ACC Abstracts from the ALTITUDE Clinical Science Program as presented at the American College of Cardiology Conference, April 2-5, 2011; New Orleans, LA USA

Atrial Fibrillation and Outcomes in a Large Cohort of CRT Recipients: Results from the ALTITUDE Study

Introduction & Objectives

The prevalence of atrial fibrillation (AF) in heart failure patients is high and the presence of AF has been associated with an increased risk of death and hospitalization. The purpose of this analysis was to evaluate the effect of AF burden on survival in patients implanted with a cardiac resynchronization therapy defibrillator (CRT-D) from a large, database reflecting natural clinical practice.

The ALTITUDE clinical science program is used to analyze comprehensive data from the LATITUDE® Patient Management system. ALTITUDE uses limited or de-identified data under terms of LATITUDE agreement signed by centers (6% of centers have opted out of limited data set use for research). The ALTITUDE program is managed in collaboration with an external physician panel.

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Methods

A total of 142 429 patients were being followed on the LATITUDE remote monitoring system ALTITUDE database as of June 4, 2010. In this analysis, those patients with CRT devices who were consistently programmed to a tracking mode during follow-up, and who had >1 year of follow up were included (N=23 743, Figure 1).

Patients were divided into 4 groups (based on [1]):

1) Persistent AF (N=4 711): atrial tachycardia response (ATR) >7 days (including those programmed VVI/R, DDI/R mode)

2) Paroxysmal AF 1-7 days (d) (N=896): ATR >1 day and <7 days

3) Paroxysmal AF <1 day (N=4 805): ATR >1 minute and <1 day

4) No AF (N=13 331): all others.

Survival status was obtained via cross reference to the Social Security Death Index prior to de-identification. Logistic regression models were used to determine the association between AF and death at 1 year.

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Table 1	Type of Atrial Fibrillation (AF)		
Characteristic[a]	No AF (N=13 331)	AF[b] (N=10 412)	*P* value[c]
Female Gender	4280 (32.1%)	2355 (22.6%)	<0.001
Age (y)[e]	68.7 ± 11.0	71.7 ± 10.8	<0.001[d]
<65 years[e]	4347 (32.6%)	2346 (22.5%)	<0.001
65 - 80 years[e]	6746 (50.6%)	5423 (52.1%)	
≥80 years[e]	2238 (16.8%)	2643 (25.4%)	
Shock within 1 year post-implant	864 (6.5%)	1343 (12.9%)	<0.001
Mean biventricular pacing during first year post-implant			
<85%	849 (6.4%)	1411 (13.6%)	<0.001
85% - 97%	3412 (25.6%)	3802 (36.5%)	
97% - 99%	3437 (25.8%)	2435 (23.4%)	
≥99%	5633 (42.3%)	2764 (26.5%)	

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Table 2		
Covariate	Comparison	HR (95% CI)[a]
AF (vs No AF)	Paroxysmal (<1d)	1.25 (1.15, 1.35)
	Paroxysmal (1-7d)	1.49 (1.29, 1.72)
	Persistent	1.46 (1.35, 1.57)
Mean biventricular pacing[b] (vs ≥99%)	97% - 99%	1.28 (1.17, 1.39)
	85% - 97%	1.31 (1.21, 1.42)
	<85%	1.37 (1.23, 1.54)
Shock[c]	At least 1 shock vs no shock	1.73 (1.58, 1.89)
Gender	Male vs Female	1.23 (1.14, 1.33)

[a]HR=Hazard Ratio, CI=Confidence Interval. Chi square test *P*<0.0001 in all cases. [b]During first year post-implant. [c]Within 1y post-implant

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Table 3	Type of Atrial Fibrillation			
Characteristic[a]	None (N=13 331)	Paroxysmal <1d (N=4 711)	Paroxysmal 1-7d (N=896)	Persistent (N=4 805)
Female Gender	4280 (32.1%)	1273 (27.0%)	151 (16.9%)	931 (19.4%)
Age (y)[b]	68.7 ± 11.0	70.1 ± 11.4	71.7 ± 10.6	73.2 ± 10.0
<65 years[b]	4347 (32.6%)	1272 (27.0%)	203 (22.7%)	871 (18.1%)
65 - 80 years[b]	6746 (50.6%)	2435 (51.7%)	455 (50.8%)	2533 (52.7%)
≥80 years[b]	2238 (16.8%)	1004 (21.3%)	238 (26.6%)	1401 (29.2%)
Shock (within 1y post-implant)	864 (6.5%)	562 (11.9%)	143 (16.0%)	638 (13.3%)
Mean biventricular pacing during first year post-implant				
<85%	849 (6.4%)	390 (8.3%)	90 (10.0%)	931 (19.4%)
85% - 97%	3412 (25.6%)	1452 (30.8%)	347 (38.7%)	2003 (41.7%)
97% - 99%	3437 (25.8%)	1303 (27.7%)	223 (24.9%)	909 (18.9%)
≥99%	5633 (42.3%)	1566 (33.2%)	236 (26.3%)	962 (20.0%)

[a]Number of patients (% of patients). [b]Age at 1 year post-implant.

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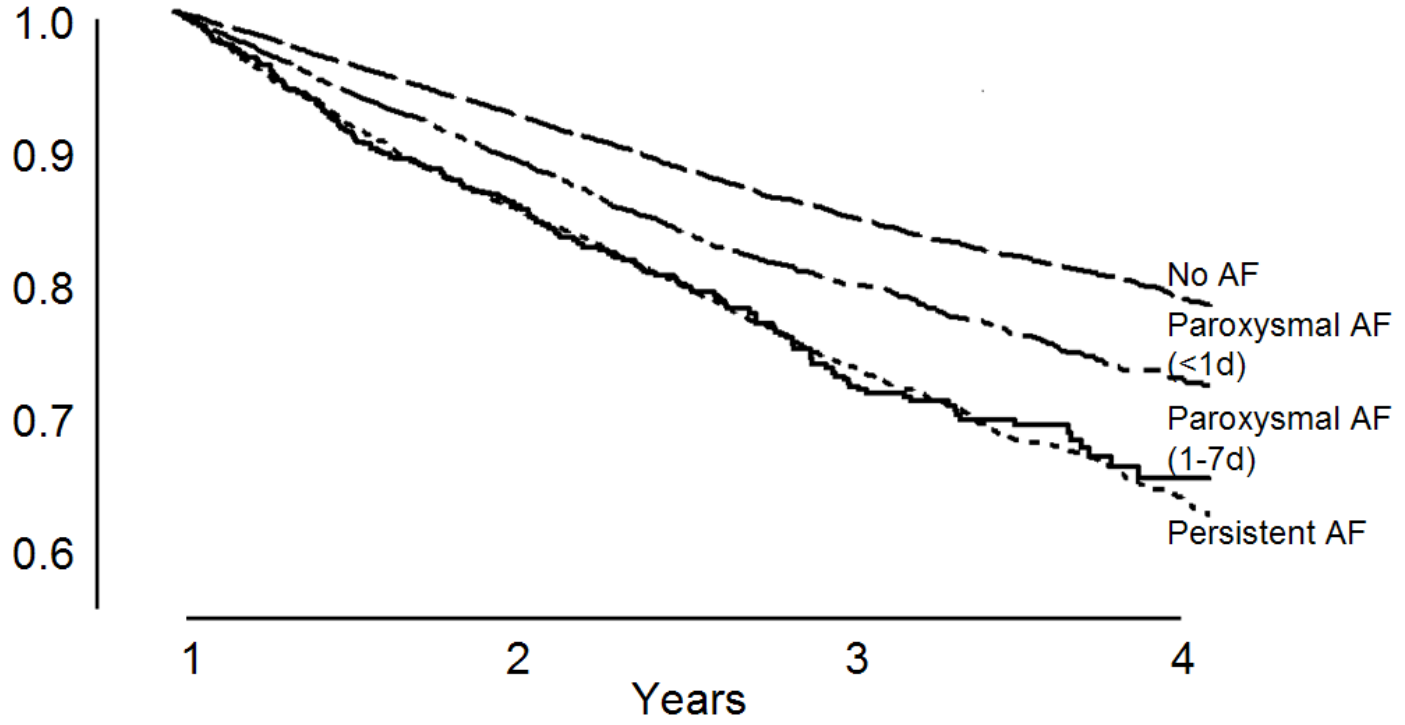
Figure 1. Survival in AF Patients



Patients at Risk (Survival Probability)

No AF	13 331 (1.00)	10 275 (0.92)	5 247 (0.95)	1 124 (0.78)
Parox. AF <1 d	4 711 (1.00)	3 446 (0.99)	1 673 (0.80)	341 (0.73)
Parox. AF 1-7d	896 (1.00)	629 (0.86)	291 (0.72)	56 (0.66)
Persist. AF	4 905 (1.00	3.329 (0.95)	1 523 (0.74)	254 (0.63)

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Atrial Pacing Frequency and Mortality in CRT Recipients: Results from the ALTITUDE Study Group

Introduction

- Few cardiac resynchronization therapy (CRT) trials have evaluated the relationship between atrial pacing and mortality outcomes in devices programmed to the DDD mode.
- The LATITUDE® remote patient monitoring system (Boston Scientific) was launched in the United States for ICD and CRT devices in 2006.
- The ALTITUDE study, which began simultaneously with the launch of LATITUDE, uses data from the LATITUDE remote patient monitoring system to address defined questions using real-world data.
- We sought to evaluate the frequency of atrial pacing and the effect on mortality in CRT recipients with devices programmed to DDD mode who transmit device data using the Boston Scientific LATITUDE® remote monitoring system.

Michael Cao, MD[1]; David L. Hayes, MD[2]; Brian D. Powell, MD[2]; Yong-Mei Cha, MD[2]; David A. Cesario, MD[1]; Milan Seth, MS[3]; Leslie A. Saxon, MD[1]
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Methods

- The LATITUDE agreement signed by the centers participating in ALTITUDE requires the use of limited or de-identified data. Six percent of centers opt out of data used in a limited data set for research.
- Data from United States CRT patients in DDD mode with lower rate limit (LRL) from 40 to 79 bpm were analyzed (n=15,703) by the ALTITUDE study group. LRL was stratified into 10-bpm increments as a proxy for intrinsic heart rate and general measure of sinus rhythm.
- Baseline pacing values were collected over a median of 2.7 months (Interquartile range: 1.1 to 7.1 months).
- All-cause mortality was determined from the Social Security Death Index.
- The association between percent atrial pacing and mortality was analyzed by pacing groups using Cox proportional hazards regression models adjusting for age, gender, percent biventricular pacing, estimated atrial fibrillation incidence, and year of implant.

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Results

- The mean age was 68.6 ± 11.6 years, 67.6% of patients were male, and the mean LATITUDE remote follow-up duration was 24.4 ± 13.6 months.
- Most patients (52%) had a LRL programmed from 60 to 69 bpm (Table 1).
- Patients programmed to a LRL of 70 to 79 bpm were more likely to have atrial fibrillation (22%) than patients programmed to an LRL<70 (4.9% to 8.4%, *P*<0.001).

Table 1	Lower Rate Limit (beats per minute)			
	40-49	50-59	60-69	70-79
Patients, n (%)	2,121 (14%)	3,699 (24%)	8,109 (52%)	1,774 (11%)
Age, years (mean±SD)	65.0±11.7	66.2±11.6	67.9±11.4	70.0±11.8
Male	67.2%	67.3%	66.7%	72.0%
Median BiV pacing	98.7%	98.7%	98.7%	97.9%
Atrial fibrillation*	4.9%	5.9%	8.4%	21.5%
*Based on >5% of atrial sensed beats greater than 180 bpm.				

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Results

- The percent of patients with atrial pacing was highest in patients programmed to a lower rate limit of 70 to 79 bpm (Figure 1).

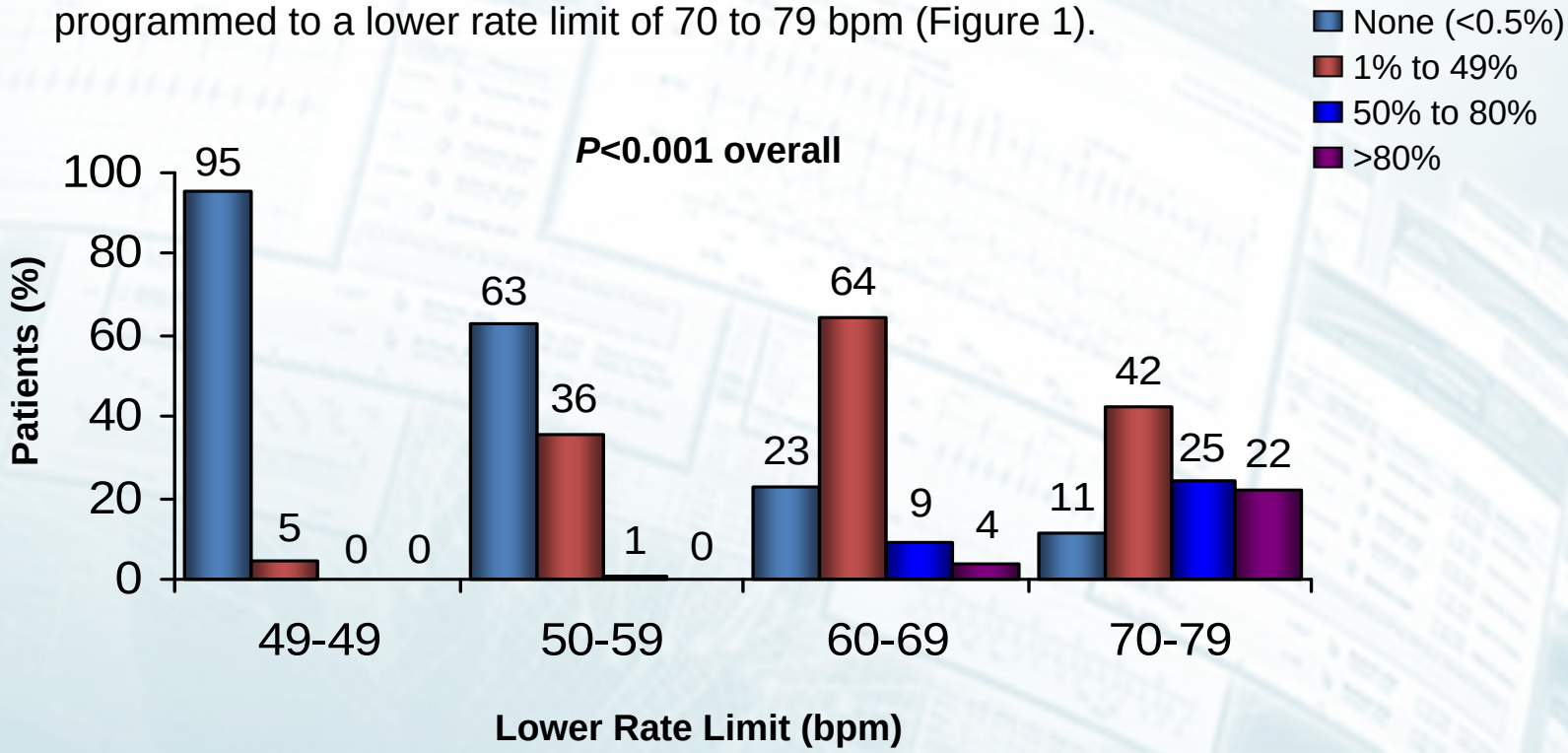

Figure 1. Percent of patients with atrial pacing by programmed lower rate limit.

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Results

- In patients with a programmed lower rate limit of 40 to 49 beats per minute, no significant association was observed between mortality and atrial pacing.
- A low burden of atrial pacing from 50 to 79 beats per minute was associated with up to a 52% reduction in mortality compared with no atrial pacing (Figure 2).

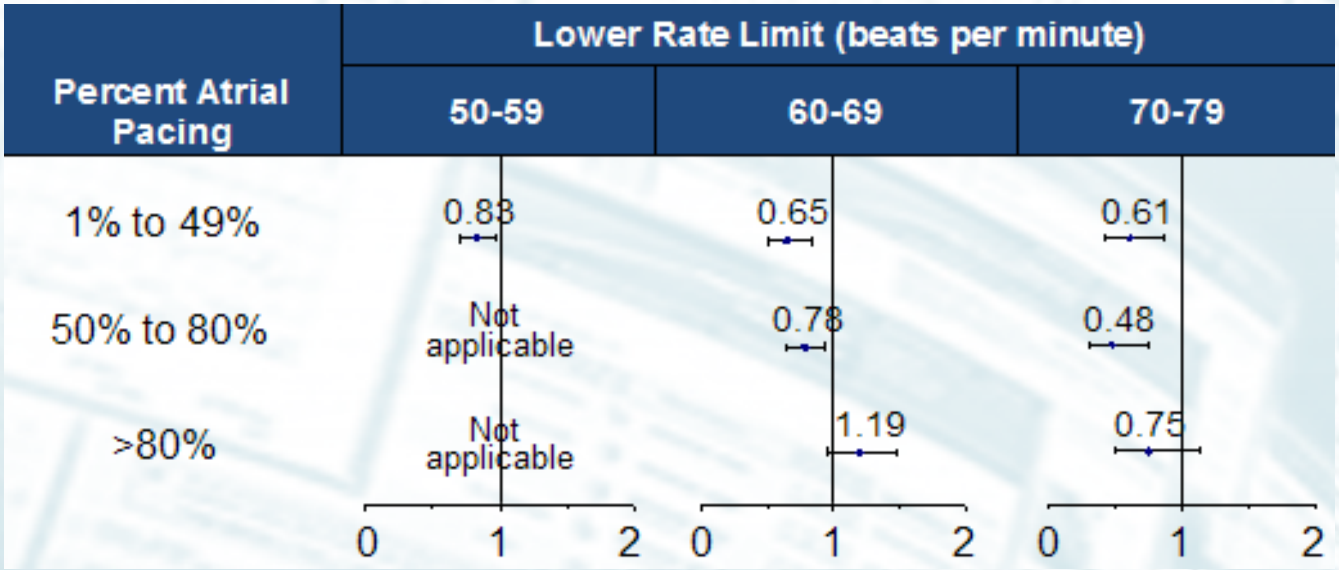

Figure 2. Hazard ratio for mortality with 95% confidence intervals by percent atrial pacing (versus no atrial pacing) for patients with programmed lower rate limit of 50 to 79 beats per minute.

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Brief Summary

CRT-D Systems from Boston Scientific CRM

CRT-D Systems from Boston Scientific CRM

Indications and Usage

These Boston Scientific Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with heart failure who receive stable optimal pharmacologic therapy (OPT) for heart failure and who meet any one of the following classifications:

• Moderate to severe heart failure (NYHA Class III-IV) with EF ≤ 35% and QRS duration ≥ 120 ms

• Left bundle branch block (LBBB) with QRS ≥ 130 ms, EF ≤ 30%, and mild (NYHA Class II) ischemic or nonischemic heart failure or asymptomatic (NYHA Class I) ischemic heart failure

Contraindications

There are no contraindications for this device.

Warnings

Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in patient injury or death. For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial-tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

Precautions

For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implant and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; hospital and medical environments; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

Potential Adverse Events

Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. Patients may develop psychological intolerance to a pulse generator system and may experience fear of shocking, fear of device failure, or imagined shocking. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. N)

Brief Summary

ICD Systems from Boston Scientific CRM

•ICD Indications and Usage

•ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. ICDs with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

•Contraindications

•Use of ICD systems are 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.

•Warnings

•Read the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD system. Such damage can result in patient injury or death. Program the pulse generator ventricular Tachy Mode to Off during implant, explant or post-mortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. 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. Patients should seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients who have a pulse generator. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator because of induced currents. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) Do not use this pulse generator with another pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction.

•Precautions

•For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation and device programming; follow-up testing; explant and disposal; environmental and medical therapy hazards; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy.

•Potential Adverse Events

•Potential adverse events from implantation of the ICD system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, psychologic intolerance to an ICD system - patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

•*Refer to the product labeling for specific indications, contraindications, warnings/ precautions and adverse events. Rx only.*

•*(Rev. M)*

Brief Summary
LATITUDE Patient Management System

- LATITUDE® Patient Management System from Boston Scientific CRM

- Intended Use
- The LATITUDE Patient Management system is intended for use to remotely communicate with a compatible pulse generator from Boston Scientific CRM and transfer data to a central database.

- Contraindications
- The LATITUDE system is contraindicated for use with any pulse generator other than a compatible pulse generator from Boston Scientific CRM. Not all Guidant or Boston Scientific pulse generators are compatible with the LATITUDE system. For contraindications for use related to the Guidant or Boston Scientific pulse generator, refer to the System Guide for the pulse generator being interrogated.

- Precautions
- The LATITUDE system is designed to notify clinicians within 24 hours if new pulse generator alert conditions are detected by the Communicator. Alert notifications are based on clinician configured alert settings. Pulse generator data will typically be available for review on the LATITUDE system within 15 minutes of a successful interrogation. However, data availability and alert notification can take up to 24 hours or the next business day. Note that data will not be available and alert notification cannot occur if:
  - The Communicator is unplugged or is not able to connect to the LATITUDE system through an active phone line.
  - The pulse generator and the Communicator cannot establish and complete a telemetry session. This session must be initiated by the patient if he or she has a pulse generator that uses inductive telemetry.
  - The Communicator becomes damaged or it malfunctions.
  - The patient is not compliant with prescribed use or is not using the LATITUDE system as described in the patient manual.
- Up to two weeks may elapse before LATITUDE first detects the conditions mentioned above and additional time may be required for clinic notification and resolution of the condition. During this time, no new patient data, device data, or alert notifications since the last successful data transmission will be available.
- Alert notifications are not intended to be used as the sole basis for making decisions about patient medical care. Alerts can be verified by reviewing supporting diagnostic information stored in the implanted device and viewing information on the LATITUDE clinician website.

- Adverse Effects
- None known.

- *Refer to the product labeling for specific instructions for use. Rx only.*
- *(Rev. J)*