in steps of 10	ppm	± 8 ms
Intervention Duration	1 – 10	min	± 2 sec
Recovery Time	Fast; Medium; Slow; Very Slow	n/a	n/a
Rest Rate	Off; 30 – 130 in steps of 5; 140; 150	ppm	± 8 ms
Maximum Tracking Rate	90 – 130 in steps of 5; 140 – 180 in steps of 10	ppm	± 8 ms
AV Delay	25; 30 – 200 in steps of 10; 225 – 300 in steps of 25; 350	ms	± 8 ms

Table 14. Programmable Parameters, Settings, and Tolerances for Integrity AFx DR Model 5346
(Table footnotes appear on page 52)

Parameter	Settings	Units	Tolerance
PV Delay	25 – 200 in steps of 10; 225 – 325 in steps of 25	ms	± 8 ms
Rate Responsive AV/PV Delay	Off; Low; Medium; High	n/a	n/a
Shortest AV/PV Delay	30 – 50 in steps of 5; 60 – 120 in steps of 10	ms	± 8 ms
Ventricular Refractory‡	125 – 500 in steps of 25	ms	± 8 ms
Atrial Refractory (PVARP)	125 – 500 in steps of 25	ms	± 8 ms
Ventricular AutoCapture	On; Off	n/a	n/a
Backup Pulse Configuration	Unipolar, Bipolar	n/a	n/a
E/R Sensitivity**	Set 1: 2.3; 4.7; 7.0; 9.4; 11.7; 14.1; 16.4; 18.8; 21.1; 23.5; 25.8; 28.2; 30.5; 32.9; 35.2; 37.6; 39.9; 42.3; 44.6; 47.0; 49.3	mV	± 30%
	Set 2: 1.2; 2.3; 3.5; 4.7; 5.9; 7.0; 8.2; 9.4; 10.6; 11.7; 12.9; 14.1; 15.3; 16.4; 17.6; 18.8; 20.0; 21.1; 22.3; 23.5; 24.7	mV	± 30%
	Set 3: 1.4; 1.9; 2.3; 2.8; 3.3; 3.8; 4.2; 4.7; 5.2; 5.6; 6.1; 6.6; 7.0; 7.5; 8.0; 8.5; 8.9; 9.4; 9.9	mV	± 30%
V. Pulse Amplitude	0.0 – 4.0 in steps of 0.25; 4.5 – 7.5 in steps of 0.5	V	10%††

Table 14. Programmable Parameters, Settings, and Tolerances for Integrity AFx DR Model 5346
(Table footnotes appear on page 52)

Parameter	Settings	Units	Tolerance
V. Pulse Width	0.05; 0.1 – 1.5 in steps of 0.1	ms	± 0.03 ms
V. Sensitivity[#]	0.5 – 5.0 in steps of 0.5; 6 – 10 in steps of 1.0; 12.5	mV	± 30%
V. Pulse Configuration	Unipolar (tip – case); Bipolar (tip – ring)	n/a	n/a
V. Sense Configuration	Unipolar Tip (tip – case); Bipolar (tip – ring); Unipolar Ring (ring – case)	n/a	n/a
A. Pulse Amplitude	0.0 – 4.0 in steps of 0.25; 4.5 – 7.5 in steps of 0.5	V	10%[††]
A. Pulse Width	0.05; 0.1 – 1.5 in steps of 0.1	ms	± 0.03 ms
A. Sensitivity[#]	0.1[***]; 0.2[***]; 0.3[***]; 0.4[***]; 0.5; 0.75; 1.0; 1.25; 1.5; 1.75; 2.0; 2.5; 3.0; 3.5; 4.0; 5.0	mV	± 30%
A. Pulse Configuration	Unipolar (tip – case); Bipolar (tip – ring)	n/a	n/a
A. Sense Configuration	Unipolar Tip (tip – case); Bipolar (tip – ring); Unipolar Ring (ring – case)	n/a	n/a
Magnet Response	Off; Battery Test; Event Snapshots; Event Snapshots + Battery Test	n/a	n/a
AutoIntrinsic Conduction Search	Off; +10 ms to +120 in steps of 10	ms	± 8 ms

Table 14. Programmable Parameters, Settings, and Tolerances for Integrity AFx DR Model 5346
(Table footnotes appear on page 52)

Parameter	Settings	Units	Tolerance
Negative AV/PV Hysteresis/Search	Off; -10 to -110 in steps of 10	ms	± 8 ms
Auto Mode Switch	Off; DDDR to DDIR; DDD to DDI; VDDR to VVIR; VDD to VVI	n/a	n/a
Atrial Tachycardia Detection Rate	110 – 150 in steps of 5; 160 – 200 in steps of 10; 225 – 300 in steps of 25	ppm	± 8 ms
AMS Base Rate	Base Rate +0 to Base Rate +35 in steps of 5	ppm	± 8 ms
Dynamic Atrial Overdrive	Off, On	n/a	n/a
Lower Rate Overdrive	10 ppm	ppm	± 8 ms
Upper Rate Overdrive	5 ppm	ppm	± 8 ms
No. of Overdrive Pacing Cycles	15 – 40 in steps of 5	cycles	n/a
DAO Rate Recovery	8;12	ms; ms	n/a
Post Ventricular Atrial Blanking (PVAB)	60; 70; 80; 85; 95; 100; 110; 115; 125; 130; 140; 150; 155; 165; 170; 180; 185; 195; 200	ms	± 8 ms
Ventricular Safety Standby	Off; On	n/a	n/a

Table 14. Programmable Parameters, Settings, and Tolerances for Integrity AFx DR Model 5346
(Table footnotes appear on page 52)

Parameter	Settings	Units	Tolerance
Ventricular Blanking	12 – 52 in steps of 4	ms	± 8 ms
PVC Options	Off; +PVARP on PVC	n/a	n/a
PMT Options	Off; 10 Beats > PMT; Auto Detect	n/a	n/a
PMT Detection Rate	90 – 150 in steps of 5; 160 – 180 in steps of 10	ppm	± 8 ms
Sensor	On; Off; Passive	n/a	n/a
Max Sensor Rate	80 – 150 in steps of 5; 160 – 180 in steps of 10	ppm	± 8 ms
Threshold	Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto (+1.5); Auto (+2.0); 1 – 7 in steps of 0.5	n/a	n/a
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto(+3); 1 – 16	n/a	n/a
Reaction Time	Very Fast; Fast; Medium; Slow	n/a	n/a
Recovery Time	Fast; Medium; Slow; Very Slow	n/a	n/a
Ventricular Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar	n/a	n/a
Atrial Lead Type	Uncoded; Unipolar; Bipolar Only; Unipolar/Bipolar	n/a	n/a

Table 14. Programmable Parameters, Settings, and Tolerances for Integrity AFx DR Model 5346
(Table footnotes appear on page 52)

* The actual pacing rate for the 30 ppm setting is 31 ppm.

† The highest available setting for *Hysteresis Rate* will be 5 ppm below the programmed *Base Rate*.

‡ In dual-chamber modes, the maximum *Ventricular Refractory Period* is 325 ms.

** The values available for *E/R Sensitivity* depend on the measured evoked response; any one of three value sets may be displayed as programming options based on the evoked response measurement. Default is Set 1.

†† Tolerances are measured against impedances 500¾ and above.

‡‡ *Sensitivity* is with respect to a 20 ms haversine test signal.

***Except in VDD(R), settings 0.1 to 0.4 mV are not available when *Atrial Sense Configuration* is set to Unipolar.

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NIPS Options

Prior to using the NIPS options, consult the Bradycardia Reference Manual.
Ventricular Support Pacing is delivered in the VOO Mode. See "VOO" on page 25 for specific contraindications.

Parameter	Settings	Units	Tolerance
NIPS Options			
Stimulation Chamber	Atrial, Ventricular	n/a	n/a
Coupling Interval*	100 – 800 in steps of 10	ms	± 8 ms
S1 Count	1 – 25 in steps of 1	n/a	n/a
S1†, S2, S3, and S4 Cycle	100 – 800 in steps of 10	ms	± 8 ms
Ventricular Support Rate (VOO pacing)	Off, 30, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95	ppm	± 16 ms
Sinus Node Recovery Delay	1 – 5 in steps of 1	sec	± 100 ms
EP Lab Options			
Sinus Node Recovery Delay	Off, 2, 3, 4, 5	sec	± 100 ms

Table 15. NIPS and EP Lab Options

* During atrial NIPS in dual-chamber modes, the shortest *Coupling Interval* will be limited by the programmed *AV/PV Delay*.
† S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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Physical Specifications

	Integrity AFx DR Model 5346
Case material	Titanium
Connector material	Epoxy resin
Case Coating	none
Dimensions (mm)*	44(h) x 52(l) x 6(t)
Weight*	23.5 g
Volume*	11 cc

Table 16. Physical Specifications (nominal values)*

Tolerances for Measured Telemetry Data

Measurement	Tolerance
Pulse Amplitude (V)	±10%
Pulse Current (mA)	±15%
Lead Impedance (¾)	±15%
Battery Current (µA)	±15%
Battery Voltage (V)	±5%
Battery Impedance (k¾)	± (0.2 +10%)

Table 17. Tolerances for Measured Data

Temperature Effects

Parameter*	at 20° C	at 43° C
Base Rate	< ± 1%	< ± 1%
Test Rate	< ± 1%	< ± 1%
Pulse Width	< ± 1%	< ± 1%
Pulse Amplitude	< ± 1%	< ± 1%
Sensitivity	± 5%	± 1%

Table 18. Maximum Temperature Effect on Different Parameters

* Parameter value deviation from 37° C

Battery Information

Description	Value
Power source	1 Lithium iodine cell
Manufacturer	Wilson Greatbatch Ltd. USA
Model	9438
Voltage at BOL	2.8 V
Voltage at RRT	2.5 V
Voltage at EOL	2.2 V
Capacity between BOL and RRT	0.95 Ah
Capacity between RRT and EOL	0.05 Ah

Table 19. Battery Information

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TECHNICAL SERVICE

You can speak directly to a Technical Service Representative 24 hours of every day for questions on any aspect of the pulse generator.

- In North America, call:
  +1-818-362-6822
  or (toll-free) +1-800-722-3774
  FAX number: +1-818-362-7182.
- Outside North America, call:
  +46 8-474 4147
  FAX: +46 8-760 5126 (during business hours only)

Your local St. Jude Medical representative can also provide customer assistance.

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May 2001
SW 9193475 Rev. A
Part No. **9193475-001**