Tendril MRI™
Model LPA1200M

Active Fixation
Bipolar
Steroid-Eluting
Endocardial
Pacing Lead

User's Manual

ST. JUDE MEDICAL

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

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Contents

Description 1
Indications and Usage 1
Contraindications 1
MR Conditional Pacing System 1
Warnings and Precautions 1
Storage and Handling 2
Lead Implantation 2
Adverse Events 2
- Reported Adverse Events 3
- Potential Adverse Events 8

Summary of Clinical Study 9
- Study Design 10
- Study Objectives 12
- Patient Selection Criteria 13
- Clinical Study Results 14

Conformance to Standards 20
How Supplied 20
Clinician Use Information 20
- Physician Training 20
- Directions for Use 20
- Position the Lead 24
- Secure the Tip 25
- Intraoperative Measurements 27
- Secure the Lead 27
- Connection to the Device 28

Maintaining Device Effectiveness 29
- Device Storage 29
- Sterilization Instructions 29

Lead Extraction 29
- Out-of-Service/Explant/Patient Death Form 29

Technical Support 29

Description

The Tendril MRI™ lead, Model LPA1200M, is an MR Conditional, bipolar, steroid-eluting, active fixation implantable lead with Optim™ insulation. The Tendril MRI lead is designed for long-term pacing and sensing in either the right atrium or right ventricle. The Tendril MRI lead has two conductors: one terminating at the tip helix and the other at the ring electrode.

The minimum recommended introducer size is 8 French without a retained guidewire and 10.5 French with a retained guidewire.

Features of the Tendril MRI lead include:

- Soft tip header — reduces lead tip pressure
- Optim insulation — a silicone-polyurethane copolymer
- Marker ring — to facilitate optimal lead positioning
- Active fixation — features a rotating, extendable/retractable helix for secure anchoring
- Steroid elution — the target dose of dexamethasone sodium phosphate (DSP) in the monolithic controlled release device (MCRD) is 460 micrograms.

Indications and Usage

The Tendril MRI™ lead is a 7.9 French, transvenous, steroid eluting, bipolar, IS-1 compliant, active fixation lead designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril MRI lead may be indicated for patients where permanent fixation of a passive lead is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril MRI lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications

The Tendril MRI™ lead is contraindicated:

- in the presence of tricuspid atresia
- for patients with mechanical tricuspid valves
- in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

MR Conditional Pacing System

The St. Jude Medical™ MR Conditional lead is part of the St. Jude Medical MR Conditional pacing system.

Patients with an implanted St. Jude Medical™ MR Conditional pacing system can have an MRI scan if the conditions for use, as described in the MRI Procedure Information document, are met.

Warnings and Precautions

- Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the device, or other forces associated with cardiac contractions and patient physical activity, posture and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors.
- Patients with implanted leads should avoid diathermy, even if the device is programmed off,

as it may damage tissue around the implanted electrodes or may permanently damage the implantable device system.

- Carefully remove the tip retainer from the lead prior to implantation.
- For single use only.
- Testing has demonstrated that the St. Jude Medical™ MR Conditional system is MR Conditional. A patient with this system may be safely scanned under the conditions given in the MRI Procedure Information document. Scanning under other conditions may result in severe patient injury or death.The St. Jude Medical MR Conditional pacing system includes a St. Jude Medical MR Conditional pulse generator connected to one or more St. Jude Medical MR Conditional leads.

Storage and Handling

- Do not stretch, crush, kink or bend the lead. Leads may be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- Do not bring the lead into contact with sharp objects that could puncture or otherwise compromise the insulation.
- Handle the lead only with powderless, sterile surgical gloves.
- Avoid handling the lead with any surgical tools such as hemostats, clamps or forceps.
- Leads have an electrostatic attraction for particulate matter; do not expose them to lint, dust or other such materials.
- Avoid touching or handling the lead tip electrode itself.
- Do not immerse the lead body in mineral oil, silicone oil, alcohol, or any liquid other than sterile saline or injectable fluid.
- Do not immerse the tip electrode in any fluid prior to implantation; immersion of the electrode may cause a small amount of steroid to be prematurely eluted.

Lead Implantation

- Before opening the lead package, confirm that the lead is compatible with the device to be implanted.
- Lead implantation should be performed only when proper emergency facilities for cardioversion and/or defibrillation are available.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- During this procedure it is advisable to also have echocardiographic equipment available.
- If subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.
- Do not slide the suture sleeve over the electrode rings. This could result in damage to the lead.
- Failure to use the suture sleeve to secure the lead may result in lead dislodgment or in damage to the lead's insulation and/or conductor coil.
- Pay close attention to the handling of the helix extension/retraction mechanism before and during implantation.

Adverse Events

The Reported Adverse Events (page 3) summarize the adverse events in the Accent MRI™

Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study). The MRI study was a prospective, multi-center clinical investigation designed to evaluate the safety and efficacy of the Accent MRI pacemaker system in a patient population indicated for implant of a pacemaker within and outside of an MRI environment.

Per the investigational plan, an adverse event was defined as any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a patient caused by or associated with a study device or intervention.

Adverse events were classified as complications or observations based on the following definitions:

- Complications are defined as adverse events that require invasive intervention (e.g. lead dislodgment requiring repositioning).
- Observations are defined as adverse events that can be managed without invasive intervention (e.g., oversensing or loss of pacing capture, which is remedied by reprogramming of the pacemaker).
- Other Reported Events are any other clinical event that is submitted by the investigator which is not caused by or associated with the study device and/or system component(s) and/or defined as an Adverse Event.

Reported Adverse Events

The tables below list the observations and complications reported from the MRI Study, see Summary Of Clinical Study (page 9). A total of 168 adverse events have been reported in 139 patients, of which 68 are complications and 100 are observations. None of the adverse events were adjudicated as related to or caused by the study MRI scans.

In addition, 103 other events were reported in 73 patients. None of these events were adjudicated as related to or caused by the study MRI scans, the study device, or system components.

Table 1. MRI study adverse events

Event Description	# of Patients with AEs[1] (n=920)	% of Patients with AEs	#AEs	AE/pt-years (n=1,535.44 yrs)
Complications (total)	63	6.85%	68	0.044
Bleeding/Hematoma	2	0.22%	2	0.001
Cardiac Perforation	2	0.22%	2	0.001
Cardiac Tamponade	3	0.33%	3	0.002
Decompensated HF	1	0.11%	1	0.001
Device Connectivity Issue	1	0.11%	1	0.001
Device Migration	1	0.11%	1	0.001
Elevated Pacing Thresholds - RA Lead	2	0.22%	2	0.001
Elevated Pacing Thresholds - RV Lead	1	0.11%	1	0.001
Hemoptysis	1	0.11%	1	0.001
Hemothorax	1	0.11%	1	0.001
Infection	5	0.54%	5	0.003
Lead dislodgement or migration - RA Lead	24	2.61%	25	0.016

[1] Some patients experienced more than one event and therefore the number of patients is less than the number of events.

Table 1. MRI study adverse events

Event Description	# of Patients with AEs[1] (n=920)	% of Patients with AEs	#AEs	AE/pt-years (n=1,535.44 yrs)
Lead dislodgement or migration - RV Lead	7	0.76%	7	0.005
Lead fracture	1	0.11%	1	0.001
Pacemaker Induced Cardiomyopathy	1	0.11%	1	0.001
Pericardial effusion	2	0.22%	2	0.001
Phrenic nerve/diaphragmatic stimulation	1	0.11%	1	0.001
Pneumothorax	4	0.43%	4	0.003
Pocket site/incision pain lasting greater than 72 hours post implant	2	0.22%	2	0.001
Stenosis of the left subclavian vein	1	0.11%	1	0.001
Thrombo-embolic event	1	0.11%	1	0.001
Twiddler's Syndrome	1	0.11%	1	0.001
Undersensing - RA Lead	1	0.11%	1	0.001
Wound dehiscence	1	0.11%	1	0.001
Observations (total)	**87**	**9.46%**	**100**	**0.065**
Atrial Arrhythmia	3	0.33%	3	0.002
Bleeding/Hematoma	9	0.98%	9	0.006
Cellulitis/thrombophlebitis	1	0.11%	1	0.001
Cerebrovascular accident	1	0.11%	1	0.001
Decompensated HF	2	0.22%	2	0.001
Elevated pacing thresholds – RA Lead	3	0.33%	3	0.002
Elevated pacing thresholds – RV Lead	1	0.11%	1	0.001
Excessive rate responsive pacing	1	0.11%	1	0.001
Extracardiac stimulation	1	0.11%	1	0.001
Infection	4	0.43%	4	0.003
Lead dislodgement or migration - RA Lead	3	0.33%	3	0.002
Lead dislodgement or migration - RV Lead	1	0.11%	1	0.001
Loss of Capture - RA Lead	1	0.11%	1	0.001
Loss of Capture - RV Lead	1	0.11%	1	0.001
Mechanical abnormality of pacemaker pocket	1	0.11%	1	0.001
Noise reversion	2	0.22%	2	0.001
Oozing from implant site	1	0.11%	1	0.001
Oversensing - RA Lead	2	0.22%	2	0.001
Pacemaker mediated tachycardia (PMT)	20	2.17%	21	0.014
Pain at device site	1	0.11%	1	0.001
Pectoral stimulation	1	0.11%	1	0.001

Table 1. MRI study adverse events

Event Description	# of Patients with AEs[1] (n=920)	% of Patients with AEs	#AEs	AE/pt-years (n=1,535.44 yrs)
Pericardial effusion	4	0.43%	4	0.003
Pericarditis	3	0.33%	3	0.002
Phrenic nerve/diaphragmatic stimulation	1	0.11%	1	0.001
Pleural effusion	1	0.11%	1	0.001
Pneumothorax	7	0.76%	7	0.005
Pocket site/incision pain lasting greater than 72 hours post implant	5	0.54%	5	0.003
Repetitive Nonreentrant Ventriculoatrial Synchrony	1	0.11%	2	0.001
Set screw damage	1	0.11%	1	0.001
Tachycardia	1	0.11%	1	0.001
Thrombo-embolic event	9	0.98%	9	0.006
Undersensing - RA Lead	2	0.22%	2	0.001
Undersensing - RV Lead	2	0.22%	2	0.001
Undersensing - PG	1	0.11%	1	0.001

Table 2. MRI study events not adjudicated as either observations or complications

ORE Description	# of Patients[2]	# of Events	Comments
Acute Encephalopathy	1	1	Hospitalized for general weakness, altered mental status and mild CHF.
Angina	6	7	Patients hospitalized for chest pain; angioplasty performed in one patient, angioplasty and stenting performed in one patient and stent placed in one patient. No action taken in one patient.
Aortic Valve Replacement	1	1	Patient had history of aortic stenosis; valve replaced with no sequelae.
Arrest – Cardiopulmonary	1	1	Patient brought to ER in full arrest; cardioverted and intubated. Patient ultimately expired.
Arrest – Respiratory	1	2	Patient aspirated on an ice chip and went into respiratory failure ultimately resulting in patient death.

[2] Some patients experienced more than one event and therefore the number of patients is less than the number of events.

Table 2. MRI study events not adjudicated as either observations or complications

ORE Description	# of Patients[2]	# of Events	Comments
Asystole	1	1	Patient suffered an acute MI at home and expired
Atrial Arrhythmia	24	26	Patients had chronic atrial arrhythmias prior to device implant or arrhythmias were not attributed to the study device/procedure.
Atrial Fibrillation	2	2	Medication adjusted in one patient; catheter ablation done in one patient.
Atrial Flutter	1	1	Medication adjusted
Cerebrovascular Accident	5	5	The CVA remained unresolved in four patients, two of whom died as a result of the CVA. One patient went through rehabilitation and recovered.
Chest Pain	5	5	Chest pain resolved with no action in three patients. Medication was adjusted on two patients one of which had cardiac catheterization.
Compression Fracture L2 Vertebral Body	1	1	Patient treated with Kyphoplasty
Decompensated Heart Failure	9	9	Medications added or adjusted. One patient died due to multiple comorbidities.
Device Upgraded to CRT	1	1	Tendril MRI RA lead retained. Patient remains active in study.
Electromagnetic Interference	1	1	Event unresolvable; no action was taken.
Elevated Pacing Thresholds	1	2	Events occurred during initial lead placement; resolved once final lead placement was obtained.
Episodic Dizziness	1	1	Event resolved with medications adjustment.
Fall	2	2	Falls unrelated to device or cardiac issues.
Gastroenteritis	1	1	Patient treated with medication; no additional sequelae.
Hypotension	2	2	Medications adjusted; no additional sequelae observed.
Left Arm Swelling	1	1	No DVT; no action required.
Left Shoulder Pain	1	1	Pain unrelated to device/implant; no action required.
Lumbar Spinal Stenosis	2	2	Patients surgically treated; unrelated to device/study procedures.
Mitral Stenosis	1	1	MVR with single vessel CABG.
Nausea & Generalized Weakness	1	1	Patient withdrew from study due to other underlying medical conditions unrelated to study device/procedures.

Table 2. MRI study events not adjudicated as either observations or complications

ORE Description	# of Patients[2]	# of Events	Comments
Perforated Appendix With Abscess	1	1	Patient had laparoscopic appendectomy.
Pericardial Effusion	1	1	Effusion occurred five months post system implant; determined to be unrelated to study system or procedure.
Pleural Effusion	1	1	Patient hospitalized prior to implant for bilateral effusions and heart block, and was implanted with study pacemaker system during the same admission. Effusion resolved with right thoracentesis one day before implant.
Pulmonary Edema	1	1	Noted on chest x-ray; no intervention required.
Shock/Hypotension	2	2	One patient treated with medication; one patient expired; death unrelated to device/study procedures.
Shortness of Breath	2	2	Device was reprogrammed in one patient. No action taken the other patient.
Syncope	2	2	Device reprogrammed
Thrombocytopenia	1	1	Unresolvable; multiple comorbidities
Thrombo-embolic Event	2	2	Patients treated with anticoagulants
Ventricular Arrhythmia	9	10	One patient died; the death was adjudicated as not related to study device/procedure.
Ventricular Tachycardia	1	1	No intervention required
Total	78	103	

Fifty-six (56) patients enrolled in the MRI study were withdrawn from the study due to death. Three (3) of the deaths were considered to be peri-operative mortalities (occurred ≤ 30 days post-implant). There were no deaths classified as related to the pacemaker or lead system. No deaths were considered or adjudicated to be related to MRI scan exposure.

A summary of the Events committee death classifications is shown in the table below.

Table 3. Events committee classification of patients deaths

Primary Cause	Number of Patients
Cardiac: Arrhythmic	4
Cardiac: Ischemic	1
Cardiac: Pump Failure	4
Cardiac: Unknown	1
Non-Cardiac	40

Table 3. Events committee classification of patients deaths

Primary Cause	Number of Patients
Unknown	6
TOTAL	**56**

Potential Adverse Events

Possible adverse events associated with the system, include, but are not limited to the following:

MRI system adverse events:

- Lead electrode heating and tissue damage resulting in loss of sensing or capture or both
- Lead heating resulting in thrombus formation or embolism
- Pulmonary embolism
- Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
- Damage to the device or leads causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Movement or vibration of the device or leads
- Lead dislodgment
- Competitive pacing and potential for VT/VF induction if asynchronous pacing is programmed when MRI Settings are enabled
- Syncope due to loss of pacing if no pacing support is programmed with MRI settings
- Death due to untreated spontaneous arrhythmia because tachy therapy is disabled when MRI settings are programmed.

Potential pacing system adverse events:

- Air embolism
- Body rejection phenomena
- Cardiac tamponade or perforation
- Hematoma, bleeding hematoma, seroma
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program due to programmer or device malfunction
- Infection/erosion
- Interruption of desired pulse generator function due to electrical interference either electromyogenic or electromagnetic
- Loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface
- Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation)
- Lead malfunction due to conductor fracture or insulation degradation

- Loss of normal pacemaker function due to battery failure or component malfunction
- Pacemaker migration, pocket erosion
- Pectoral muscle stimulation
- Phrenic nerve or diaphragmatic stimulation
- Pneumothorax/hemothorax
- Endocarditis
- Excessive bleeding
- Induced atrial or ventricular arrhythmias
- Myocardial irritability
- Pericardial effusion
- Pericardial rub
- Pulmonary edema
- Rise in threshold and exit block
- Valve damage

Potential lead related adverse events:

- Cardiac tamponade
- Diaphragmatic/phrenic nerve stimulation
- Embolism
- Excessive bleeding
- Induced ventricular ectopy
- Infection
- Loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the pacing lead
- Thrombosis

Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death.

Summary of Clinical Study

The Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study) was conducted under an IDE (investigational device exemption).

The purpose of the MRI study was to assess the safety and efficacy of the Accent MRI pacemaker system in a patient population indicated for implant of a pacemaker within and outside of the MRI environment.

The Accent MRI pacemaker was not pursued for approval but instead the next generation version Assurity MRI™ and Endurity MRI™ pacemakers were approved. The Assurity MRI and the Endurity MRI pacemakers utilize a MRI filter and MRI settings which are identical to the MRI filter and parameter set incorporated in the Accent MRI pacemakers. In addition, all other device components which could have an impact on compatibility with the magnetic resonance environment are unchanged from the Accent MRI pacemaker; therefore all Accent MRI endpoint data collected during the study that provided reasonable assurance of safety and effectiveness within and outside of an MRI environment is applicable to the Assurity MRI and Endurity MRI devices.

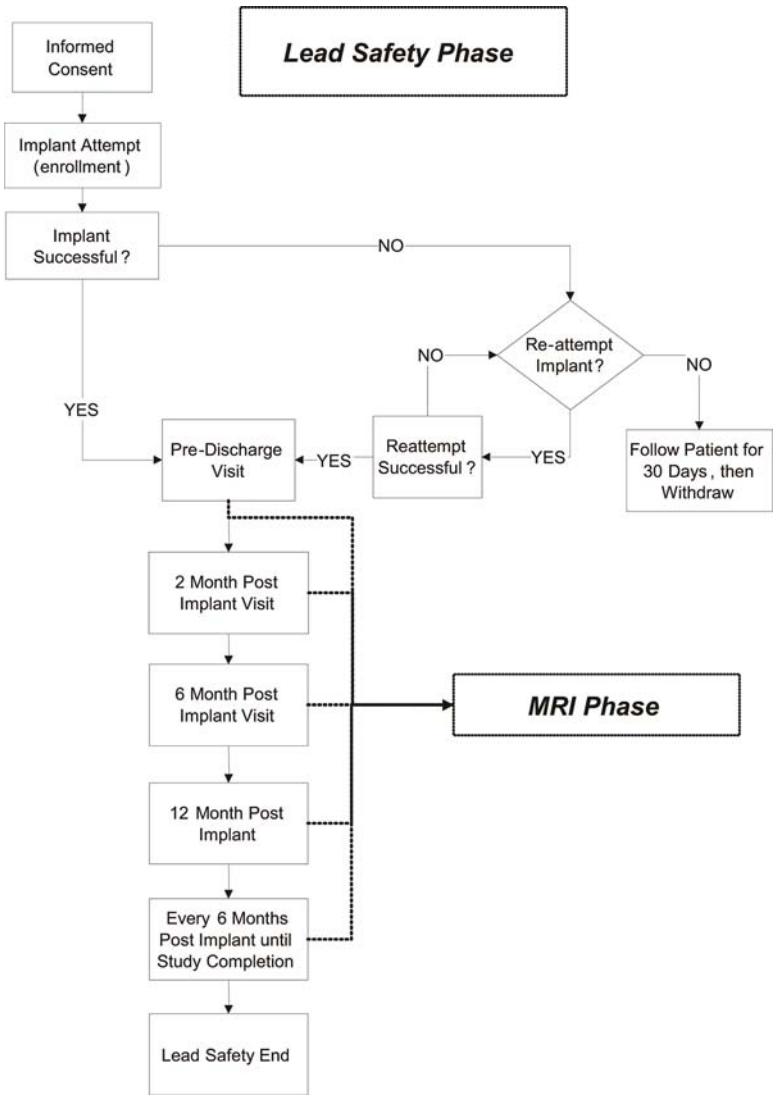
Study Design

The MRI study was a prospective multi-center clinical investigation, consisting of a Lead Safety Phase and an MRI Phase, designed to evaluate the safety and efficacy of the Accent MRI™ pacemaker system indicated for implant of a pacemaker within and outside of the MRI environment. The products being evaluated were the Accent MRI pacemaker, Tendril™ MRI lead and the SJM MRI Activator™ handheld device.

The Lead Safety Phase assessed the safety of the Tendril MRI lead and safety of the Accent MRI pacemaker system; the MRI Phase assessed the safety and efficacy of the Tendril MRI lead and the Accent MRI pacemaker system in an MRI environment.

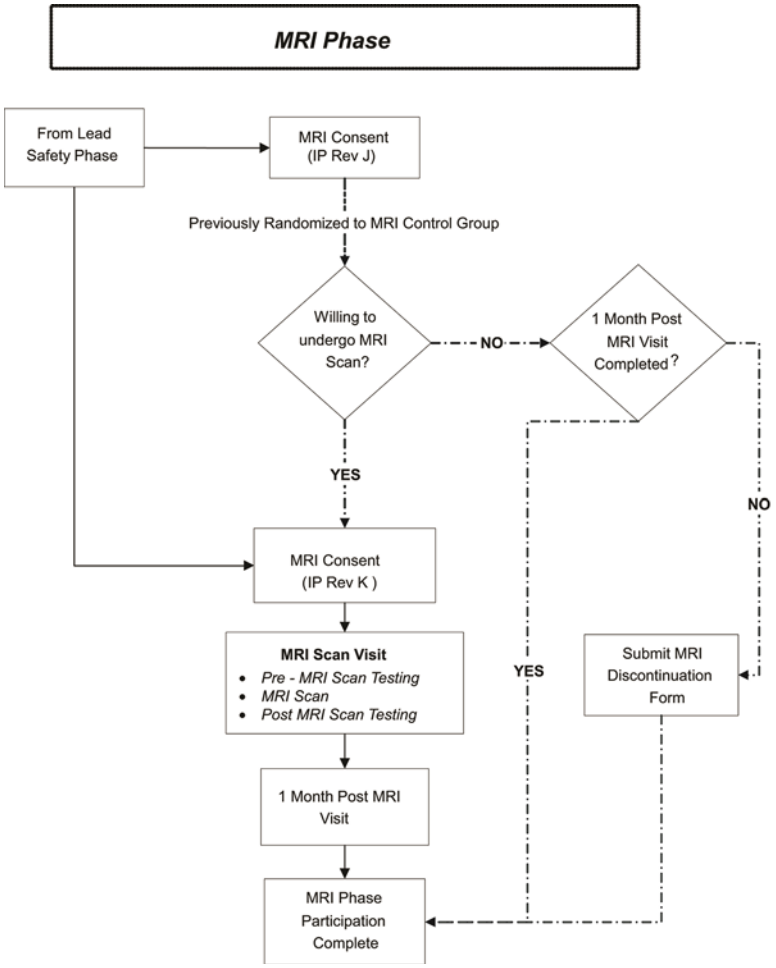
The figure below depicts the Lead Safety Phase of the MRI Study.

Figure 1. Lead Safety Phase



The figure below depicts the MRI Phase.

Figure 2. MRI Phase



Study Objectives

The objective of this clinical study was to verify the safety and efficacy of the Accent MRI™ pacemaker system indicated for implant of a pacemaker within and outside of the MRI environment.

Primary Objectives

The following are the primary safety and efficacy objectives defined for this study.

Lead Safety

Safety of the Tendril MRI™ lead was evaluated in terms of freedom from RA and RV lead-related complications for the acute (implant to two-month visit) and chronic (two-month visit through the 12 month visit) time frames.

MRI Safety

The safety of the Accent MRI system was evaluated in terms of freedom from MRI scan-related complications in the month following the MRI scan.

Lead Efficacy

Efficacy of the Tendril MRI™ lead in was evaluated in terms of the change in bipolar atrial and ventricular capture and sensing thresholds before and after the MRI scan.

Secondary Objectives

The secondary objectives are listed below.

Safety

Safety of the Accent MRI™ system was evaluated in terms of freedom from system-related complications through the 12 month visit.

Efficacy

Efficacy of the Tendril MRI™ lead was evaluated in terms of the bipolar atrial and ventricular capture thresholds at the MRI Visit.

Patient Selection Criteria

Inclusion Criteria

Eligible patients met all of the following:

1. Had an approved indication per ACC/AHA/HRS guidelines for implantation of a pacemaker.
2. Received a new pacemaker and lead.
3. Was willing to undergo an elective MRI scan without sedation.
4. Was able to provide informed consent for study participation (legal guardian is NOT acceptable).
5. Was willing and able to comply with the prescribed follow-up tests and schedule of evaluations.
6. Was not contraindicated for an MRI scan (per the pre-MRI safety screening form)[3].

Exclusion Criteria

Patients were excluded if they met any of the following:

1. Had an existing pacemaker or ICD. A new pacemaker and lead is required for enrollment.
2. Had an existing active implanted medical device, e.g., neurostimulator, infusion pump, etc.[4]
3. Had a non-MRI compatible device or material implanted (e.g., intracranial aneurysm clip, non-MRI compatible devices or material, metals or alloys, etc.).[5]
4. Had a lead extender or adaptor.
5. Was unable to fit in MRI bore; will come into contact with the magnet façade inside the MRI bore.

[3] Applies only to those patients who will participate in the MRI Phase of the study
[4] Applies only to those patients who will participate in the MRI Phase of the study
[5] Applies only to those patients who will participate in the MRI Phase of the study

6. Had a prosthetic tricuspid heart valve.
7. Was currently participating in a clinical investigation that includes an active treatment arm.
8. Was allergic to dexamethasone sodium phosphate (DSP).
9. Was pregnant or planning to become pregnant during the duration of the study.
10. Had a life expectancy of less than 12 months due to any condition.
11. Had exclusion criteria required by local law (e.g., age).
12. Were unable to comply with the follow-up schedule.

Clinical Study Results

Patient Population

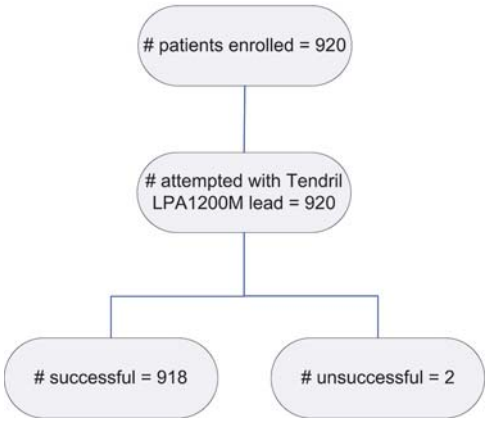
As of October 30, 2014, 920 patients were enrolled at 68 clinical sites in the Lead Safety Phase of the MRI Study. The first Accent MRI™ PM2218 pacemaker and Tendril MRI ™ LPA1200M leads were implanted on March 30, 2012.

Of the 920 patients enrolled in the MRI Study, 918 were successfully implanted with an Accent MRI pacemaker system. Two implants were unsuccessful due to an inability to implant the Tendri MRI lead due to difficulty in obtaining access in one patient and a persistent left SVC in the other patient. Both patients received a market-released pacemaker system, followed for 30 days for safety after the study implant attempt, and then were withdrawn from the study per protocol.

Two hundred twenty-five (225) patients were enrolled in the MRI Phase of the MRI Study in the United States. An additional 30 supplemental scans were performed in Australia, for a total of 255 patients who contributed data to the MRI Phase. The first MRI scan was performed on April 2, 2014.

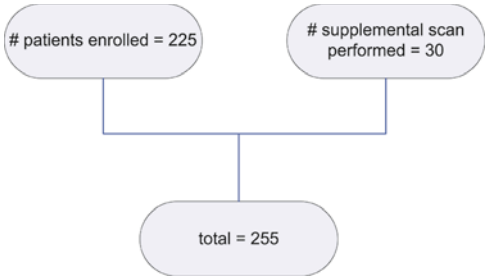
The figure below displays the number of successful and unsuccessful implants in the MRI Study.

Figure 3. Number of patients attempted and implanted with the Accent MRI pacemaker and Tendril MRI lead



The figure below displays the number of patients who contributed data to the MRI phase.

Figure 4. Number of patients participating in MRI phase/contributing scan data



As of October 30, 2014, the total time of follow-up from the time of successful implant was 18,425 patient-months. The average time of follow-up was 20.00 ± 4.66 (range 0.09 to 30.68) patient-months.

Demographic Data

As part of the Lead Safety Phase of the MRI Study, patients who were successfully implanted with the Accent MRI™ pacemaker system were seen at a pre-discharge visit during which the following tests/assessments were performed: electrical measurements on the RA and/or RV leads and identification of the radiopaque markers on the lead and pacemaker. Patients were again seen at two months post-implant, six months post-implant, 12 months post-implant, and every six months thereafter, during which the following tests/assessments were performed: electrical measurements on the RA and/or RV leads. Patients were also assessed for adverse events at all study visits.

For the MRI Phase of the study, patients completed an MRI Visit, and returned approximately thirty days later for a one-month post-MRI visit. At the MRI visit, for patients consenting to undergo an MRI scan, the following tests/assessments were performed: safety screening for the MRI scan, the study MRI scan, assessment for adverse events, including MRI scan-related adverse events, and electrical measurements on the RA and/or RV leads. At the one-month post-MRI visit, the following tests/assessments were performed: assessment for adverse events, including MRI scan-related adverse events, and electrical measurements on the RA and/or RV leads

The table below summarizes all the reported data on the 920 patients who completed the implant visit.

Table 4. Summary of demographic variables for all enrolled patients

Demographic Variable	All Enrolled Patients (N = 920)
Age	
Mean ± SD	73.0±10.8

Table 4. Summary of demographic variables for all enrolled patients

Demographic Variable	All Enrolled Patients (N = 920)
Range (min, max)	(27,101)
Gender, n (%)	
Female	421 (45.8%)
Male	499 (54.2%)
Cardiovascular History, n (%)	
Coronary Artery Disease	338 (36.7%)
Myocardial Infarction	119 (12.9%)
Unstable Angina	73 (7.9%)
Prior Cardiac Interventions, n (%)	
CABG	130 (14.1%)
PTCA/Stents/Atherectomy	152 (16.5%)
Ablation	100 (10.9%)
Non-Ventricular Arrhythmia History, n (%)	
None	370 (40.2%)
AF	481 (52.3%)
Paroxysmal	316 (65.7%)
Permanent	63 (13.1%)
Persistent	100 (20.8%)
AFL	123 (13.4%)
AT	41 (4.5%)
SVT	55 (6.0%)
Primary Indication for Device Implant, n (%)	
AV Block	244 (26.5%)
Pacemaker Generator Change	2 (0.2%)
Prevention/Termination of Tachyarrhythmias By Pacing	13 (1.4%)
Sinus Node Dysfunction	581 (63.2%)
Syncope	60 (6.5%)
Other	20 (2.2%)

The table below summarizes all the reported data on the 225 patients who were enrolled in the MRI Phase of the study, and the 30 patients who contributed supplemental MRI scan data.

Table 5. Summary of demographic variables for all patients contributing data to the MRI phase

Demographic Variable	Patients Enrolled in the MRI Study (N = 225)	Patients Contributing Supplemental MRI Scan Data (N = 30)	Total (N = 255)
Age			
Mean ± SD	69.8±11.6	73.0±5.9	70.2±11.1
Range (min, max)	(30.0,92.0)	(59.0,81.0)	(30.0,92.0)
Gender, n (%)			
Female	98 (43.6%)	16 (53.3%)	114 (44.7%)
Male	127 (56.4%)	14 (46.7%)	141 (55.3%)
Cardiovascular History, n (%)			
Coronary Artery Disease	26 (11.6%)	9 (30.0%)	35 (13.7%)
Myocardial Infarction	5 (2.2%)	0 (0.0%)	5 (2.0%)
Unstable Angina	6 (2.7%)	0 (0.0%)	6 (2.4%)
Prior Cardiac Interventions, n (%)			
CABG	1 (0.4%)	1 (3.3%)	2 (0.8%)
PTCA/Stents/Atherectomy	4 (1.8%)	4 (13.3%)	8 (3.1%)
Ablation	33 (14.7%)	5 (16.7%)	38 (14.9%)
Non-Ventricular Arrhythmia History, n (%)			
None	107 (47.6%)	4 (13.3%)	111 (43.5%)
AF	98 (43.6%)	20 (66.7%)	118 (46.3%)
Paroxysmal	62 (63.3%)	17 (85.0%)	79 (66.9%)
Permanent	15 (15.3%)	1 (5.0%)	16 (13.6%)
Persistent	21 (21.4%)	2 (10.0%)	23 (19.5%)
AFL	33 (14.7%)	6 (20.0%)	39 (15.3%)
AT	10 (4.4%)	6 (20.0%)	16 (6.3%)
SVT	10 (4.4%)	0 (0.0%)	10 (3.9%)
Primary Indication for Device Implant, n (%)			
AV Block	59 (26.2%)	6 (20.0%)	65 (25.5%)
Pacemaker Generator Change	1 (0.4%)	0 (0.0%)	1 (0.4%)
Prevention/Termination of Tachyarrhythmias By Pacing	5 (2.2%)	0 (0.0%)	5 (2.0%)
Sinus Node Dysfunction	141 (62.7%)	18 (60.0%)	159 (62.4%)
Syncope	15 (6.7%)	3 (10.0%)	18 (7.1%)
Other	4 (1.8%)	3 (10.0%)	7 (2.7%)

Primary Safety Endpoint Results

RA Lead-Related Complications (Implant through 2 month visit)

Eight hundred twenty-one (821) patients who had a Tendril MRI lead attempted or successfully implanted were analyzed for this endpoint. Twenty-three (23) RA lead-related complications were

observed.

The probability of RA lead-related complication-free survival at the two-month follow-up visit was calculated as 97.20% with a 95% lower confidence bound of 95.81%, which is greater than the objective performance criterion of 92%.

RV Lead-Related Complications (Implant through 2 month visit)

Nine hundred nineteen (919) patients who had a Tendril MRI lead attempted or successfully implanted were analyzed for this endpoint. Ten RV lead-related complications were observed.

The probability of RV lead-related complication-free survival at the two-month follow-up visit was calculated as 98.45% with a 95% lower confidence bound of 96.81%, which is greater than the objective performance criterion of 92%.

RA Lead-Related Complications (2 month through 12 month visit)

Eight hundred and six (806) patients who had a Tendril MRI lead attempted or successfully implanted and who were not withdrawn before the two-month visit were analyzed for this endpoint. Six RA lead-related complications were observed.

The probability of RA lead-related complication-free survival at the 12-month follow-up visit was calculated as 98.82% with a 95% lower confidence bound of 97.04%, which is greater than the objective performance criterion of 95%.

RV Lead-Related Complications (2 month through 12 month visit)

Nine hundred two (902) patients who had a Tendril MRI lead attempted or successfully implanted and who were not withdrawn before the two-month visit were analyzed for this endpoint. No RV lead-related complications were observed.

The probability of RV lead-related complication-free survival at the 12-month follow-up visit was calculated as 100% with a 95% lower confidence bound of 100%, which is greater than the objective performance criterion of 95%.

MRI Scan-Related Complications

One hundred eight-one (181) patients who received a study scan were analyzed for this endpoint. No MRI scan-related complications were observed.

The proportion of patients free from MRI scan-related complications was calculated as 100% with a 95% lower confidence bound of 97.83%, which is greater than the objective performance criterion of 90%.

Primary Effectiveness Endpoints Results

MRI RA Lead Capture Threshold Efficacy

One hundred forty-four (144) patients who were implanted with an RA lead, received a study scan, and had capture threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a capture threshold increase of ≤0.5 V at 0.5 ms from before to the one-month post-MRI visit was calculated as 100% with a 95% lower confidence bound of 97.47%, which is greater than the objective performance criterion of 90%.

MRI RV Lead Capture Threshold Efficacy

One hundred sixty-seven (167) patients who were implanted with an RV lead, received a study scan, and had capture threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a capture threshold increase of ≤0.5 V at 0.5 ms from before to the one-month post-MRI visit was calculated as 100% with a 95% lower confidence

bound of 97.82%, which is greater than the objective performance criterion of 90%.

MRI RA Lead Sensing Threshold Efficacy

One hundred twenty-one (121) patients who were implanted with an RA lead, received a study scan, and had sensing threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a sensing threshold decrease of ≤50% and atrial sensing amplitude at one-month post-MRI visit of ≥1.5 mV was calculated as 92.56% with a 95% lower confidence bound of 86.35%, which is greater than the objective performance criterion of 85%.

MRI RV Lead Sensing Threshold Efficacy

One hundred thirty-four (134) patients who were implanted with an RV lead, received a study scan, and had sensing threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a sensing threshold decrease of ≤50% and ventricular sensing amplitude at one-month post MRI visit of ≥5 mV was calculated as 97.76% with a 95% lower confidence bound of 93.60%, which is greater than the objective performance criterion of 87%.

Secondary Endpoint Results

System-Related Complications

Nine hundred twenty (920) patients who had an Accent MRI pacemaker system attempted or successfully implanted were analyzed for this endpoint. Forty-five (45) system-related complications (RA lead, RV lead, pacemaker- and system-related complications) were observed.

The probability of system-related, complication-free survival at the 12-month follow-up visit was calculated as 94.64% with a 95% lower confidence bound of 92.76%, which is greater than the objective performance criterion of 80%.

RA Lead Capture Threshold at the MRI Visit (pre-scan)

The proportion of patients who experienced a capture threshold of ≤2.0 V at 0.5 ms at the MRI visit (pre-scan) was calculated as 100% with a 95% lower confidence bound of 97.69%, which is greater than the objective performance criterion of 85%.

RV Lead Capture Threshold at the MRI Visit (pre-scan)

The proportion of patients who experienced a capture threshold of ≤2.0 V at 0.5 ms at the MRI visit (pre-scan) was calculated as 100% with a 95% lower confidence bound of 97.98%, which is greater than the objective performance criterion of 85%.

Additional Data

Patient Discontinuation/Withdrawals

A total of one hundred and five (105) patients participating in MRI Study were withdrawn from the study. Two (2) patients were withdrawn approximately one month after unsuccessful system implants in accordance with the protocol. Fifty-six (56) patients died and were also withdrawn from the study. In addition to these two unsuccessful implants and 56 deaths, 47 additional patients were withdrawn from the study. The table below summarizes the reason for all the patient withdrawals.

Table 6. Patient withdrawals, including deaths and unsuccessful implants

Reason for Withdrawal	# of Patients
Patient and/or Family Request	27
Patient Death	56
Patient Lost To Follow-Up	2
Patient Participation Terminated By Investigator	5
System Explanted Without A System Replacement	13
Unsuccessful Implant	2
Total	105

Conclusions Drawn from the Study

In patients indicated for implantation of a pacemaker, this study demonstrated that the Accent MRI™ pacemaker and Tendril MRI™ lead is effective and can be safely scanned in an MRI environment.

Conformance to Standards

The lead complies with IS-1 connector standard ISO 5841-3.

How Supplied

The lead is packaged one lead per package in a sterile package. Each package contains:

- One lead
- One radiopaque suture sleeve attached to lead
- One spare suture sleeve
- One vein lifter
- Two clip-on tools
- One tip retainer (to be removed prior to implant)
- Stainless steel stylets with knob colors designating degree of firmness
- One literature packet.

Clinician Use Information

Physician Training

Physicians should be familiar with sterile implant procedure and follow-up evaluation.

The following sections describe various stages of lead implantation. Procedures included in these sections are only recommendations. Actual implant procedures are left to the discretion of the implanting physician.

Directions for Use

Preparation

Before implanting the lead:

- confirm compatibility between the device and the lead and review the implantation instructions
- select an appropriate venous route
- select and install an appropriate stylet

- test the mechanical function of the helix
- confirm the helix is completely retracted before implantation.

The Fixation Tool

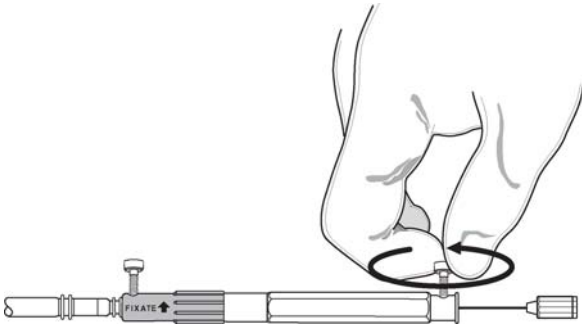
Selected St. Jude Medical™ stylet kits[6] include a simple fixation tool designed to insert and secure the stylet in the lead and to allow extension and retraction of the helix.

The tool is made up of two linked pieces. The proximal (white) portion contains a thumbscrew which holds the stylet in place. The distal (gray) portion contains a thumbscrew which secures the fixation tool to the lead's marker ring. While holding the fixation tool in one hand, use the other hand to unscrew/screw the fixation tool to the connector pin.

Removing and Inserting the Stylet

To remove a stylet from the fixation tool, unscrew the proximal thumbscrew on the tool by turning it counter-clockwise and withdraw the stylet.

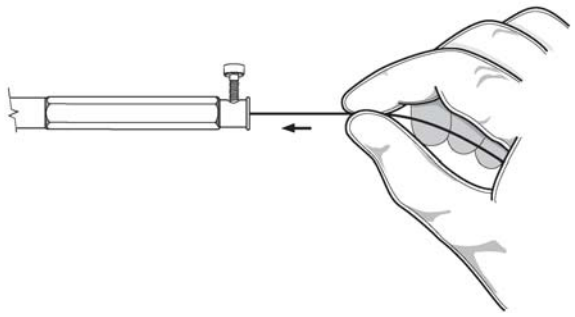
Figure 5. Unscrew the proximal thumbscrew on the fixation tool before you withdraw the stylet



To insert a stylet into the fixation tool, attach the terminal lead pin into the distal (gray) portion of the tool, then insert the stylet through the proximal (white) portion. The stylet should be inserted into the lead before the lead is inserted into the vein.

[6] For additional information, contact your St. Jude Medical Sales Representative.

Figure 6. Insert the stylet into the fixation tool



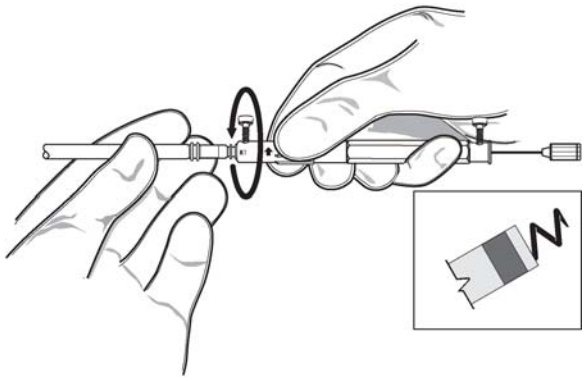
Test the Mechanical Operation of the Helix with the Fixation Tool

Before implanting the lead, the mechanical operation of the helix should be tested.

With both thumbscrews secured and with the fixation tool in one hand, hold the lead stationary with the other hand.

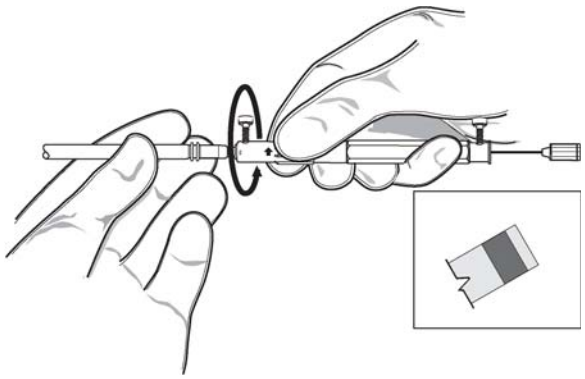
Extend the helix by using the thumb and forefinger to rotate only the gray portion of the tool in the direction of the arrow on the tool marked "FIXATE" (clockwise). Check to see if the helix extends from the lead tip. The helix is considered fully extended when two turns are visible beyond the lead's marker ring.

Figure 7. Extend the helix by rotating the fixation tool clockwise



Retract the helix by holding the lead body stationary in one hand and turning only the gray portion of the tool opposite the direction indicated by the arrow "FIXATE" (counterclockwise).

Figure 8. Retract the helix by rotating the fixation tool counterclockwise



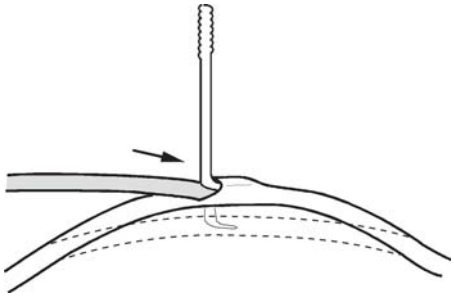
Test the Mechanical Operation of the Helix with the Clip-On Tool

For information on using the clip-on tool, see Secure the Tip with the Clip-On Tool (page 25).

Using the Vein Lifter

A vein lifter is supplied to facilitate the introduction of the lead into a free-standing vein. Insert the tip of the vein lifter into the vein incision and gently lift it while introducing the lead underneath, into the vein.

Figure 9. Vein lifter



Using the Lead Introducer

If a lead introducer is used, follow the instructions provided with the introducer.

CAUTION

- **If using a percutaneous lead introducer with a hemostasis valve, make sure the valve allows for appropriate passage of the lead without damaging the lead body.**
- **Be certain the vein lifter does not puncture the silicone rubber insulation of the**

lead. This could prevent proper lead function.

- Do not use excessive force while inserting the stylet.
- When subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.
- Avoid positioning the lead so that it becomes sharply bent or subjected to tension.
- Do not grip the lead with surgical instruments.
- Do not leave a lead unconnected in a patient unless the lead is capped.

Position the Lead

Confirm that the helix is completely retracted before implantation.

Note

If blood clogs the helix, repositioning may require a greater number of pin rotations to extend the helix. Repeated repositioning attempts may impair the helix extension mechanism.

Atrial Lead Placement

1. Using a straight stylet, introduce the lead into the atrium so that it rests on the floor of the atrial chamber.
2. Replace the straight stylet with a J-shaped stylet, or withdraw the existing stylet, bend it into a soft J-shape, and reinsert the curved stylet into the lead.
3. As the stylet approaches the electrode tip, introduce more lead to ensure that the tip remains in the atrium as the lead takes its "J" shape.
4. Retract the lead as necessary to ensure that the electrode tip slides into the atrial appendage. Observe the fluoroscopy monitor to verify that the "J" is straightening.
5. When the lead is past the appendage and in the chamber, feed more lead into the heart so that it regains its "J" shape.
6. Take a firm grip on the stylet, then introduce more of the lead so that the electrode tip goes as far as possible into the atrium. On fluoroscopy, the electrode tip will "tilt over" as proof that it can go no further.
7. With the clip-on tool or the fixation tool, extend the helix so that the lead is fixed to the atrial wall. See Secure the Tip with the Clip-On Tool (page 25).
8. Retract the entire stylet from the lead with a smooth and steady motion.
9. Check that the lead is properly anchored by introducing more of it into the heart until the loop that forms either lies on the bottom of the atrium, or is about to enter the inferior vena cava or the right ventricle. Retract any excess lead until it acquires the correct "J" shape.
10. Ask the patient to breathe deeply and check that the lead keeps its "J" shape.
11. Ask the patient to cough to ensure that the electrode is securely anchored.

Ventricular Lead Placement

1. Advance the lead into the atrium.
2. Pull the stylet back a few centimeters to reduce the risk of the lead damaging the valves or

penetrating the heart muscle when it continues down into the ventricle.

3. Continue to advance the lead. When the tip reaches the desired implant location, retract the stylet an additional ten centimeters or more.
4. With the clip-on tool or the fixation tool, extend the helix to fix the lead tip to the ventricular wall. If the tip is correctly secured, the lead will be felt to jerk slightly.
5. Remove the stylet completely. Adjust the lead so that it lies in the desired position in the ventricle.

Secure the Tip

Secure the Tip with the Clip-On Tool

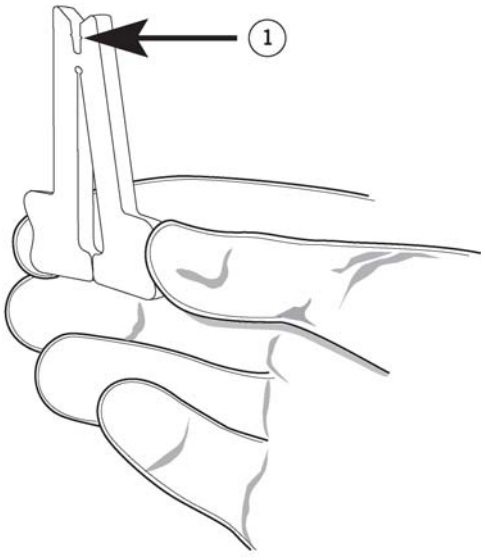
The lead is packaged with the clip-on tool only.

Insert the stylet into the lead and pinch open the clip-on tool. Place the lead terminal pin into the open notch of the clip-on tool so that the pin snaps into place and release the handles. Rotate the clip-on tool clockwise to extend the helix. To remove the clip-on tool, pinch it together and withdraw it from the lead connector.

Note

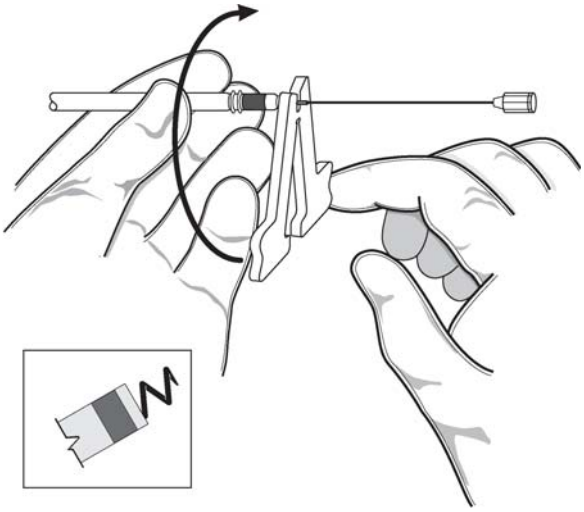
The stylet should be removed before testing the lead for mechanical stability or making intraoperative measurements.

Figure 10. Open the clip-on tool



1. Insert lead into notch

Figure 11. Extend the helix by rotating the clip-on tool clockwise



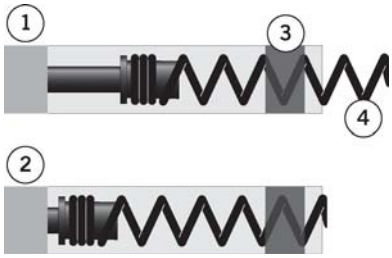
Secure the Tip with the Fixation Tool

As an alternative to the clip-on tool, the fixation tool may be used to extend or retract the helix.

After the fixation site has been selected, hold the lead body stationary in one hand and turn the distal (gray) portion of the fixation tool in the direction marked "FIXATE" (clockwise). See the enclosed specification sheet for the approximate number of turns required for each lead length. On the fluoroscopic image, the helix will be extended beyond the marker ring.

The helix is fully extended when two turns of the helix extend past the marker ring, as shown in the following figure. It may be necessary to reposition the fluoroscopy camera or to advance the lead body in order to see the entire helix.

Figure 12. Extension and retraction of the helix



1. Helix fully extended
2. Helix fully retracted
3. Marker ring
4. Electrically active helix

Once fixation is verified, loosen the proximal thumbscrew on the fixation tool and carefully withdraw the stylet under fluoroscopic observation. The lead tip should remain in position.

Exercise caution during stylet retraction to avoid dislodging the lead.

Retraction of the J-shaped stylet may be more difficult than retraction of a straight stylet. A recommended method for retracting a J-shaped stylet is to loosen the proximal thumbscrew and hold the stylet handle manually; then gently advance the lead body into the atrium while simultaneously, but more slowly, advancing the stylet. Advance about twice as much lead as stylet; in this way, the J shape widens and the stylet can be more readily removed.

Intraoperative Measurements

It is important to verify stimulation threshold and sensing capability during implantation. A pacing system analyzer (PSA) is recommended for these electrical measurements.

A low threshold value and high intracardiac signals are signs that the lead has been positioned satisfactorily.

WARNING

A pacing lead inserted into the heart presents a direct, low-impedance pathway for current flow to the myocardium. Use only battery-powered test equipment for electrical measurements.

Connection to the Pacing System Analyzer

Remove the stylet from the lead once the lead is in what is believed to be a suitable location.

Exercise caution when applying alligator clips to the lead's connector pin to avoid damaging the insulation between terminals.

For more information on the use of the PSA, please refer to the PSA manual.

Recommended Values

If the initial measurements are different from those recommended in the following table, it is best to wait a while and then repeat the measurements. If the values do not stabilize at an acceptable level it may be necessary to alter the position of the electrode tip.

Table 7. Recommended values on implantation, measured with a PSA

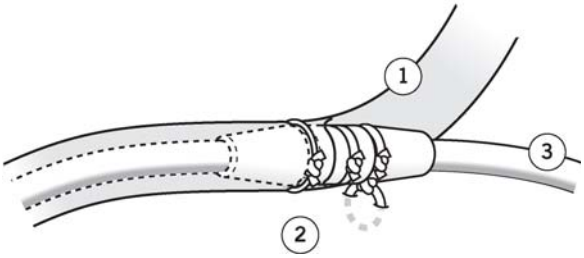
	Ventricle	Atrium
Maximum stimulation threshold value	0.5 V (1 mA)	1.0 V (2 mA)
Minimum intracardiac amplitude	5 mV	2 mV
Lead impedance	500–2000 Ω	500–2000 Ω

Secure the Lead

Once the lead has achieved a stable position with good thresholds, securely anchor the lead at or near the venous entry site using a nonabsorbable synthetic suture. First secure the suture sleeve to the underlying tissue, then recheck lead position visually and under fluoroscopy (to prevent twisting of the lead and identify inadvertent retraction or advancement of the lead).

Tie sutures firmly around each available groove on the suture sleeve. The most distal groove may be used to tie off the vein over the suture sleeve.

Figure 13. Suture the lead



1. Vein
2. Fascia
3. Lead body

CAUTION

- Use the suture sleeve to distribute the tension created by the suture. Failure to use the suture sleeve may result in damage to the lead's insulation or conductor coil.
- Do not slide the suture sleeve over the electrode rings. Suture sleeve sticking can occur. If this occurs, carefully twist the sleeve off the ring toward the connector pin; pulling the suture sleeve when it is positioned over the electrode ring may cause a tear in the lead body near the electrode ring.
- Do not tie the suture around the suture sleeve and lead too tightly, as this may result in excessive stress applied to the lead body.

Connection to the Device

Once the lead is anchored, connect the lead to the device following the instructions in the device manual.

Grasp the lead connector as close as possible to the connector pin while inserting the lead connector straight into the device port. If necessary, regrip the lead and continue to insert the lead connector until it is fully seated in the device port.

CAUTION

Orient the excess lead length and the device to minimize the potential for insulation damage resulting from lead-to-lead or device-to-lead interaction. For example, minimize the potential for leads lying on top of each other under the device and ensure that there are no sharp bends in the lead. Lead insulation damage can create an alternate electrical current path which may result in compromised therapy delivery. Current practice indicates that a subcutaneous pocket is preferred over a subpectoral pocket.[7][8]

[7] Furman S, Hayes DL, Holmes DR. A Practice of Cardiac Pacing. 3rd ed. New York: Futura Publishing, Inc.; 1993:286-289.
[8] Belott, PH, Reynolds, DW. Permanent Pacemaker and Implantable Cardioverter-Defibrillator Implantation. In: Ellenbogen KA, Kay GN, Wilkoff BL, eds. Clinical Cardiac Pacing and Defibrillation. 2nd ed. Philadelphia, Pa: WB Saunders; 1995:613-615.

Maintaining Device Effectiveness

Device Storage

- The lead should be stored at controlled room temperature, 25°C (77°F); excursions permitted between 15°C and 40°C (59°F and 104°F).
- The lead package has been sterilized with ethylene oxide for direct introduction of the inner tray into the surgical field.
- Before the package is opened, inspect it visually for any damage that may have compromised sterility.
- Do not implant the lead if the sterility indicator dot within the inner package is purple, because it may not have been sterilized.

Sterilization Instructions

- The package contents have been sterilized with ethylene oxide before shipment. This lead is for single use only and is not intended to be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.

Lead Extraction

CAUTION

- **Lead extraction carries with it clinical risk. If a pacing lead must be removed due to infection or other serious reason, great care should be exercised.**
- **A pacing lead explanted for any reason should never be implanted in another patient.**

If the lead or any portion of it is extracted, return it to the manufacturer.

It is generally recommended that a chronically implanted endocardial pacing lead not be repositioned except in special circumstances.

Out-of-Service/Explant/Patient Death Form

Return all extracted leads, whether intact or not, and all unused leads, to St. Jude Medical for investigation.

Complete an Out of Service/Explant/Patient Death form and return it to St. Jude Medical with the extracted leads. Whenever possible, send along a printout of the programmed settings of the pulse generator. For information on printing reports, see the appropriate manual.

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.

Cardiac Rhythm Management Division

St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

sjm.com

ST. JUDE MEDICAL

100126459

EN

February 2017
Art 60066161 C

Help Manual

For the following devices:
Accent™, Accent™ RF,
Allure™, Allure Quadra™, Allure Quadra™ RF, Allure™ RF
Anthem™, Anthem™ RF
Assurity™, Assurity MRI™
Current™, Current™ RF, Current™+, Current Accel™
Ellipse™
Endurity™, Endurity MRI™
Fortify™, Fortify Assura™
Promote™, Promote™ RF, Promote™+, Promote Accel™, Promote™ Q, Promote Quadra™
Quadra Allure MP™, Quadra Allure MP™ RF, Quadra Assura™, Quadra Assura MP™
Unify™, Unify Quadra™, Unify Assura™

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

Contents

Tools Menu 1
? Button 1
Tools 1
Session Records 1
PDFs 3
Preferences 3
Print Screen 4
Export Screen 4
Rhythm Display 5
Rhythm Display 5
ECG 5
Markers 6
EGM 12
Waveform Control 12
Rhythm Display Setup Instructions 12
Adjust Display 12
Freeze Capture 14
FastPath™ Summary Screen 15
FastPath™ Summary 15
Alerts 15
Patient Data 16
Patient Data: Lead Information 16
Additional Cardiac Hardware? 16
Clear Trends 16
Indications for Implant 16
Note 17
On-Screen Keyboard 17
Select Additional Reports to be Printed with the FastPath™ Summary 17
Episodes 19
Episode Directory, VT/VF Episodes and Other Episodes 19
Episode Detail 20
ATP Therapy Details 21
Diagnosis Details 21
SVT Criteria Statistics 21
Episode Tree 22
Logs 22
High Ventricular Rate Log 22
Logs & Summaries 23
SVT Diagnosis Summary & Morphology Template Details 23
HV Charging and Non-sustained RV/V Oversensing Details 24
Therapy Summary Details 24
Diagnostics 25
Rates 25
Conduction 26
Mode Switch and AT/AF 26
Mode Switch 26
AMS Summary 27
V Rates During AMS 27
AMS Log and AT/AF Log 27
AMS Log 27
AT/AF 28
AT/AF Log 28
Exercise & Activity 29
Exercise & Activity Diagnostic Tools 29
Impedance Monitoring 29
Add/Edit Clinical Comment 30
Tests 31
Real-Time Measurements 31
Capture & Sense 31
Battery & Leads 37
Sensor 39
Timing Optimization/CRT Toolkit Tab 40
Fibber & NIPS 50

Temporary Pacing....58
Brady Parameters....61
Basic Operation....61
Rates....66
Delays....69
VIP™ Parameter Settings....73
Capture & Sense....73
Cap Confirm/V. AutoCapture™ Settings....76
SenseAbility™ Sensing Algorithm Settings....77
Advanced Settings....79
Leads....79
Lead Monitoring Parameters....80
Refractories & Blanking....80
Additional Settings, PVC & PMT....83
AT/AF Detection & Response....86
Rates & Refractories....88
Tachy Parameters....89
ShockGuard™ Technology Settings (Zone Configuration Window)....89
Detection Criteria....89
SecureSense™ Settings....90
SVT Discrimination....91
SVT Discrimination Details....92
SVT Discriminators....93
Sinus Tach Rate Branch Control....94
Morphology Window....95
Advanced Settings....98
Interval Stability Window....100
Sudden Onset Window....102
Morphology Template....103
Morphology Scoring Window....104
Zone Therapy....105
Therapy....106
ATP Prior to Charging....107
ATP While Charging....107
ATP Details....108
ATP Parameters....108
ATP Therapy Configurations....111
DeFT Response™ Technology Settings (Shock Waveform)....114
Waveform Settings....115
Tuned Waveform Help....116
Redetection & Post Detection Criteria....119
Post Detection Description....120
Post-Shock Pacing....121
Capacitor Maintenance....122
Tachy Therapy Detailed Descriptions....123
Zone Descriptions....123
Tachyarrhythmia Detection Description....123
Rate Zone Legend....124
SVT Discrimination Description....124
Tachyarrhythmia Therapy Description....131
VT Therapy Timeout Description....132
Alert Notification Parameters....133
Alert Notification....133
Alert Triggers....133
High Ventricular Rate: Episode Trigger & Alert Trigger....134
AT/AF Alert Triggers....134
Patient Notifier Delivery....136
Patient Notifier Description....136
Percent Pacing Alert Triggers....137
Episode Settings....139
Episode Settings....139
Stored EGM Configuration....139
Episode Triggers....142
Episode Trigger: High Ventricular Rate....143
Episode Trigger: Atrial Episode....144
Diagnostic Settings....145
CorVue™ Thoracic Impedance Monitoring Feature....145

Custom Sets 147
Create and Save a Custom Set 147
Load a Custom Set 147
Delete a Custom Set 147
Rename a Custom Set 148
Export a Custom Set 148
Import a Custom Set 148
MRI Settings 149
MRI Settings 149
MRI Checklist 150
MRI Settings: Active 150
Wrap-up™ Overview 151
Wrap-up™ Overview 151
Export Data 151
Clear Trends 151
Clear Diagnostics 151
Restore Initial Values 152
Mode Descriptions 153
DDD 153
DDI 154
DDT 155
DOO 155
DVI 156
VVI 157
VOO 157
VDD 158
VVT 159
AAI 159
AAT 159
AOO 160
Pacing Off 160
Rate-Responsive Modes 160
Operating Modes for Single-Chamber Accent™ Devices 161
Additional Programming Information 163
Technical Support 163
Supported Devices 163
Main Programming Window 165
Telemetry Communication 165
Tachy Therapy Enable/Disable 168
Device Parameters and Settings Selection 168
Preview Changes 169
Start Temporary 169
Print Menu 169
Reports 169
Episodes Settings 170
Select Diagnostics Reports for Printing 171
Test Results Settings 172
Select Episodes for Printing 172
Select Freezes for Printing 172
Select Referral Reports for Printing 172
Wrap-up™ Overview Settings 172
Settings 172
Reports Printed at Interrogation 173
Reports Selected for Printing 173
Page Header & Footer Settings 173
Emergency Operation 173
Emergency Shock 173
Emergency VVI Settings 174
Reset Function 175
MRI Settings Reset Values 176
Backup VVI and Backup Defibrillation Only Settings 177
Feature Capabilities Lists 179
ACap™ Confirm Capability 179
AT/AF Alert Triggers Capability 180
ATP Therapy Prior to Charging and ATP Therapy While Charging Capability 181
Auditory Patient Notifier Capability 181
Auto VectSelect Quartet™ Test Capability 181

Battery Model 2356 182
Battery Model 2555 182
Battery Model 2662 182
Battery Model 2753 183
Battery Model 2850 183
Battery Model 2950 183
BiVCap™ Confirm Capability 183
Chamber Onset Discrimination Capability 184
CorVue™ Thoracic Impedance Monitoring Capability 184
DecisionTx™ Programming Capability 185
DynamicTx™ Over-Current Detection Algorithm Capability 185
Enhanced AT/AF Diagnostics Capability 185
Enhanced Diagnostic Trend Capability 186
Enhanced Diagnostic Trend (1-Year Daily Reports) Capability 186
Enhanced Rate Responsive Pacing Capability 187
Far Field MD™ Morphology Discrimination Capability 187
Follow-up EGMs Capability 188
High Ventricular Rate Diagnostic Capability 188
Low Frequency Attenuation Capability 189
MR Conditional Programming Capability 189
SJM MRI Activator™ Handheld Device Capability 189
MultiPoint™ Pacing Capability 189
Non-sustained VT/VF Episode Capability 189
Patient Notifier Capability 190
Percent Pacing Alert Capability 191
Plugged Port Lead Type Capability 191
QuickOpt™ Timing Cycle Optimization Capability 192
RF Telemetry Capability 192
SecureSense™ RV Lead Noise Discrimination Capability 193
SyncAV™ CRT Capability 193
V AutoCapture™ Capability 194
VectSelect Quartet™ LV Pulse Configuration and IS4-LLLL Lead Capability 194
Ventricular Triggering Capability 194

Parameter Availability and Settings 197

Accent™ Devices Technical Data 227
Shipped and Standard Settings 227
Operating Parameters Tolerances 230
NIPS Tolerances 231
Physical Specifications 232
Battery Voltage 232
X-ray Identification 232
Spare Parts and Accessories 232

Allure™, Allure Quadra™, Quadra Allure MP™, and Quadra Allure MP™ RF Devices Technical Data 233
Shipped and Standard Settings 233
Operating Parameters Tolerances 235
NIPS Tolerances 236
Physical Specifications 237
Battery Voltage 237
X-ray Identification 237
Spare Parts and Accessories 237

Anthem™ Devices Technical Data 239
Shipped and Standard Settings 239
Operating Parameters Tolerances 241
NIPS Tolerances 242
Physical Specifications 242
Battery Voltage 243
X-ray Identification 243
Spare Parts and Accessories 243

Assurity™ and Assurity MRI™ Devices Technical Data 245
Shipped and Standard Settings 245
Operating Parameters Tolerances 248
NIPS Tolerances 250
Physical Specifications 250
Battery Voltage 250
X-ray Identification 250
Spare Parts and Accessories 251

Current™, Current™+, Current™ RF, and Current Accel™ Devices Technical Data 253

Physical Specifications 254
Device Configurations 255
Battery Voltage 256
Operating Parameters Tolerances 256
X-ray Identification 257
Spare Parts and Accessories 257
Ellipse™ Devices Technical Data 259
Physical Specifications 260
Device Configurations 260
Battery Voltage 260
Operating Parameters Tolerances 261
X-ray Identification 262
Spare Parts and Accessories 262
Endurity™ and Endurity MRI™ Devices Technical Data 263
Shipped and Standard Settings 263
Operating Parameters Tolerances 266
NIPS Tolerances 268
Physical Specifications 268
Battery Voltage 268
X-ray Identification 268
Spare Parts and Accessories 268
Fortify™ Devices Technical Data 271
Physical Specifications 271
Device Configurations 271
Battery Voltage 272
Operating Parameters Tolerances 272
X-ray Identification 273
Spare Parts and Accessories 273
Fortify Assura™ Devices Technical Data 275
Physical Specifications 275
Device Configurations 276
Battery Voltage 276
Operating Parameters Tolerances 276
X-ray Identification 277
Spare Parts and Accessories 277
Promote™, Promote™ RF, Promote Accel™, Promote™+, Promote™ Q, and Promote Quadra™ Devices Technical Data 279
Physical Specifications 280
Device Configurations 281
Battery Voltage 282
Operating Parameters Tolerances 282
X-ray Identification 283
Spare Parts and Accessories 283
Quadra Assura™, and Quadra Assura MP™ Devices Technical Data 285
Physical Specifications 286
Device Configurations 286
Battery Voltage 287
Operating Parameters Tolerances 287
X-ray Identification 288
Spare Parts and Accessories 288
Unify™, Unify Assura™, Unify Quadra™ Devices Technical Data 289
Physical Specifications 289
Device Configurations 290
Battery Voltage 290
Operating Parameters Tolerances 291
X-ray Identification 291
Spare Parts and Accessories 292
Clinician Use Information for Bradycardia Devices 293
Device Longevity 293
Elective Replacement Indicator (ERI) 312
End-of-Life 313
Clinician Use Information for Tachycardia Devices 315
Patient Selection and Treatment 315
Detailed Device Description 315
Implanting the Pulse Generator 319

Patient Follow-Up 321
Device Longevity 322
Device Longevity Tables 323
Using a Magnet 351
Explanting the Pulse Generator 351
Clinical Studies 353
Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study) 353
Performance of Chamber Onset and Far Field Morphology SVT Discriminators 365
Detect Fluid Early from IntrA-thoracic Impedance MoniToring (DEFEAT-PE STUDY) 368
Promote™ Q CRT-D and Quartet™ Left Ventricular Heart Lead Study 372
DecisionTx™ Programming 387
Acute IEGM Studies 388
ADOPT-A Study 391
AF Suppression™/CRT-D Study 394
Automaticity Clinical Investigation 399
DEFINITE Trial 402
Frontier II: Summary of Clinical Investigations 406
PAVE Study 411
RHYTHM ICD Study 414
RHYTHM ICD Study: V-V Optimization Phase 421
Zephyr IDE Clinical Trial 423
MultiPoint™ Pacing IDE Study 425
Index 438

Tools Menu

Contents:

- **? Button** (page 1)
- **Tools** (page 1)
- Session Records. Opens the Session Records (page 1) and PDFs (page 3) windows.
- **Preferences** (page 3)
- **Customer Support**. Provides contact information for Technical Support representatives. See also Technical Support (page 163).
- **Print Screen** (page 4)
- **Export Screen** (page 4)

? Button

The ? button opens a window that provides access to the Help manual. You can also access the manual if you select Tools (page 1) > Educational Materials > Help.

Accessed From: Help button

Tools

The Tools menu provides access to a number of programmer tools, including:

- **PSA**. Opens the PSA application. See the Merlin™ PCS PSA Reference Manual.
- **Session Records**:
  - **Session Records** (page 1). Opens archived data.
  - **PDFs** (page 3). Opens the PDFs window to manage the reports stored as PDFs on the programmer's hard disk.
- **Educational Materials**:
  - **Help**. Opens links for on-line Help for all supported devices.
  - **Demos**. Opens device demonstrations.
- **Maintenance**. Opens utilities for programmer maintenance (for use by St. Jude Medical personnel only).
- **Clinical Studies**. Opens information for studies (for use by St. Jude Medical personnel only).
- **Preferences** (page 3). Opens the Merlin PCS settings.
- **Customer Support**. See Technical Support. (page 163)
- **Print Screen** (page 4)
- **Export Screen** (page 4). Exports an image to a USB flash drive or floppy drive.

Accessed From: Tools menu

Session Records

The Session Records window allows you to search, review, and export programming session records that are recorded on the programmer's hard disk. Each session record contains one or more snapshots of the session captured during programming, measurement, and testing. Each snapshot is a representation of the programmer screen performed when the operation took place. The records can be exported to an external media device or a PC in a format for an external PC database or for Merlin.net™ PCN.

To retrieve a specific session record, you can use the Search function, which filters the data by Patient Name, Patient ID, and device Serial Number (obtained from the Patient Data information) and the Device Model and Session Date.

A new Session Record is created at the beginning of each programming session. You can review any operation performed during the session up to the time the Session Records button is selected.

You can open the Session Records function from the Start-Up screen or during a programming session.

You can also export a Session Record without viewing the record or starting a Session Records session from the Tools Menu. To do this, select the Export Data (page 151) button from the Wrap-Up™ Overview (page 151) during the programming session.

> CAUTION
>
> **Session Records and PDF Reports are erased from the Merlin PCS after the number of days specified in the Data Management Preferences (page 3). Make sure you select the time limit from the Start-Up Screen > Tools >Preferences > Data Management.**

See also:

- Find a Session Record (page 2)
- Export a Session Record (page 2)
- Review a Session Record (page 2)
- Import a Session Record (page 2)

Accessed From: Tools menu > Session Records button

Find a Session Record

To find a record from the Sessions Record window:

1. Select Tools > Session Records.
2. Select the device model you want to access.

   The Session Records window opens. You can search by device model type, patient name, patient ID, date range, and device serial number.
3. Select a search field and enter the data.

   When you select the device model type and date range, a drop-down menu appears. When you select any other field, an on-screen keyboard appears to enter the data. If a data field is left blank, the search function reviews all entries. The search text is not case-sensitive.
4. Select the Search button.

   The Session Records meeting the Search criteria appear in the table below. You can sort the data by selecting a column heading.

Instructions to Export a Session Record

1. After obtaining a record, select the Export button on the left side of the window.
2. Select a record to export.
3. Connect a USB flashdrive, USB floppy, or a PC connected by a 9-pin serial to USB cable into one of the USB ports on the Merlin PCS.
4. Select the Export Selected button.
5. Select the type of data you want to save.

   The PC database-compatible record is smaller and contains only data for PC-based database programs. The Merlin.net PCN-compatible record is larger and contains more detailed information.
   The programmer locates any connected media devices and asks you to which device would you would like to export the record.
6. Select the desired media option and then the Export button.

   Merlin.net PCN-compatible records are saved in a folder entitled "Unity" that contains a compressed file named after the device's model number, serial number, and session date. PC database-compatible records are saved to a file called "XXXXXX.log," where "XXXXXX" is the device serial number.

Review a Session Record

1. After obtaining a record, select the Review button on the left side of the window.
2. Select the record to review.

   The Session Files window shows the device model, serial number, and session date and time. The window also shows all the operations performed during the session and the time each was performed. Each operation is a snapshot of all programmer screens at that moment. Select the View Most Recent button to see the last operation performed.
3. Select the operation you would like to see or the Most Recent Button.

   The Session File window opens, which shows the snapshot of the programmer screen, with the device and session information in the Rhythm Data window. You can select the buttons on the right side to see other screens captured during the operation. However, you cannot perform any functions that would require communication with the device. This includes the ability to change parameter settings, run tests, update or clear diagnostics, read device battery and lead data, acquire a morphology template, etc.
   You can perform the following operations from the Session File window:
   - View Alerts from the FastPath™ Summary window
   - Export Data from the Wrap-Up™ window
   - Print Reports from any window
   - End Session from any window where it is displayed
   - Close the Session File and view another Session Record.
4. Navigate through the Session File. When you have finished, select the Select New File Button to continue to view other Session Records or End Session, to return to the Session Records window.

Import a Session Record

1. Select the Import button on the left side of the window.
2. Connect a USB flashdrive, USB floppy, or a PC connected by a 9-pin serial to USB cable into one of the USB ports on the Merlin™ PCS.
3. Select the Read Ext. Media button.
4. Select the media from which to import.

5. Select the Import button.

   The session records are read from the external media and presented in the table. To sort the records, select a column heading. To review the session record prior to copying it to your Merlin PCS, select the record.

6. Select the records you want to copy to your Merlin PCS.

7. Select the Copy to Merlin PCS button.

PDFs

Every time you select any Print button to create a report, the Merlin PCS programmer saves the report as a PDF (portable document file[1]). This file can be exported to a flash drive connected to one of the programmer's USB ports. You must install Adobe™ Acrobat™ Reader or Adobe Reader™ on your PC to view the PDF[2].

From the PDFs window, you can:

- Check the number of PDFs stored on the programmer's hard disk that have not been exported
- Export all the stored PDFs.
- Export the Most Recent PDFs (created in the last actual session or demo session, including your current session.
- Delete all PDFs.

When you select one of the Export buttons, the Export Data (page 151) screen appears.

The file naming and storing of the PDFs are as follows:

All PDFs are stored in a folder entitled "PDFs."

Subfolder Name: "Date of PDF creation"

Sub-subfolder Name: "Patient Name_Model Number_Device Serial Number" (read from the Patient Data)

File Name: "Device name_Device Model Number_Device Serial Number_Reportname.pdf"

Example: In the PDF folder is a subfolder called "2008-03-22." In this subfolder is a sub-subfolder called "John Smith_PromoteRF_3207-36_201399." Inside the sub-subfolder is the PDF titled: "PromoteRF_3207-36_201399_TestResults.pdf "containing the test results for John Smith on 3/22/2008.

The Merlin PCS can store a total of 30 "Date of PDF creation" subfolders containing PDFs. When 30 subfolders are stored on the programmer, the oldest subfolder is erased when a newer subfolder is created.

CAUTION

Session Records and PDF Reports are erased from the Merlin PCS after the number of days specified in the Data Management Preferences (page 3). Make sure you select the time limit from the Start-Up Screen > Tools >Preferences > Data Management.

Accessed From: Tools menu > Session Records > PDFs

Preferences

The Preferences window contains the following tabs for setting the Merlin PCS options:

- **Date & Time**. Sets the year, date, and local time
- **Language & Formats**. Sets the:
  - Display and Help Language
  - Date Format
  - Time Format
  - Number Format
  - ECG Notch Filter. The ECG Notch Filter Frequency reduces ECG interference from the programmer's AC power line frequency. Check with your local authorities for your power line frequency.
- **Audio** (page 4)
- **Printer** (page 4)
- **Wireless**. Sets the wireless communications on or off.
- **Data Management**. Sets the time limit for the oldest Session Records (page 1) and PDF Reports stored on the Merlin PCS. After the time setting selected, the programmer erases all Session Records and PDF Reports older that the Data Management setting.

Accessed From: Tools menu > Preferences button

Note

It is important to set an accurate date and time because the device's diagnostic tests and other functions use the date and time from the programmer.

[1] The programmer does not create a PDF for Freezes printed from the Start-Up screen, the Print Screen function, real-time printing, or on-screen Help.
[2] Adobe, Acrobat, and Adobe Reader are trademarks of Adobe Systems Incorporated.

Audio Preferences

This screen contains two panels:

- **General Audio.** Select the On button to allow audio cues for programmer activity. You can also select a volume level. The Off button turns all sounds off (except Charging Audio).
- **Charging Audio** (Tachy devices only). Select the On button for an audio cue when the capacitors charge during a programming session.

  Note

  An audio cue is always emitted during charging for an Emergency Shock (page 173), regardless of the Charging Audio setting.

Accessed From: Tools menu > Preferences button > Audio tab

Printer Preferences

Every time you select any Print button to create a report, the Merlin™ PCS programmer saves the report as a PDF (portable document file)[3]. This file can be exported to a flash drive connected to one of the programmer's USB ports. You must install Adobe™ Acrobat™ Reader or Adobe Reader™ on your PC to view the PDF.

To view the number of stored PDFs and to export or delete PDFs, select Tools > Session Records > PDFs (page 3).

The Printer Preferences window contains two panels:

- **Selected Printer.** You have three choices:
  - PDF Only (Paperless). Sends reports to the programmer's hard disk as a PDF (paperless printing) with no paper documents.
  - Internal & PDF. Sends the report to the programmer's internal printer and simultaneously creates a PDF on the hard disk.
  - External & PDF. Sends the report to an external USB printer and simultaneously creates a PDF on the hard disk. Before reports can be sent to an external printer, you must first connect the external printer to any one of the USB ports on the programmer. For more information on connecting an external printer, see the Merlin PCS User's Manual.
- **Number of Paper Copies.** This selects how many reports are printed by the internal or external printer whenever a Print button is selected.

To view the number of stored PDFs and to export or delete PDFs, select Tools > Session Records > PDFs (page 3).

Note

Supported Printers. The Merlin PCS can print to many laser jet printers. For a list of compatible printers, contact your St. Jude Medical Representative or Technical Support (page 163).

Accessed From: Tools menu > Preferences > Printer tab

Print Screen

The Print Screen button prints an image of the current screen. To send the image to an external printer, go to the Tools Menu > Preferences > Printer tab and select the External button.

This function does not create a PDF.

For more information on printing, see Print Menu Settings.

Accessed From: Tools menu > Print Screen button

Export Screen

The Export Screen button opens the Export Data (page 151) window, which allows you to save the current screen as an electronic (.png) file and send the file to any storage device (floppy drive, or flash drive) connected to one of the programmer's USB ports. The Merlin™ PCS detects all connected devices and asks you to select the device to receive the data.

Accessed From: Tools menu > Export Screen button

[3] The programmer does not create a PDF for Freezes printed from the Start-Up screen, the Print Screen function, real-time printing, or on-screen Help.

Rhythm Display

Contents:

- **Rhythm Display** (page 5)
- **ECG** (page 5)
- **Markers** (page 6)
- **EGM** (page 12)
- **Waveform Control** (page 12)
- **Rhythm Display Setup Instructions** (page 12)
- **Adjust Display** (page 12)
- **ECG Configuration** (page 13)
- **EGM Configuration** (page 13)
- **Freeze Capture** (page 14)

Rhythm Display

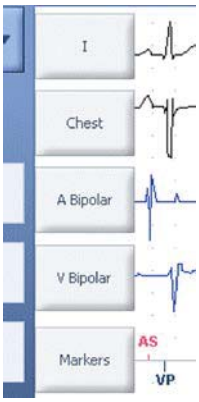
The Rhythm Display, seen on the Main Programming Window, can show up to five concurrent waveforms (or channels) that can be individually configured and adjusted. You can drag and drop any waveform to a new position when you select the Channel Control buttons on the left edge of the waveform. You can also freeze the display or print it in real time.

Three types of waveforms can be shown in the Rhythm Display:

- ECG (electrocardiogram) (page 5)
- Markers (page 6)
- EGM (intracardiac electrogram) (page 12)

The controls for the Rhythm Display include the:

- **Channel Control buttons.** Indicates the current waveform for each channel. Select this button to show the Waveform Control buttons or the Marker Control buttons.



- **Waveform Control buttons**, which are opened from the Channel control buttons on the left side of the display. The first button opens the ECG (page 5) or EGM (page 12) window.

- **Adjust Display (page 12) button**

- **Freeze Capture button**

See also:

- Rhythm Display Setup Instructions (page 12)

ECG

The Rhythm Display can show up to five ECG waveforms simultaneously from seven possible ECG vectors. There are two ways to change the ECG display:

- Adjust Display (page 12) button, which selects the waveform source and configuration and the ECG filter
- Waveform Control (page 12) buttons, which set the gain and the waveform source

For an example of a typical ECG setup, refer to the Merlin™ PCS Model 3650 User's Manual.

See also:

- ECG Configuration

Markers

Markers are symbols that represent therapies, paced and sensed events, intervals, refractory periods, and algorithm activity.

You can choose markers as one of the five channels. Markers can be configured either as:

- **Basic.** Basic markers appear along a time line and include:
  - Brady Basic Event Markers (page 6)
  - Tachy Basic Event Markers (page 7)
  - Brady Special Event Markers (page 7)
  - Episode Trigger Event Markers (page 8)
  - Discrimination Channel (Far Field MD™/SecureSense™) Markers (page 8)
  - Tachy Detection, Diagnosis, and Therapy Markers (page 9)
  - Tachy Charge Delivery Markers (page 10)
  - Morphology Markers (page 10)
  - User Initiated and Test Markers (page 10)
  - Waveform Channel Markers (page 11)
- **Full**. In addition to the basic markers, the following markers also appear:
  - Interval and Refractory Markers (Full Markers)

There are two ways to change the marker configuration:

- Select the Adjust Display (page 12) button and select the desired configuration.
- Select the marker Waveform Control (page 12) button on the left of the Rhythm Display and select the desired configuration.

Brady Basic Event Markers

Table 1. Brady basic event markers

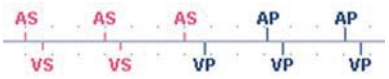
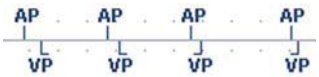
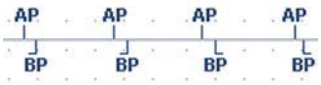
Marker	Description	Example
AR	Atrial event sensed in refractory period	
AS	Atrial sensed event	
AP	Atrial paced event	
VS	Ventricular sensed event	
VP	Ventricular paced event	When the Ventricular Pacing parameter is set to: • **RV Only**. The VP marker has a right-pointing tick mark. • **Biventricular**. The marker is BP. See below. 
BP	Biventricular paced event	When the Ventricular Pacing parameter is set to Biventricular and the Interventricular Delay parameter is set to: • **RV First**. The **BP** marker points right. • **LV First**. The **BP** marker points left. • **Simultaneous**. The BP tick-mark points down. 
BiS	Biventricular sensed event	
VSP	Ventricular Safety Standby	

Table 1. Brady basic event markers

Marker	Description	Example
BiSt	Biventricular triggered event	
ASt	Atrial triggered event	
VSt	Ventricular triggered event	
APP	Atrial paced event followed by ACap™ Confirm backup pulse	
VPP	Ventricular paced event followed by RVCap™ Confirm or V. AutoCapture™ backup pulse	

Tachy Basic Event Markers

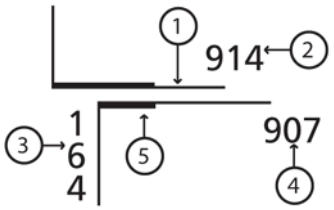
Table 2. Tachy basic event markers

Marker	Description	Example
T	Binned interval: VT zone	
T1	Binned interval: VT-1 zone	
T2	Binned interval: VT-2 zone	
F	Binned interval: VF zone	
X	Binned interval reconfirmed (underlined)	
–	Unbinned interval (dash)	
Return to Sinus	Return to sinus rhythm after Tachy therapy	

Interval and Refractory Markers (Full Markers)

Interval and refractory markers are shown in the following diagram. For CRT-Ds and CRT-Ps, only the first ventricular pacing pulse is identified by a marker. The location of the second ventricular pacing pulse must be calculated based on the Interventricular Delay setting.

Figure 1. Interval and refractory markers (full markers)



1. Refractory Period (Line)
2. A-A Interval
3. A-V Interval
4. V-V Interval
5. Absolute Refractory Period (Thicker Line)

Brady Special Event Markers

Table 3. Brady special event markers

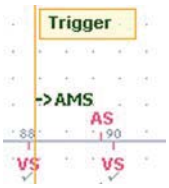
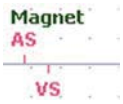
Marker	Description	Example
AMS	AMS ongoing (appears with each ventricular event)	
AFx	AF Suppression algorithm operation	
SIR	Activity Sensor-indicated rate	
HYS	Rate Hysteresis started by search timer or sensed event	
VIP™	VIP search started	

Table 3. Brady special event markers

Marker	Description	Example
Neg-HYS	Negative AV Hysteresis Search started	
SyncAV	SyncAV CRT started	
--> A-Noise or --> V-Noise	Entry into noise reversion mode	
A-Noise or V-Noise	Continuation of noise reversion mode	
<-- A-Noise or <-- V-Noise	Exit from noise reversion mode	
LOC	Loss of capture	

Episode Trigger Event Markers

Table 4. Episode trigger event markers

Marker	Description	Example
-->AMS	AMS entry	If an event triggers EGM storage, a vertical bar with a "Trigger" flag appears at the trigger point.
<--AMS	AMS Exit	
AT/AF	AT/AF Detection	
PMT	PMT detection	
VT/VF	VT/VF detection or diagnosis	
Magnet	Magnet reversion	
Noise	Noise reversion	
HAR	High atrial rate	
HVR	High ventricular rate	
PVC	PVC detection	
HYS	Advanced hysteresis	

Discrimination Channel (Far Field MD™/SecureSense™) Markers

Table 5. Discrimination Channel (Far Field MD/SecureSense) Markers

Marker	Description	Example
NSO[4]	Non-sustained oversensing	
RV Lead Noise[5]	RV lead noise episode	
SecureSense™ Timeout[6]	SecureSense RV lead noise algorithm has timed out	
NSVT or NSVF[7]	Non-sustained episodes of VT/VF	
VS2[8]	Ventricular beats sensed on the SecureSense EGM channel	

[4] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[5] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[6] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[7] Available in devices with Non-sustained VT/VF Episode Capability.
[8] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

Tachy Detection, Diagnosis, and Therapy Markers

Table 6. Tachy detection, diagnosis, and therapy markers

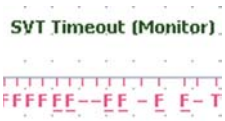
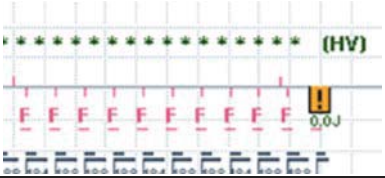
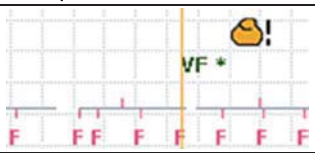
Marker	Description	Example
VT	VT, VT-1, or VT-2 diagnosis	The marker display formula for tachy detection, diagnosis, and therapy delivery is [Diagnosis] [Discriminator] ([Therapy]). If the diagnosis is VF or SVT discrimination is disabled, then the marker display formula is [Diagnosis] ([Therapy]).
VF	VF diagnosis	
SVT	SVT diagnosis	
(Monitor)	VT or VT-1 diagnosis in a monitor-only rate zone	
<	AF/AFL rate zone classification appended to the diagnosis	
=	Sinus Tach rate zone classification appended to the diagnosis	
>	VT/VF rate zone classification appended to the diagnosis	
(ATP---)	ATP therapy	Dashes (---) appear for the length of time that ATP therapy is ongoing.
(ATP---)	ATP prior to charging	
(ATP*---)	ATP while charging	Asterisks (***) appear for the length of time that it takes the capacitors to charge to the programmed energy/voltage.
(No More Therapies)	No additional therapies available	
VT Timeout	Expired VT Therapy Timeout	
SVT Timeout	Expired SVT Discrimination Timeout	
Bigeminy	SVT diagnosis due to bigeminal rhythm	
SVT Timeout-Bigeminy	Expired SVT Discrimination Timeout but therapy inhibited due to bigeminal rhythm	
DBT	A shock is delivered via Manual or Timed Device Based Testing	
Manual	A shock has been delivered via the programmer Shock button	
High voltage lead issue	High current due to high voltage lead issue detected. HV therapy not delivered.	

Table 6. Tachy detection, diagnosis, and therapy markers

Marker	Description	Example
High voltage circuit damage	Charge aborted due to possible high voltage circuit damage	

Tachy Charge Delivery Markers

Table 7. Tachy charge delivery markers

Marker	Description	Example
*	Charging for shock delivery	Asterisks (***) appear for the length of time that it takes the capacitors to charge to the programmed energy/voltage.
(HV)	High-voltage therapy	
Fibber: DC	DC Fibber induction	
Fibber: Shock-T	Shock-on-T delivered	
DBT	Device-based testing	
Manual	Emergency shock delivered	
Shock icon	Shock delivered	
(nn) J	Programmed energy (in Joules)	
(nn) V	Programmed voltage (in Volts)	

Morphology Markers

Table 8. Morphology markers

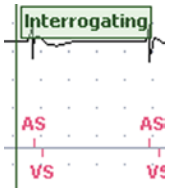
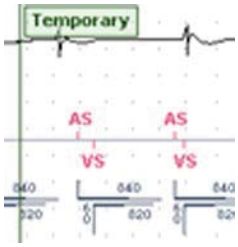
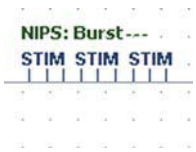
Marker	Description	Example
X	Template non-match	The morphology score, template match, and template non-match markers are shown only with full markers, or when the Morphology Template window is open. These markers are not displayed after a VF diagnosis until return to sinus is confirmed. Markers are green when a potential template is scored.
✓	Template match	
nn	Morphology Score (% Match)	

User Initiated and Test Markers

Table 9. User initiated and test markers

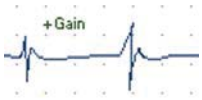
Marker	Description	Example
Programmed	Device programming	
Interrogating	Device interrogation	

Table 9. User initiated and test markers

Marker	Description	Example
Template	A template was acquired or retrieved	
Temporary	Temporary programming	
[Test Value]	Test parameter setting	Test value markers appear each time a test parameter setting is changed during a test. 
[Test Type] Test Started	The type of test started	
[Test Type] Test Ended	The type of test ended	
Test Canceled	Test canceled	
Capture Lost/Sensing Lost	Capture/sensing lost during test	
NIPS: Extrastimuli ---	NIPS extrastimuli delivered	 Dashes (---) appear for the length of time that stimulation is ongoing.
NIPS: Burst ---	NIPS S1 Burst stimulation	
Fibber: Burst ---	Fibber Burst stimulation	
Fibber: DC	DC Fibber induction	
Fibber: Shock-T	Shock-on-T delivered	
STIM	NIPS, Shock-on-T, or ATP Therapy stimulation	
LOC	Loss of Capture	

Waveform Channel Markers

Table 10. Waveform channel markers

Marker	Description	Example
[New Configuration]	The ECG or EGM channel configuration was changed	
+ Gain	An increase in the gain setting	
- Gain	A decrease in the gain setting	

EGM

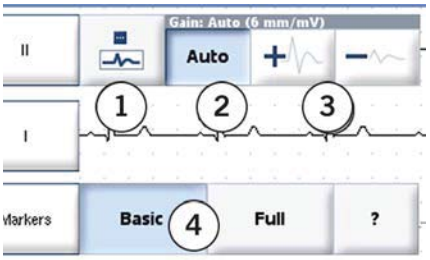
EGMs (intracardiac electrograms) show the heart's electrical activity as sensed by the device. The shape and size of the waveform depend on the available EGM Configuration (page 13) and the Gain setting. The number and type of configurations available depend upon the device type and implanted leads.

The Rhythm Display can show up to three EGM waveforms simultaneously in a variety of configurations. Select the Adjust Display (page 12) button to select the waveform source, configuration, and gain as well as the ECG Filter.

Waveform Control

The Waveform Control buttons on the left side of the Rhythm Display control the waveform's appearance. To open the controls, select one of the buttons. A button assigned to **Markers** (page 6) opens three buttons. Buttons assigned to the EGM or ECG open four additional buttons:

Figure 2. Waveform control buttons



1. Configuration button. Opens the ECG Configuration, the EGM Configuration (page 13) window, or the Markers (page 6) selection buttons (Basic or Full).
2. AutoGain button. Allows the programmer to continually and automatically set the gain.
3. Plus (+) and Minus (-) buttons. Allow you to set the gain manually.
4. Markers button. Allows you to show Basic or Full markers on the Rhythm Display and provides access to Markers help.

Accessed From: Rhythm Display > Waveform Control button

Rhythm Display Setup Instructions

1. Select the Adjust Display button to the right of the Rhythm Display.

   The Adjust Display (page 12) window appears.
2. Locate position 1.
3. Select the Source you want to see in position 1 (ECG, EGM, Markers, or Off).

   The programmer selects a default Configuration for the Source.
4. Select the Configuration button.

   If you selected ECG or EGM for the Source, the ECG Configuration or EGM Configuration (page 13) window opens. If you selected Markers (page 6), select the Basic or Full button.
5. Choose the configuration.
6. Repeat these steps for the remaining waveforms.
7. To change the default sweep speed, select the Sweep Speed button and choose a speed.
8. To set the ECG filter (to reduce electromagnetic interference), select the ECG Filter button.
9. To refresh the AutoGain settings, select the Update AutoGains button.

   Note

   Rhythm Display Settings. The Rhythm Display settings for each device model are stored in the programmer. For example, when you select Rhythm Display settings for a Promote device session, the same Rhythm Display settings are used for the next Promote device session, until you readjust the Rhythm Display settings.

Adjust Display

The Adjust Display window changes the:

- **Source** for each waveform in the Rhythm Display window (ECG (page 5), Markers (page 6), or EGM (page 12))
- **Configuration** of the waveform
- **Sweep Speed**
- **ECG Filter** to reduce electromagnetic interference

The following buttons are also available:

- **Update AutoGains**. Recalculates the gain of waveforms currently displayed in the Rhythm Display and that are set to Auto.

See also:

- **ECG Configuration** (page 13)
- **EGM Configuration** (page 13)
- **Rhythm Display Setup Instructions** (page 12)

Accessed From: Rhythm Display > Adjust Display button

ECG Configuration

The ECG Configuration window changes the ECG vector on the Rhythm Display.

See **ECG** (page 5) for a typical ECG setup.

To achieve the ECG vectors, select the following electrodes:

- **I**. LA(+) – RA(-)
- **II**. LL(+) – LA(-)
- **III**. LL(+) – RA(-)
- **aVR**. RA(+) – LA(-) + LL(-)
- **aVL**. LA(+) – RA(-) + LL(-)
- **aVF**. LL(+) – RA(-) + LA(-)
- **Chest**. V

Accessed From: Adjust Display > Configuration button

EGM Configuration

The EGM Configuration window changes the EGM source on the Rhythm Display.

The available settings depend upon the device type and the Lead Type setting.

In devices with Far Field MD™ Morphology Discrimination Capability (page 187) and SecureSense™ RV Lead Noise Discrimination Capability (page 193), the Ventricular or Right Ventricular EGM Configuration contains a "Discrimination" setting. This option displays the device's far-field channel (secondary sensing channel) used for Far Field Morphology and SecureSense sensing.

Leadless ECG Settings

In CRT-Ds (page 163) and Dual-Chamber ICDs (page 163), the Leadless ECG setting is equal to the A-tip to RV-coil configuration.

In Single-Chamber ICDs (page 164), the Leadless ECG setting is equal to the SVC to Can configuration. For single-chamber ICDs without an SVC coil, select a cathode.

In Dual-Chamber Pacemakers (page 164), the Leadless ECG setting is equal to the A-tip to V-ring configuration when the ventricular lead is programmed to Bipolar. When the ventricular lead is programmed to Unipolar or Uncoded, the LeadLess ECG setting is equal to A-tip to V-tip.

In CRT-Ps (page 164), the Leadless ECG setting is equal to the A-tip to RV-ring configuration when the right ventricular lead is programmed to Bipolar. When the right ventricular lead is programmed to Unipolar or Uncoded, the LeadLess ECG setting is equal to A-tip to RV-tip. When the atrial port is plugged, the Leadless ECG setting is ineffective; choose custom electrodes instead.

In Single-Chamber Pacemakers, (page 164) the Leadless ECG setting is not available.

In CRT-Ds, dual-chamber ICDs, single-chamber ICDs, and CRT-Ps (page 164) with VectSelect Quartet™ LV Pulse Configuration capability (page 194), you can also create a customized EGM configuration. In the Custom[9] column, select the "…" button to open a window to choose the cathode and anode for the configuration. The tables below show the custom configurations for each device type.

See also:

- Stored EGM Configuration (page 139).

Table 11. Custom EGM cathode and anode settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

CRT-Ds	Dual-Chamber ICDs	Single-Chamber ICDs
A-tip	A-tip	V-tip
A-ring	A-ring	V-ring
RV-tip	V-tip	RV-coil
RV-ring	V-ring	Can
LV-tip[10]	RV-coil	SVC
LV-ring[11]	Can	Leadless ECG
RV-coil	SVC	

[9] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[10] Available in CRT-D devices without VectSelect Quartet™ LV Pulse Configuration Capability.
[11] Available when the LV Lead Type parameter is set to Bipolar.

Table 11. Custom EGM cathode and anode settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

CRT-Ds	Dual-Chamber ICDs	Single-Chamber ICDs
Can	Leadless ECG	
SVC		
Leadless ECG		
LV Distal Tip 1[12]		
LV Mid 2[13]		
LV Mid 3[14]		
LV Proximal 4[15]		

Table 12. Custom EGM cathode and anode settings for CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers

CRT-Ps	Dual-Chamber Pacemakers	Single-Chamber Pacemakers
A-tip	A-tip	V-tip
A-ring	A-ring	V-ring
RV-tip	V-tip	Can
RV-ring	V-ring	
LV-tip[16]	Can	
LV Distal Tip 1[17]	Leadless ECG	
LV Mid 2[18]		
LV Mid 3[19]		
LV Proximal 4[20]		
LV-ring[21]		
BV-tip		
BV-ring		
Can		
Leadless ECG		

Accessed From: Adjust Display > Configuration button

Freeze Capture

The Freeze button captures the most recent 30 s of the waveform and shows the data in the Freeze Captures window. You can drag and drop any waveform to a new position. The controls on the Freeze Captures window include the:

- **Waveform Control** (page 12) buttons, including the Hide button, which hides the selected waveform
- **Marker Control** (page 5) buttons
- Restore Channels button, which restores the hidden waveforms
- **Sweep Speed** button
- **Show Calipers** button, which shows calipers that can be moved with button controls to display time measurements for a portion of the freeze
- **Hide Calipers** button, which toggles to the Show Calipers button
- **Scroll** buttons

You can also print the frozen waveform immediately (select the Print button) or at the end of the session (select the Print with Wrap-up™ button).

Accessed From: Freeze button

[12] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[13] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[14] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[15] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[16] Available in CRT-P devices without VectSelect Quartet™ LV Pulse Configuration Capability.
[17] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[18] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[19] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[20] Available in devices with VectSelect Quartet™ LV Pulse Configuration Capability.
[21] Available when the LV Lead Type parameter is set to Bipolar.

FastPath™ Summary Screen

Contents:

- FastPath™ Summary (page 15)
- Alerts (page 15)
- Patient Data (page 16)
- Patient Data: Lead Information (page 16)
- Clear Trends (page 16)
- Indications for Implant (page 16)
- Note (page 17)
- On-Screen Keyboard (page 17)
- Select Additional Reports to be Printed with the FastPath Summary (page 17)

FastPath™ Summary

Select any button on the FastPath™ Summary window for more detail.

- **Alerts (page 15) button.** Opens a list of conditions requiring attention.
- **Battery button.** Shows the last measured battery voltage[22] or remaining capacity to ERI percentage[23], a longevity gauge illustrating the time left to ERI (based on the current rate of usage and other data), and the date and duration of the last max charge (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164)). When the longevity estimate includes ERI in its range of values, the gauge is red and the message reads "ERI in <3 mos." Select this button to open the Battery Details (page 37) window.
- **Brady Parameters button.** Opens the Brady Parameters (page 61) window.
- **Tachy Zone button.** Opens the Tachy Parameters (page 89) window.
- **Episodes button.** In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, the VT/VF Episodes button opens the VT/VF Episodes (page 19) directory. In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), the Episodes button opens the Episode directory (page 19).
- **Diagnostics button.** In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, the Diagnostics button shows the percentage of paced events and the percentage of time the device was in either Mode Switch and AT/AF (page 26) or AT/AF (page 28). Select this button to open the Rates (page 25) window. In CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers, there are two Diagnostics buttons. The Diagnostic Rates button opens the Rates window, which displays the percentage of paced events and the percentage of time the devices was in either and the percentage of time the device was in either Mode Switch and AT/AF or AT/AF. The Mode Switch button opens the Mode Switch (page 26) window, which displays the AT/AF Burden (page 27), V Rates During AMS (page 27), the AMS Log (page 27) button, and the AT/AF Alert Triggers (page 134) button.
- **Test Results buttons.** Shows the current test or measurement status and the previous results for each available test or measurement (including those out-of-clinic). Each button opens a test window or the latest results of a test or impedance measurement (see the Capture & Sense test (page 31) window and the Battery & Leads (page 37) window).
- **End Session** button
- **Print button.** Opens the Select Additional Reports to be Printed with the FastPath Summary (page 17) window, which allows you to select additional reports to be printed with the FastPath Summary Report. For information on the contents of the FastPath Summary Report, see Reports (page 169).
- **Perform QuickOpt™ button.** Opens the QuickOpt™ Timing Cycle Optimization window to evaluate and change the Paced AV Delay, Sensed AV Delay, and Interventricular Delay settings.

Accessed From: FastPath Summary button

Alerts

The Alerts window lists conditions or patient notifications detected since the last follow-up. The list contains buttons that open related windows. Alerts that have not been viewed are in bold.

Accessed From: FastPath Summary button > Alerts button

[22] Battery voltage is not shown for devices with a Greatbatch Medical Models 2753, 2850, and 2950 batteries.
[23] Devices with a Greatbatch Medical Model 2850, Model 2950, or Model 2753 battery only.

Patient Data

The Patient Data window displays patient, lead, and device information and allows you to enter this data in the device's memory. If you change the Lead Implant Data from the Patient Data: Lead Information (page 16) window, you can also clear the sense, high voltage, and low voltage lead impedance trends. For data fields that open an on-screen keyboard, you can alternatively use a USB keyboard connected to one of the USB ports.

When you are finished entering data, select the Program button to permanently store the data.

The data fields include:

- **Patient Name and ID**. Opens an on-screen keyboard for data entry.
- **Birth Date buttons.** This setting determines the Patient's Age setting in the calculation of the Target Heart Rate (page 29) for the Exercise & Activity (page 29) diagnostic data.
- **EF button.** Set the patient's Ejection Fraction.
- **Lead Information buttons.** Opens the Patient Data: Lead Information (page 16) window to set the manufacturer, model, length, and serial number, and lead implant date. If you change the lead implant date, the programmer displays the Clear Trends (page 16) window.
- **Device Implant Date button.** You can automatically Select Today's Date or separately enter data for the month, day, and year.
- **Indications for Implant button.** Opens the Indications for Implant window.
- **Implant Notes button.** Opens a field for entering implant notes.
- **Physicians.** Opens on-screen keyboards for data entry.

Accessed From: Main Programming window

Patient Data: Lead Information

The Patient Data: Lead Information window allows you set the following characteristics for all implanted leads:

- **Manufacturer**
- **Lead Model**
- **Lead Length**
- **Lead Serial Number**
- **Lead Implant Date**
- **Chamber**

If you change the Lead Implant Date, the programmer displays the Clear Trends (page 16) window to clear the Sense and Lead Impedance trends.

Setting the Lead Model for certain SJM leads autoprograms the Lead Type (page 79) parameter to the appropriate setting. That is, if you select a unipolar lead model in this window, the Lead Type parameter is re-set to Unipolar from Bipolar.

For single-chamber devices, select the Lead Chamber button to choose an Atrial or Ventricular implant site.

Accessed From: Main Programming window > Patient Data button > Lead Information button

Additional Cardiac Hardware?

Select the Additional Cardiac Hardware? button to record the presence or absence of any active or abandoned cardiac hardware that may reside in the patient at the time of implant. The presence of any additional cardiac hardware contraindicates the use of an MRI scan even in patients with MR Conditional pacing systems. You may also indicate that the presence of hardware is unknown.

Available In: Devices with MR Conditional Programming Capability (page 189)

Clear Trends

The Clear Trends window allows you to clear the following trends:

- **Lead Impedance** (page 38) for all leads
- **HV Lead Impedance** for the RV lead (see Ventricular HV Lead (page 39) Impedance)[24]
- **Sense** (amplitude trend) for leads (see Sense Tests (page 34))
- **AutoCapture™ pacing** and **Cap Confirm** (see This Session (page 33))

Accessed From: Main Programming window > Patient Data button > Lead Information button > Implant Date button

Indications for Implant

The Indications for Implant window allows you to select one of more standard indications or enter a custom indication.

Accessed From: Main Programming window > Patient Data button> Indications for Implant button

[24] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Note

The Note window allows you to enter additional information about the patient.

When you select the Highlight At Every Follow-up check-box, the pencil icon on the main programming window is highlighted and the information appears as an Alert at the next programming session.

Accessed From: Main Programming window > Note button

On-Screen Keyboard

Use the On-Screen Keyboard to enter data.

- **Special Char key.** Select the Special Char key and then select another key to display the special character (labeled in green on the key).
- **Inactive Keys.** Inactive keys mean that the device does not support the character.
- **Repeating Keys.** If you press and hold most keys on the on-screen keyboard, they are not repeatedly typed. The exceptions are the arrow keys, the Space key, the Enter key, and the Backspace key.
- **External Keyboard.** You can use an external keyboard connected to the programmer through any of its USB ports. Both keyboards can operate simultaneously.

Select Additional Reports to be Printed with the FastPath™ Summary

The Select Additional Reports to be Printed with the FastPath™ Summary window allows you to include three additional reports when you queue the FastPath Summary report for printing. For a full explanation of the content of the reports, select the hyperlinks for each report.

- Select the **check-box** for each report you would like to print with the FastPath Summary.
- Select **Cancel** to exit the window without selecting additional reports.
- Select **Print** to print the FastPath Summary Report and each checked report.
- **Save Settings** button. Select this button to store your preferences for future programming sessions.

For information on the contents of the FastPath Summary Report, see Reports (page 169).

The additional reports are:

- **Episode Summary** or **Extended Episodes** (see Episodes Settings (page 170))
- **Diagnostics Summary** or **Extended Diagnostics** (see Select Diagnostics Reports for Printing (page 171))
- **Parameters**
  - Patient and device data
  - All programmed parameter and trigger settings

See also:

- Reports (page 169)

Accessed From: FastPath Summary window > Print button

Episodes

In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), the Episodes button opens a window that contains the:

- **VT/VF Episodes and Other Episodes**. See Episode Directory, VT/VF Episodes and Other Episodes (page 19).
- **Episode Detail** (page 20)
- **Episode Tree** (page 22)
- **Logs & Summaries** (page 23)

In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), the Episodes button opens a window that contains the:

- **Episode Directory** (page 19). See Episode Directory, VT/VF Episodes and Other Episodes (page 19).
- **Logs** (page 22).

For information on selecting the triggers for recording episodes, see Episode Triggers (page 142).

Accessed From: Episodes button

Episode Directory, VT/VF Episodes and Other Episodes

The Episode Directory (page 19), VT/VF Episodes (page 19) and Other Episodes (page 20) windows list all episodes recorded by the device.

When you select the Episode Directory, VT/VF Episodes or Other Episodes tab, the window shows only "new" episodes, which are the episodes recorded since the last programming session or when the Update Episodes button was last selected. Any stored EGMs not cleared from the device at a previous follow-up are "old" episodes. Select the **Include Old Episodes** button to view all episodes.

For an explanation of each of the columns in these directories, see Episode Display Column Headings (page 20).

From the Episode Directory, VT/VF Episodes, and Other Episodes windows, you can:

- **View an Episode**. Select an episode from the list. Each episode in the list is a button that opens the Episode Detail (page 20) window.
- **Sort the Directory**. Select a column heading
- **Retrieve EGMs from the Device.** Select the Update Episodes button to manually retrieve stored EGMs.
- **Print a Single Episode.** Select the Print Selected button to print a detailed report for any episode selected for printing.
- **Print All Episodes**. Select the Select All for Printing button, then select the Print Selected button.

Episode Directory

The Episode Directory is available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers. Episodes listed here include:

- High Ventricular Rate
- AT/AF Detection
- High Atrial Rate
- AMS Entry
- AMS Exit
- Consecutive PVCs
- Noise Reversion
- PMT
- Magnet Response
- Advanced Hysteresis

VT/VF Episodes

The VT/VF Episodes Directory is available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs. Episodes listed here include:

- VT
- VT-1
- VT-2
- VF
- Non-sustained (VT/VF)[25] (See Note below)
- VT Timeout
- SVT Timeout
- SVT
- Return to Sinus
- Fibber
- RV Lead Noise[26] (VT, VT-1, VT-2, or VF zones or during an SVT or SVT Timeout episode)

[25] Available in devices with Non-sustained VT/VF Episode Capability.
[26] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

- SecureSense™ Timeout[27] (VT, VT-1, VT-2, or VF zones) (see SecureSense™ Settings (page 90))

  Note

  Non-sustained VT/VF. In devices with Non-sustained VT/VF Episode Capability (page 189), non-sustained VT/VF episodes are defined as VT/VF episodes that are longer than six intervals but shorter than the programmed No. Intervals required for classification as tachyarrhythmia.

Other Episodes

The Other Episodes Directory is available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs. Episodes listed here include:

- AT/AF Detection
- AMS
- Noise Reversion
- PMT
- Magnet Response
- Emergency Shock
- Morphology Template Update
- Non-sustained RV Lead Noise[28] (see SecureSense™ Settings)

Episode Display Column Headings

Not all episode directories contain all of these column types.

- **Alerts**. Indicates if a related alert exists.
- **Date and Time**.
- **Type**. Type of episode.
- **Duration**. (CRT-Ds, dual-chamber ICDs, and single-chamber ICDs only)
- **CL**. The episode cycle length. (CRT-Ds, dual-chamber ICDs, and single-chamber ICDs only)
- **Status**. See Status explanations below.
- **Print icon**. The episode is selected for printing.

The Status column lists the status of stored EGMs associated with that episode. The Status icons indicate the following states:

- **Blue Circling Arrow.** The SEGM is being retrieved.

- **New EGM.** The episode detail has been retrieved and is ready to view.
- **Cleared.** The episode has been cleared from the device.
- **Old EGM.** The episode was viewed in a previous session.
- **No EGM.** The episode is corrupted or was cleared before it was read.

See also:

- Episode Settings (page 139)
- Clear Diagnostics (page 151)

Accessed From: Episodes button > Episode Directory, VT/VF Episodes tab or Other Episodes tab

Episode Detail

The Episode Detail window shows the EGM (page 12) and Markers (page 6) data that precede and follow a recorded trigger event, with information on the date, time, trigger type, and alert status.

You can change the appearance of the waveform just as you would change a frozen waveform (See Freeze Capture).

The Episode Details window also includes the:

- **Select for Printing** button, which places the episode in the Episode Report (See Print Menu (page 169))
- **Arrow** buttons, which scroll to the previous or next episode
- **Restore Channels** button, which shows hidden waveforms.
- **Date, Time, and Type** of the episode
- **Duration** of the episode (VT/VF[29], AMS, and AT/AF episodes only)
- **Diagnosis** button (VT/VF Episodes only). A large Diagnosis button appears if an SVT diagnosis is followed by a VT diagnosis during the episode. A small Diagnosis button appears if the diagnosis remained unchanged during the episode. It contains information on

[27] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[28] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[29] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

the diagnosis, the CL (cycle length), and the Time to Diagnosis. If the diagnosis is VF, the button is only informational. For other diagnoses, select this button to open the Diagnosis Details (page 21) window[30].

- **Therapy and Results** (VT/VF Episodes only) button. Lists all therapies (ATP, VF, etc.) delivered during an episode along with the results of each. Aborted therapies and any special events such as device reversions or ongoing charging are also listed[31].
- **ATP Therapy Details** button (VT/VF Episodes only). This button appears if any ATP therapies were delivered. Select this button to open the ATP Therapy Details (page 21) window[32].
- **Alerts**. Lists any alert conditions associated with an episode. See Alerts (page 15).
- **HV Therapy** (VT/VF Episodes only). If a high-voltage shock was delivered during the episode, this button lists detailed information on the capacitor charge times, the last lead impedance measurement, and the shock waveform settings for that episode[33].
- **AMS or AT/AF Diagnostics[34].** Lists the diagnostic summary information for either AMS or AT/AF episodes. Select this button to open the Mode Switch and AT/AF (page 26) or AT/AF (page 28) window.
- **Display SecureSense™ Markers[35]**. Select this check-box to view the VS^2 markers generated on the secondary sensing channel on the EGM (see Waveform Channel Markers (page 11)).
- **Print** button. Prints the episode information and the stored EGM.

Note

Zone Nearest Detection. The Episode Detail for Non-sustained VT/VF episodes specifies a "Zone Nearest Detection" in the Diagnosis box. This is defined as the rate zone in which the arrhythmia would have been classified had it continued rather than reverting to sinus rhythm.

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)) Episodes button > VT/VF Episodes tab or Other Episodes tab > Specific Episode Detail button

Accessed From: (CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164)) Episodes button > Episodes tab

ATP Therapy Details

The ATP Therapy Details window lists the burst cycle lengths (BCL) of the first and last ATP bursts delivered and the successful BCL for all ATP therapies.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > VT/VF Episodes tab or Other Episodes tab > Specific Episode Detail button > ATP Therapy Details button

Diagnosis Details

The Diagnosis Details window displays the SVT diagnostic details for the current episode at the time of the initial diagnosis. The details include the condition initially diagnosed, CL (cycle length), Time to Diagnosis, and Zone. If the device's final diagnosis was different from its initial diagnosis, a second panel shows the condition and other details of the final diagnosis.

Select the SVT Criteria Statistics (page 21) button for information on all SVTs detected during the entire episode.

Note

No. of SVT Diagnoses. This is the number of episodes in the current directory that were determined to be SVT throughout the entire episode. "No. of SVT Diagnoses" is distinguished from "SVT Diagnoses in Episodes" reported in the SVT Diagnosis Summary & Morphology Template Details (page 23) window, which is the number of times SVT was diagnosed by the device, even if the final diagnosis of the episode was VT/VF.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > VT/VF Episodes tab or Other Episodes tab > Specific Episode Detail button > Diagnosis Details button

SVT Criteria Statistics

The SVT Criteria Statistics window shows the number of SVT diagnoses and the measured SVT discriminator values for the selected episode.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

[30] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[31] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[32] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[33] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[34] Available in CRT-Ps and dual-chamber pacemakers.
[35] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

Accessed From: Episodes button > VT/VF Episodes tab or Other Episodes tab > Specific Episode Detail button > Diagnosis Details button > SVT Criteria Statistics button

Episode Tree

The Episode Tree window is a graphic summary of new tachy episodes (detected from the time that the diagnostic data were last cleared until the last interrogation).

The window presents a graphic distribution of all VT/VF episodes categorized into each programmed therapy zone or "branch" (for example, VT-1, VT-2, VF, SVT Timeout). At the top of each zone is an Episode button that shows the number of episodes recorded in that zone and if there is an associated stored EGM.

Under each Episode button are Diagnosis buttons ("leaves") showing the diagnosis of each episode (see Leaf types in the table below). If therapy was delivered for VT or VF, then therapy results are listed below.)

In devices with Non-sustained VT/VF Episode Capability (page 189), the Episode Tree also contains a "Non-Sustained" column showing the number of VT/VF episodes where the tachyarrhythmia exceeded six cycles but did not reach the detection limit (that is, specified by the No. Intervals parameter setting).

Select any button in the window to view the Episode Detail (page 20) of all episodes in that category. Select the Previous/Next buttons on the detail window to view each episode in that category.

Table 13. Leaf definition for the Episode Tree

Type of Leaf	Found in Branch	Leaf Definition
SVT	VT, VT-1, VT-2	Supraventricular tachycardia
NSVT[36]	VT, VT-1, VT-2, SVT Timeout	Non-sustained ventricular tachycardia (no therapy delivered)
RV Lead Noise[37]	VT, VT-1, VT-2, VF	RV Lead Noise as defined by the SecureSense™ algorithm has inhibited therapy
VT	VT, VT-1, VT-2, SVT Timeout	Ventricular tachycardia
NSVF	VF	Non-sustained ventricular fibrillation (no therapy delivered)
VF	VF	Ventricular fibrillation
VT, VT-1, VT-2	SVT Timeout	Occurring in the VT, VT-1, or VT-2 zones

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > Episode Tree tab

Logs

The Logs window (available in CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers) displays compilations of recorded episodes detected from the time that the diagnostic data were last cleared until the last interrogation. The window contains the:

- **Triggers List** button, which shows all Episode Settings (page 139) enabled the last time the episodes were read and the number of times each episode occurred. Select this button to open the Episode Triggers (page 142) window for programming.
- **AMS Log**. Lists the diagnostic summary information for AMS episodes. Select this button to open the AMS Log (page 27) window.
- **High Ventricular Rate Log**. Lists the number of high ventricular rate episodes and the date of the most recent episode recorded since the episodes were last cleared. Select this button to open the High Ventricular Rate Log window.
- **Device Reversions** button, which lists the type and number of reversions and the date and time of the most recent reversions. Resets are also listed here.

Available in: CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)

Accessed From: Episodes button > Logs tab

High Ventricular Rate Log

The High Ventricular Rate Log displays details of each recorded episode of high ventricular rate, that is, rates exceeding the Ventricular Rate Threshold and the Number of Cycles specified in the High Ventricular Rate: Episode Trigger and Alert Trigger (page 134) window. The details include:

- The EGM of the episode. Select the EGM button to open the Episode Detail (page 20).
- Date of the episode
- Time of the episode
- Average high ventricular rate, calculated from the start to the end of the episode

[36] For episodes in the VT/VF zones, NSVT or NSVF refers to VT/VF rhythms that exceeded the No. Intervals parameter setting but did not result in delivery of therapy. This should be distinguished from the "Non-sustained" Episode Tree column that records VT/VF where the tachyarrhythmia exceeded six cycles but did not reach the number of intervals for detection (specified by No. Intervals).

[37] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

- Duration, which includes the intervals recorded above the Ventricular Rate Threshold setting

Logs & Summaries

The Logs & Summaries window (available in CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs) displays compilations of recorded episodes detected from the time that the diagnostic data were last cleared until the last interrogation. The windows contain the:

- **Triggers List** button, which shows all Episode Settings (page 139) enabled the last time the episodes were read and the number of times each episode occurred. Select this button to open the Episode Triggers (page 142) window for programming.
- **SVT Diagnosis Summary and Morphology Template** button, which lists all SVT episodes categorized by the Rate Branch (page 94) and Zone Configuration (page 89) parameters and a summary of Morphology Template Update activity. Select this window to open the SVT Diagnosis Summary & Morphology Template Details (page 23) window. The Rate Branches include:
  - **AF/AFL** (V<A) (Atrial fibrillation/atrial flutter). The number of VT-1/VT-2 episodes in the V<A Rate Branch.
  - **Sinus** (V=A). The number of VT-1/VT-2 episodes in the V=A Rate Branch.
  - **VT** (V>A). The number of VT-1/VT-2 episodes in the V>A Rate Branch.
  - **SVT Episodes**. The number of VT-1/VT-2 Episodes with all VT/VF diagnoses inhibited.
- **HV Charging/Non-sustained RV Lead Noise** button, which lists the number of HV charges and, in devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193), the total number of non-sustained lead episodes. Select this window to open the HV Charging & Non-sustained RV Lead Noise Details window.
- **Therapy Summary** button, which lists number of ATP and Shocks delivered for each Zone Configuration, the last HV lead impedance measurement, the number of aborted shocks, and the results of ATP therapy in devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability (page 181). If the Zone Configuration parameter is not set to Off, select this window to open the Therapy Summary Details (page 24) window.
- **Device Reversions** button, which lists the type and number of reversions and the date and time of the most recent reversions. Resets are also listed here.

Available in: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > Logs & Summaries tab

SVT Diagnosis Summary & Morphology Template Details

The SVT Diagnosis Summary & Morphology Template Details consists of three panels:

- **SVT Diagnosis Summary**, a table showing all SVT diagnoses for all programmed rate zones. The list of reported diagnoses differs according to the settings for Zone Configuration, SVT Discrimination Mode, and SVT Upper Limit. The number in parenthesis at the top of each column shows the total number of episodes at initial diagnosis for the VT zone.

Table 14. SVT diagnosis summary definitions

Abbreviation	Definition
AF/AFL (V<A)	Number of VT-1 or VT-2 diagnoses where the atrial rate was faster than the ventricular rate
Sinus Tach (V=A)	Number of VT-1 or VT-2 diagnoses where the atrial rate was equal to the ventricular rate
VT (V>A)	Number of VT-1 or VT-2 diagnoses where the atrial rate was slower than the ventricular rate
SVT Episodes	Number of VT-1 or VT-2 episodes with all diagnoses inhibited
SVT Diagnoses in Episodes	Total number VT-1 or VT-2 episodes with a diagnosis inhibited
Sinus Tach diagnoses (V=A) due to AV Interval	Total number of episodes where VT-1 diagnosis occurred due to AV Association in the A=V Rate Branch

Note

Diagnoses in Episodes. This is the number of times SVT was diagnosed by the device, even if the final diagnosis of the episode was VT/VF. "Diagnosis in Episodes" is distinguished from the "No. of SVT Episodes" reported in the Diagnosis Details (page 21) window, which is the number of episodes in the current directory that were determined to be SVT throughout the entire episode.

- **Discrimination Criteria for SVT Diagnoses**, a table showing the number of times each discriminator was used to diagnose the SVT (and to inhibit therapy) or where bigeminal rhythm avoidance was used to inhibit therapy and a button that opens the SVT Discrimination Details (page 92) window.
- **Morphology Template**, a list showing details of Morphology Template Auto Update attempts, the number of Morphology Update stored EGMs of a morphology update, an stored EGM icon than be selected to open the Morphology Update Episode Detail, the date of the last manual activation, and a button to open the Morphology Window (page 95).

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > Logs & Summaries tab > SVT Diagnosis Summary button

HV Charging and Non-sustained RV/V Oversensing Details

For devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193), the HV Charging and & Non-sustained RV/V Oversensing details window contains two panels: the HV Charging Panel (page 24) and the Non-sustained RV/V Oversensing Details (page 24) panel. For devices without the SecureSense™ RV Lead Noise Discrimination Capability, the window contains the HV Charging Panel only.

HV Charging Panel

The HV Charging Panel contains:

- Total HV charges
- Voltage range of all charges recorded over the sampled and lifetime periods
- Button linking to the Capacitor Maintenance (page 122) parameters

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Non-sustained RV/V Oversensing Details

The Non-sustained RV/V Oversensing Details panel contains the Non-sustained Oversensing (NSO) Episode Log, which lists the total number of NSO episodes, the date and time of each episode, and an icon indicating an NSO stored EGM. The Log holds up to 32 of the most recent episodes and can be sorted by selecting the column headings.

Available In: Devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193)

Accessed From: Episodes button > Logs & Summaries tab > HV Charging button

Therapy Summary Details

The Therapy Summary Details window lists the:

- Number of ATP therapies and shocks delivered in each Zone Configuration (page 89)
- Last measured HV lead impedance
- Information on aborted shocks
- ATP therapy result for each Zone Configuration
- Graphs that show the number of ATP bursts delivered for each successful therapy for Therapy 1 and Therapy 2 (available in devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability (page 181)).
- Lifetime ATP in the VF Zone, showing the number of total ATP therapies delivered and their effect on VF termination (available in devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability).

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Episodes button > Logs & Summaries tab > Therapy Summary button

Diagnostics

Contents:

- Rates (page 25)
- Conduction (page 26)
- Mode Switch and AT/AF (page 26)
- Exercise & Activity (page 29)
- CorVue™ Thoracic Impedance Monitoring (page 29)

See also:

- Clear Diagnostics (page 151)

Accessed From: Diagnostics button

Rates

The Rates tab of the Diagnostics window contains four panels:

- Atrial Heart Rate Histogram (page 25)
- Events (page 25) diagnostics
- Total time sampled and total time in AMS or AT/AF
- Last read data

Accessed From: Diagnostics button > Rates tab

Atrial Heart Rate Histogram

The Atrial Heart Rate Histogram display shows the distribution of all atrial paced and sensed events by rate (bpm) recorded since the diagnostics were last cleared[38]. Each histogram bar represents the percentage of time the patient's intrinsic or paced rate fell within a specific rate range. Each bar is divided into color-coded segments, which indicate the portion that was paced or sensed.

The Histogram display also contains the settings of certain rate parameters, a histogram legend, the percentage of total time sampled at Max Track Rate (page 67), and the percentage of overall atrial paced events that are AP overdrive events AF Suppression™ Algorithm (page 87)-paced, if the AF Suppression parameter is On.)

If the Sensor parameter is programmed On or Passive, a yellow dot appears in each rate range. The position of the dot on the bar graph represents the percentage of paced events that would result if the rate was determined exclusively by response to the activity sensor.

Events

The Events display includes:

- A summary of the percentage of the time that all events were paced and triggered, for both the current time sampled and over the lifetime of the device[39], and
- A bar graph that shows the percentage of the total time sampled for each event type. Thus, an Events display with an AS-VS event type of 94% indicates that during the last sampling period (defined below the graph), 94% of the time, events were of the AS-VS type. The percentage calculation is based on the time sampled of the events divided by the total time of the histogram.

A summary of all paced events, described in the following table, is listed above the Events graph.

Table 15. Explanation of event summary data

Event Summary Symbol	Dual-Chamber Modes	Single-Chamber Modes
AP	AP-VP + AP-VS	AP
VP	AS-VP + AP-VP	VP
RVP	AS-RVP + AP-RVP	N/A
BP	AS-BP + AP-BP	N/A
VSt	AS-VSt +AP-VSt	VSt
AV Conduction	AP-VS + AS-VS	N/A

The Events histogram does not include time in AMS.

Biventricular event types include:

- **AS-RVP.** Atrial sensed, right ventricular paced
- **AP-RVP.** Atrial paced, right ventricular paced
- **AS-BP.** Atrial sensed, biventricular paced
- **AP-BP.** Atrial paced, biventricular paced.

[38] If the device has mode-switched, the Heart Rate Histogram does not record any events. Events during PMT Response and PVC Response do not update the Atrial Heart Rate Histogram.
[39] Includes events during Auto Mode Switch.

Dual-chamber event types include:

- **AS-VP.** Atrial sensed, ventricular paced
- **AS-VS.** Atrial sensed, ventricular sensed
- **AS-VSt.** Atrial sensed, ventricular triggered (on sensed event)
- **AP-VP.** Atrial paced, ventricular paced
- **AP-VS.** Atrial paced, ventricular sensed
- **AP-VSt.** Atrial paced, ventricular triggered (on sensed event)
- **PVC.** Premature ventricular contraction (a ventricular sensed event after a VS or VP event not preceded by a sensed atrial event)

Single-chamber event types include:

- **VS.** Ventricular sensed
- **VP.** Ventricular paced
- **VSt**. Ventricular triggered (on sensed event).

Note

Rounding. Values >0 but <1 are designated as <1. Numbers from 1 to 10 are rounded up to the closest single-digit decimal number. Numbers from 10 to 99 are rounded up to the closest integer. Numbers greater than 99 and less than 100 are shown as ">99."

Conduction

The Conduction tab of the Diagnostics window contains four panels:

- Ventricular Heart Rate Histogram (page 26)
- AV Intervals (page 26) diagnostics
- Total time sampled and total time in AMS or AT/AF
- Last read data

Accessed From: Diagnostics button > Conduction tab

Ventricular Heart Rate Histogram

The Ventricular Heart Rate Histogram shows the distribution of all ventricular paced and sensed events by rate (bpm) recorded since the diagnostics were last cleared[40]. Each histogram bar represents the percentage of time the patient's intrinsic or paced rate fell within a specific rate range. Each bar is divided into color-coded segments, which indicate the portion that was paced or sensed or that was a PVC.

The Histogram display also contains the settings of certain rate parameters, a histogram legend, the percentage of total time sampled at Max Track Rate (page 67), and the number of PMT detections (page 85) (if the PMT Response parameter is enabled).

If the Sensor parameter is programmed On or Passive, a yellow dot appears in each rate range. The position of the dot on the bar graph represents the percentage of paced events that would result if the rate was determined exclusively by response to the activity sensor.

AV Intervals

The AV Intervals display is available in dual-chamber modes and includes:

- The percentage of all AV intervals that were paced and the number of VS-AS intervals that were less than 80 ms
- A bar graph that shows the distribution of all recorded AV intervals by interval duration. Each histogram bar represents the percentage of time the patient's AV interval fell within a specific interval duration range. Each bar is divided into color-coded segments, which indicate the portion that was paced or sensed.

Mode Switch and AT/AF

This window will show the Mode Switch (page 26) window when the Auto Mode Switch parameter is enabled, or the AT/AF (page 28) window if the Auto Mode Switch Parameter is set to Off.

Mode Switch

The Mode Switch tab of the Diagnostics window is available when the Auto Mode Switch (page 86) parameter is enabled. The window contains the:

- AT/AF Burden (page 27)
- AMS Summary (page 27)
- V Rates During AMS (page 27)
- AMS Log and AT/AF Log (page 27) button, which opens the AMS Log window
- AT/AF Alerts button, which opens the AT/AF Alert Triggers (page 134) window to set AT/AF Alert Notification
- Total time sampled and total time in AMS
- Last read data

[40] The histogram does not include events that occurred during Auto Mode Switch.

Accessed From: Diagnostics button > Mode Switch tab

AT/AF Burden

The AT/AF Burden display shows a graph of the percentage of AT/AF Burden over a 52-week period. Each data point on the graph equals the percentage of time the patient was in AT/AF for a seven-day period.

In addition, the display shows two figures:

- **AT/AF Burden**. The percentage of time that AT/AF was detected since the diagnostics were last cleared (see Clear Diagnostics (page 151)).
- **Total AT/AF Burden**. The percentage of time that AT/AF was detected since the Trends were cleared (that is, since the Clear Trends (page 151) button was selected).

  Note

  The AT/AF Burden trend is not cleared when you select the Clear Diagnostics (page 151) button in the Wrap-up™ Overview (page 151).

  The Total AT/AF Burden is calculated based on the all the information in the Trends database. This may exceed the 52-week display in the AT/AF Burden graph.

AMS Summary

The AMS Summary contains information on mode-switch activity, including two histograms:

- **Peak A Rate.** Each bar represents the number of mode-switch episodes that occurred at a filtered atrial rate within the rate range.
- **Duration.** Each bar represents the number of episodes that occurred in a single duration range.

Percentage mode switch is the time the device spent in mode switch divided by the total time sampled. The histogram does not show an ongoing AMS episode[41].

V Rates During AMS

The V Rates During AMS panel contains a histogram showing ventricular activity during mode switches. Use this histogram to determine if the mode switch algorithm has successfully suppressed high ventricular pacing.

Each bar represents the percentage of the total time that ventricular events fell inside a specific rate range. Each bar is divided into paced (VP) and sensed (VS) events.

Note

Rounding. Values >0 but <1 are designated as <1. Numbers from 1 to 10 are rounded up to the closest single-digit decimal number. Numbers from 10 to 99 are rounded up to the closest integer. Numbers greater than 99 and less than 100 are shown as ">99."

AMS Log and AT/AF Log

This window will show the AMS Log (page 27) window when the Auto Mode Switch parameter is enabled, or the AT/AF Log (page 28) window if the Auto Mode Switch Parameter is set to Off.

AMS Log

The AMS Log lists all mode-switch events stored in the device's memory.

The Log contains five columns. To change the sort order, select the button at the top of the desired column.

- **EGM.** (page 12) An EGM icon indicates that an episode was stored with the log entry. Select the icon button to view the Episode Detail (page 19).
- **Date**
- **Time**
- **Peak Atrial Rate**
- **Duration**
- **Peak Ventricular Rate** during the episode (for devices with Enhanced AT/AF Diagnostics Capability (page 185)).

Capacity. The AMS Log can hold up to 32 events. The episode with the longest duration, the atrial episode with the fastest rate, and the first 16 events are frozen in the device memory (but can be cleared). The remaining events are recorded "continuously." That is, when the memory is full, events continue to be recorded and newer events overwrite older events.

Note

Rounding. Values >0 but <1 are designated as <1. Numbers from 1 to 10 are rounded up to the closest single-digit decimal number. Numbers from 10 to 99 are rounded up to the closest integer. Numbers greater than 99 and less than 100 are shown as ">99."

[41] The duration of an ongoing episode is factored into Percentage Mode Switched and Number of AMS Episodes.

AT/AF

The AT/AF (atrial tachycardia/atrial fibrillation) tab of the Diagnostics window is available when the Auto Mode Switch parameter is off. The window contains:

- AT/AF Burden (page 27)
- AT/AF Summary (page 28)
- V Rates During AT/AF (page 28)
- AT/AF Log (page 28) button, which opens the AT/AF Log window
- **AT/AF Alerts** button, which opens the AT/AF Alert Triggers (page 134) window to set AT/AF Alert Notification
- **Total time sampled and total time in AT/AF**
- **Last read data**

See also:

- AT/AF Definition (page 29)

Accessed From: Diagnostics button > Mode Switch tab

AT/AF Burden

The AT/AF Burden display shows a graph of the percentage of AT/AF Burden over a 52-week period. Each data point on the graph equals the percentage of time the patient was in AT/AF for a seven-day period.

In addition, the display shows two figures:

- **AT/AF Burden**. The percentage of time that AT/AF was detected since the diagnostics were last cleared (see Clear Diagnostics (page 151)).
- **Total AT/AF Burden**. The percentage of time that AT/AF was detected since the Trends were cleared (that is, since the Clear Trends (page 151) button was selected).

  Note

  The AT/AF Burden trend is not cleared when you select the Clear Diagnostics (page 151) button in the Wrap-up™ Overview (page 151).

  The Total AT/AF Burden is calculated based on the all the information in the Trends database. This may exceed the 52-week display in the AT/AF Burden graph.

AT/AF Summary

The AT/AF Summary display shows the total number of AT/AF episodes sampled and two histograms:

- **Peak A Rate.** Each bar represents the number of AT/AF events that occurred at an atrial rate within the rate range.
- **Duration.** Each bar represents the number of AT/AF events that occurred in a single duration range.

V Rates During AT/AF

The V Rates During AT/AF panel contains a histogram showing ventricular activity during AT/AF episodes.

Each bar represents the percentage of the total time that ventricular events fell inside a specific rate range. Each bar is divided into paced (VP) and sensed (VS) events.

Note

Rounding. Values >0 but <1 are designated as <1. Numbers from 1 to 10 are rounded up to the closest single-digit decimal number. Numbers from 10 to 99 are rounded up to the closest integer. Numbers greater than 99 and less than 100 are shown as ">99."

AT/AF Log

The AT/AF Log lists all AT/AF events stored in the device memory.

The log contains five columns. To change the sort order of the log, select the button at the top of the desired column.

- **EGM.** (page 12) An EGM icon indicates that an episode was stored with the log entry. Select the icon button to view the **Episode Detail** (page 20).
- **Date**
- **Time**
- **Peak Atrial Rate**
- **Duration**
- **Peak Ventricular Rate during the episode** (for devices with **Enhanced AT/AF Diagnostics Capability** (page 185))**.**

Capacity. The AT/AF Log can hold up to 32 events. The episode with the longest duration, the episode with the fastest rate, and the first 14 events are frozen in the device memory (but can be cleared). The next 16 events are recorded "continuously." That is, when the memory is full, events continue to be recorded and newer events overwrite older events.

AT/AF Definition

AT/AF (atrial tachycardia/atrial fibrillation) is defined as an average atrial rate greater than the Atrial Tachycardia Detection Rate (ATDR) setting. To determine if AT/AF has occurred, the device computes an average atrial rate. If that average and the current rate are higher than the setting for the ATDR parameter, the device records a single episode of AT/AF. The calculation does not distinguish between tachycardia and fibrillation.

Exercise & Activity

The Exercise & Activity tab of the Diagnostics window contains:

- Daily Exercise Training (page 29)
- Total Daily Activity (page 29)
- **Diagnostic Tools** button, which shows the Target Heart Rate and opens the Exercise & Activity Diagnostic Tools (page 29) window
- **Total time sampled**
- **Last read data**

Accessed From: Diagnostics button > Exercise & Activity tab

Daily Exercise Training

The Daily Exercise Training trend is a bar graph that indicates how much exercise a patient performed each day for the last 30 days. Exercise is activity lasting longer than one minute, and it stops after activity has stopped for two minutes. The trend shows the amount of time the patient approached his or her maximum heart rate each day when exercising. The algorithm that computes the heart rate avoids counting high heart rates or high activity sensor values not associated with exercise. The first 48 hours after implant are used to establish a baseline, and no trend data is available until after this time.

Each histogram bar is divided into durations of "light," "moderate," and "vigorous" activity. The assignment to each division is based on the patient's Target Heart Rate (page 29), which is set in the Exercise & Activity Diagnostic Tools (page 29) window.

If the patient's condition changes, you should adjust the Target Heart Rate (page 29) from the Exercise & Activity Diagnostic Tools (page 29) window.

Total Daily Activity

The Total Daily Activity trend is a bar graph that indicates how many hours each day the patient was "active" for the last 30 days. In this trend, "Activity" is defined as input to the sensor that exceeds the resting heart rate. That threshold rate is determined by the Activity Recalibration (page 29) procedure (performed from the Exercise & Activity Diagnostic Tools (page 29) window).

The Total Daily Activity trend includes both "activity" (sensor input over a certain threshold) and "exercise," (maximum heart rate approaching a patient's Target Heart Rate, as defined in the Daily Exercise Training (page 29) trend).

If a patient's condition changes, you should recalibrate the activity threshold from the Exercise & Activity Diagnostic Tools (page 29) window.

Exercise & Activity Diagnostic Tools

The Exercise & Activity Diagnostic Tools window contains two functions:

Target Heart Rate

The Target Heart Rate setting determines what heart rates are considered "exercise" in the Daily Exercise Training (page 29) trend (from "light" to "vigorous.") The Target Heart Rate is a percentage of the Patient's maximum heart rate (220 bpm minus the patient's age, as determined by the patient's Birth Date setting which is selected in the Patient Data window.)

The programmer selects a nominal percentage of a maximum heart rate, but you can change this setting. To use the programmer's nominal Target Heart Rate, select the Select Nominal Target Rate button.

If the patient's age is not available, select the See Patient Data parameters... button, which opens the Patient Data (page 16) window and enter the patient's date of birth.

Activity Recalibration

Select the Activity Recalibration button to recalibrate the patient's resting rate. This calculation is used to determine what level of activity can be considered "rest" or "activity," as plotted on the Total Daily Activity (page 29) trend.

Impedance Monitoring

The CorVue™ Thoracic Impedance Monitoring tab of the Diagnostics window displays up to a year of results of the Impedance Monitoring feature that is designed to detect increasing fluid retention in the chest cavity.

When enabled, the feature obtains intra-thoracic impedance measurements every two hours from the RV-can and RV-coil vectors for ICDs and CRT-Ds, and from the RV ring to can vectors for CRT-Ps. It then calculates a running average of intra-thoracic impedance measurements over 14 days for ICDs and CRT-Ds, and over 16 days for CRT-Ps. This average is called the "Reference Impedance" that is illustrated in the top graph. The feature then compares this long-term running average to a Daily Impedance, which is a short-term average of impedance measurements. Studies (page 368) have shown that when the Daily Impedance measurement remains consistently below the Reference Impedance, the patient is at greater risk for heart failure-related hospitalization.

The clinician can set the number of days that the Daily Impedance must be lower than the Reference Impedance by using the CorVue™ Threshold (page 30) parameter (nominal setting for ICDs and CRT-Ds = 14 days; nominal setting for CRT-Ps = 16 days). The period of time following the CorVue Threshold setting that the Daily Impedance must be below the Reference Impedance is considered an "impedance episode." It is recommended that the nominal setting be used unless diagnostic information on impedance episodes is available for the patient. A diagram of the reprogramming process can be found here (page 369).

Note

If after reviewing available diagnostic information, it is determined that the patient is experiencing too many impedance episodes that are not associated with clinical evidence of fluid accumulation, the CorVue Threshold setting may be set too low and should be increased. If the patient experiences clinical evidence of fluid accumulation without impedance episodes being detected, the CorVue Threshold may be set too high and should be decreased.

Impedance episodes are summarized in the printed CorVue Thoracic Impedance Monitoring Referral Report (see Reports).

To operate the CorVue Thoracic Impedance Monitoring feature, the diagnostic must be turned on from the Diagnostic Settings window.

The Diagnostics window contains:

- **Impedance Monitoring Graph.** The top graph shows the Daily Impedance calculation (in red) and the Reference Impedance calculation (in black) over time. The occurrence of an AT/AF alert is shown by a vertical line. To view the graph in greater detail, select the Slide & Zoom box and slide it to any section of the graph. Select the Zoom in button to increase the resolution.
- **Impedance Status Graph.** This bar graph shows the period where the Daily Impedance measurement fell below the Reference Impedance for longer than seven days. The number at the top right of the blue bar indicates the total number of days below the reference impedance. The user programmed CorVue Threshold is compared to this value, and any impedance episodes longer than the programmed CorVue Threshold are listed in the CorVue™ Log.
- A Legend explaining the symbols.
- Zoom In/Zoom Out buttons. Select a button to choose the period of time (1 month, 3 months, or 1 year) shown in the graphs.
- See Clinical Comments button. Select this button to add or edit a comment or see a complete list of all comments entered. Any clinical comments are noted, by date, on the impedance status graph. When you select the Add/Edit button on the pop-up menu, the Add/Edit Clinical Comment window appears.
- CorVue™ Log button.
- CorVue™ Threshold button. This displays the current setting for the CorVue Threshold parameter. Select this button to change the setting.

You can turn the CorVue™ Thoracic Impedance Monitoring Feature On or Off.

Note

CorVue Thoracic Impedance Monitoring measurements may be affected in patients undergoing dialysis or parenteral inotrope therapy. The Impedance Monitoring feature has not been specifically evaluated in patients with capped or unused leads, coronary stents, or metal artificial heart valves.

Available in: Devices with CorVue™ Thoracic Impedance Monitoring Capability (page 184)

Accessed From: Diagnostics button > Impedance Monitoring tab

CorVue™ Log

Use this button to display a particular episode. When you select this button, the Date Logged window shows a list of the 20 most recent impedance episodes organized by date. Select a date and then select the Go To button. The selected impedance episode is highlighted in the Impedance Monitoring graph and Impedance Status graph.

If there are no impedance episodes, the button is inactive and is labeled "No Impedance Episodes."

Accessed From: Diagnostics button > Impedance Monitoring tab> See CorVue Log button.

CorVue™ Threshold

This parameter sets the number of consecutive days of "impedance measurements" (when the short-term impedance measurement is lower than the reference or long-term impedance average) that must occur before an impedance episode is recorded.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Diagnostics button > Impedance Monitoring tab> CorVue Threshold button.

Add/Edit Clinical Comment

Use this window to add or delete clinical comments. Select the clinical Comment button to open an on-screen keyboard.

Accessed From: Diagnostics button > Impedance Monitoring tab> See Clinical Comments button.

Tests

The Tests window contains the following tabs:

- Capture & Sense (page 31)
- Battery & Leads (page 37). Battery voltage, signal amplitude, and pacing lead impedance measurements
- Capacitor (page 39). Capacitor maintenance
- Sensor
- Timing Optimization. QuickOpt™ Timing Cycle Optimization (page 48) (in dual-chamber devices with QuickOpt Timing Cycle Optimization and devices without VectSelect Quartet™ LV Configuration capability)
- CRT Toolkit (in devices with Auto VectSelect Quartet LV Pulse Configuration capability (page 194)):
  - Auto VectSelect Quartet™ Test
  - VectSelect Quartet MultiVector Tools (page 42) for LV thresholds
  - SyncAV™ CRT (page 46) (in devices with SyncAV™ CRT capability (page 193))
  - QuickOpt™ Timing Cycle Optimization (page 48)
- CRT Toolkit (in devices with Auto VectSelect Quartet LV Pulse Configuration capability (page 194) and without Auto VectSelect Quartet™ Test capability)
  - RV-LV Conduction Time Measurements
  - VectSelect Quartet MultiVector Tools (page 42) for LV thresholds
  - QuickOpt™ Timing Cycle Optimization (page 48)
- Fibber & NIPS (page 50)
- Temporary Pacing (page 58)

The Real-Time Measurements button opens the Real-Time Measurements (page 31) window, which allows you to measure cardiac signal amplitude, lead impedance, and high-voltage lead impedance[42] in a single operation.

Accessed From: Tests button

Real-Time Measurements

The Real-Time Measurements window provides a means to obtain frequently used measurements in a single operation without performing each individual measurement. The window shows the last measured data above each check-box for each chamber and for the Sense, Lead Impedance, and High-Voltage Lead Impedance[43] measurements.

To acquire the real-time measurements:

1. Select the Real Time Measurements panel from the Capture & Sense (page 31) or Battery & Leads (page 37) windows.
2. If you want to acquire only selected measurements, select the appropriate check-boxes for the desired measurements.
3. Set the test parameters for the measurements (Mode, Base Rate, Paced AV Delay, and Sensed AV Delay).
4. Select the Start Temporary button to implement the test settings.
5. Select the Update All or Update Selected button.
6. The window updates the measurements above each selected button. You can print the results in the Wrap-Up™ Report.

Accessed From: Tests button > Capture & Sense tab > Acquire RTM button

Capture & Sense

The Capture & Sense Test window shows recent capture and sense test results. To start a test, select any button.

A green button indicates that the test has not been performed in the current session. A blue button indicates that a test has been performed. A red button indicates that the Pulse Amplitude or Sensitivity safety margin is less than 2:1 or the Pulse Width safety margin is less than 3:1.

The Update Sense button automatically performs the available atrial and right ventricular Sense Tests.

This window also contains a button to Real-Time Measurements (page 31).

- Capture Test (page 32)
- Sense Tests (page 34)

Accessed From: Tests > Capture & Sense tab

[42] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[43] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Capture Test

See Capture Test Instructions (page 32).

The Capture Test measures the atrial or ventricular capture thresholds to help determine an appropriate Pulse Amplitude or Pulse Width setting. Two test methods are available:

- AutoCapture™ Pacing and Cap Confirm Test Methods (page 33), automatically measures the signal amplitude and reports the results
- Decrement Test Method (page 32) incrementally reduces the Pulse Amplitude or Pulse Width setting during the test and reports the results.

The Capture Test window contains these tabs:

- Perform Test (page 32), used to set up and run the test
- This Session (page 33), reports the results from the current session
- Last Session (page 34), reports the results from the last session
- Follow-up EGM (page 34) reports the most recent automatic, out-of-clinic measurements.

NOTE

When both MultiPoint™ Pacing and V. Triggering are enabled, both the CapConfirm Setup Test and the CapConfirm Test Option are not available. To enable CapConfirm testing, disable either MulitPoint Pacing or V. Triggering, perform the testing, and then re-enable the MulitPoint Pacing or V. Triggering parameter.

Accessed From: Tests > Capture & Sense tab > Capture button

Perform Test

The Perform Test window contains a test button and the:

- Current permanent settings for the Mode, Base Rate, Paced/Sensed AV Delay (dual-chamber modes, Decrement Test Method only), and Starting Pulse Width or Pulse Amplitude parameters (Decrement Test Method only). Select the "…" button for more settings.
- Options (page 34) button. Opens the Options window where you can select the Capture Test Method (Decrement or AutoCapture/CapConfirm) and other Decrement test parameters.
- Additional Parameters (page 34) button. Opens a window to temporarily set other test parameters.
- Start Temporary button.
- Setup button for RVCap™ Confirm, LVCap™ Confirm or AutoCapture™ Test Confirm. This button is available when the Test Method is set to Decrement. Select this button to change the Test Method to CapConfirm/AutoCapture and to allow the Setup Test to run prior to the Capture Test.
- Perform AutoCapture test, LVCap Confirm Setup, or RVCap Confirm Setup button. For ventricular capture tests, check this button to run an AutoCapture or CapConfirm test before the capture test. When you select this button, the Test Method changes from Decrement to AutoCapture pacing[44] or Cap Confirm (when the Decrement Test Method is selected from the Options window).
- MultiVector Testing button. For LV capture tests, this button opens the VectSelect Quartet™ MultiVector Tools window for devices with Auto VectSelect Quartet ™ Testing capability (page 181) or the VectSelect Quartet Multivector Testing window for devices with VectSelect Quartet LV Pulse Configuration capability (page 194) and without the Auto VectSelect Quartet Testing capability (page 181).

Capture Test Instructions

- Decrement Test (page 32)
- AutoCapture™ Pacing and Cap Confirm Test Methods (page 33)

Decrement Test Method

1. Open the Tests page.

   There are two ways to navigate to the Tests Page:
   - a) From the FastPath Summary window, select the button in the Capture column for the chamber you want to test.
   - b) From the Main Menu, select the Tests button and then choose the chamber you want to test.

   The Perform Test window opens.
2. To change the Test Method from the Cap Confirm or AutoCapture method to the Decrement method, select the Options button. Otherwise, skip to Step 7.

   The Options window opens.
3. Select the Decrement Mode button.
4. Select the Decrement Mode (Pulse Amplitude or Pulse Width).
5. Select a setting for the Number of Cycles/Step parameter.

   This parameter determines how many paced cycles the programmer counts before it reduces the Pulse Amplitude or Pulse Width setting to the next step.

[44] In CRT-Ps, AutoCapture™ pacing is not available when the Sense Configuration is set to BV Bipolar or BV Unipolar

6. Close the Test Options window.

   The Perform Test window opens.

7. Review the temporary settings for the test. Select the Additional Parameters (page 34) button to determine if additional parameters need to be reset. If necessary, select the Waveform Control button on the Rhythm Display to reset the waveform.

   To program the device to the temporary settings before the test begins, select the Start Temporary button.

8. To begin the test, select and hold the Hold to Test button.

   The device delivers the starting pulse for the programmed Number of Cycles/Step. After the cycles have elapsed, the device's Pulse Amplitude or Pulse Width setting is reduced to the next setting, until you release the test button or the device reaches 0.25 V or 0.1 ms.

9. Watch the EGM for loss of capture. When this occurs, release the test button.

   The This Session (page 33) window appears with the test results and a button to program the Pulse Amplitude or Pulse Width setting.

   Note

   You can stop the test at any time by releasing the Hold to Test button.

AutoCapture™ Pacing and Cap Confirm Test Methods

The AutoCapture™ pacing and Cap Confirm methods automatically determine the capture threshold when the AutoCapture or Cap Confirm parameters are programmed On.

1. Select the Tests button.
2. Select the appropriate Capture button.
3. For atrial testing, if the Decrement Test Method is indicated on the Options (page 34) button, select the Test Options button. Otherwise, skip to Step 8.
4. For ventricular testing, if the Decrement Test Method is indicated on the Options (page 34) button, you can either:
   - Select the Options button and change the Test Method setting to AutoCapture or Cap Confirm setting, or
   - Select the AutoCapture, RVCap Confirm, or the LVCap Confirm Setup button and skip to Step 8. This runs the AutoCapture Setup function or Cap Confirm Setup Test, which tests if the pulse generator system can operate the V. AutoCapture or Cap Confirm function.

   Note

   Select the AutoCapture or Cap Confirm Setup button only if you are setting up the feature for the first time or if you have recently changed any of the following parameters: V. AutoCapture, Cap Confirm, Pulse Width, Pulse Configuration, Lead Type, AutoCapture/Cap Confirm Paced/Sense AV Delay parameters. If you select the button, the Test Method is automatically changed to the AutoCapture or Cap Confirm method.

5. For Test Method, select the AutoCapture or Cap Confirm setting.
6. Close the Test Options window.

   The Perform Test window appears.

7. For ventricular testing, check or un-check the AutoCapture or Perform Cap Confirm Setup button.
8. Review the temporary test settings and reset any parameters that require it. Review the Additional Parameters (page 34) button to determine if these need to be reset.

   To program the device to the temporary settings before the test begins, select the Start Temporary button.

9. Select the Start Test button.

   If the Perform AutoCapture, RVCap Confirm, or LVCap Confirm Setup button is checked, the Setup test precedes the capture test. If the device passes the Setup Test, then the capture test proceeds. You can monitor the test from the waveform. Select the Cancel button to stop the test. When the test is complete, the This Session (page 33) window appears with the test results.

   Note

   Selecting the Cancel button aborts the test and does not record a result.

This Session

This window contains the Capture Test waveform recorded during the most recent programming session. You can view, change, or print the waveform like any Freeze Capture. The window shows:

- For the Decrement Test, a "Capture Lost" flag on the waveform at the programming step (vertical line) next to where the test was ended. If this flag in not correctly set, touch the strip where the capture was lost to reset the flag.
- For the Decrement Test, a button showing the current setting for the parameter tested (Pulse Amplitude or Pulse Width). Select the button to change the setting.

- If the AutoCapture™ pacing or Cap Confirm Setup Test was run, the Setup Test recommendation.
- The **AutoCapture Trend** or **Cap Confirm Trend**, a line graph showing up to 52 weeks of measured capture threshold readings. Samples are recorded every seven days.
- A list of other test parameters and a Program button to program the V. AutoCapture or Cap Confirm parameter is highlighted in green (if the Setup Test was successfully run).
- A Print button to print the results.

The Safety Margin is highlighted in orange if the ratio is less than 2:1 for Pulse Amplitude or 3:1 for Pulse Width. The Safety Margin is highlighted in blue if it is greater than or equal to these margins.

Available In: Tests > Capture & Sense tab > Capture button > This Session tab

Last Session

The Last Session window contains the results of the last Capture test recorded before the current programming session.

Accessed From: Tests > Capture & Sense tab > Capture button < Last Session tab

Options

From the Capture Test: Options window, select a setting for the following parameters:

- **Test Method**. Decrement, AutoCapture, or Cap Confirm (available in devices with ACap™ Confirm Capability (page 179), BiVCap™ Confirm Capability (page 183), or V. AutoCapture™ Capability (page 194)).
- **Decrement Mode**. This mode determines which parameter is reduced during the test.
- **Number Cycles/Step**. This parameter determines how many paced cycles the programmer counts before it reduces the Pulse Amplitude or Pulse Width setting to the next step.

Accessed From: Tests > Capture & Sense tab > Capture button> Test Settings tab > Options button

Additional Parameters

The Additional Parameters window temporarily sets other test parameters. Temporarily programmed parameter settings are restored when the test ends or is canceled.

Accessed From: Tests>Capture & Sense tab>Capture button> test Settings tab>Additional Parameters button

Follow-up EGM

The Follow-up EGM window is available when Cap Confirm/V. AutoCapture™ parameter (page 73) is set to On or Monitor. The window contains:

- A Follow-up EGM showing five complexes from the most recent out-of-clinic automatic capture threshold measurement that was used to identify capture (the complexes are shown chronologically from left to right).
- The AutoCapture Trend or the Cap Confirm Trend, a line graph showing up to 52 weeks of measured capture threshold readings. Samples are recorded every seven days.
- The current programmed settings for the V. AutoCapture, Cap Confirm, Pulse Amplitude, Pulse Configuration, and Pulse Width parameters (the green A symbol indicates automatic operation).
- Print button

  Note

  If the tab is labeled "Today" the EGMs were recorded within the last 24 hours. Otherwise, the tab displays the date of the last recording.

  Only automatic, out-of-clinic measurements are saved in the AutoCapture or Cap Confirm Trend. Measurements obtained during a programming session are noted in the trend with a green dot, but are not saved in memory.

Accessed From: Tests > Capture & Sense > Capture/Ventricle button > Today/[Date] tab

Sense Tests

Sense Threshold tests measure atrial or ventricular signal amplitude and help determine an appropriate Sensitivity setting. Two test methods are available:

- Automatic (page 35). Automatically measures the signal amplitude and reports the results
- Increment (page 35). Manually reduces the Sensitivity setting during the test, reports the results, and reports the current Sensitivity setting.
  For CRT-Ds (page 163) and Dual-Chamber ICDs (page 163), the Increment Sense Test method is available in the Atrial Sense Test.
  For CRT-Ps (page 164) and Dual-Chamber Pacemakers (page 164), the Increment Sense Test method is available in the Atrial Sense Test and Ventricular Sense Test.

Note

In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, the V. Sensitivity (page 76) setting is auto-adjusted and cannot be set manually. In all devices with atrial sensing, the A. Sensitivity setting can be adjusted when AutoSense (page 75) is Off.

The Sense Test window contains the following tabs:

- Perform Test (page 32). Used to set up the test
- This Session (page 33). Reports the results from the current session
- Last Session (page 34). Reports the results from the last session
- Follow-up EGM (page 34). Reports the most recent automatic, out-of-clinic measurements.

See also:

- Options (page 34)
- Sense Test Instructions (page 35).

Accessed From: Tests > Capture & Sense tab > Sense/Ventricle or Sense/Atrium button

Perform Test

The Perform Test window contains a test button and the:

- Current permanent settings for the starting Sensitivity (Increment only), Mode, Base, Rate, and Paced/Sensed AV Delay (dual-chamber modes) parameters. Select the "..." button for more settings.
- Options (page 34) button. Chooses the sense test method (Atrial Sense Test only).
- Additional Parameters (page 34) button. Opens a window to temporarily set other test parameters.
- Start Temporary button.

Sense Test Instructions

- Automatic Test (page 35)
- Increment Test (page 35)

Automatic

The Automatic method automatically determines the signal amplitude.

1. Select the Tests button.
2. Select the appropriate Sense button.
3. If the Options button indicates Increment (Atrial Sense Test only) as the Test Method or if you want to change the Number of Measurements parameter, select the Options (page 34) button. Otherwise, skip to Step 7.
4. For Test Method, select Automatic.
5. Select a setting for the Number of Measurements parameter.

   This parameter determines how many times the system measures the signal amplitude before stopping the test. The Monitor setting allows the test to run for 120 cycles.
6. Close the Options window.

   The Perform Test window appears.
7. Review the temporary settings for the test and reset any parameters that require it. Review the Additional Parameters (page 34) button to determine if these need to be reset. If necessary, select the Waveform Control button on the Rhythm Display to reset the waveform.

   To program the device to the temporary settings before the test begins, select the Start Temporary button.
8. To begin the test, select the Start Test button.

   The system measures the signal amplitude (shown in the Rhythm Display) and the test completes automatically. The This Session (page 33) window appears with the test results.

Increment

The Increment method manually determines the chamber's signal amplitude.

1. Select the Tests button.
2. Select the Sense/Atrium or Sense/Ventricle button.
3. If the Automatic Test Method is indicated on the Options (page 34) button or if you want to change the setting for the Number of Cycles/Step parameter, select the Options button. Otherwise, skip to Step 7.
4. For Test Method, select Increment.
5. Select the setting for the Number of Cycles/Step parameter.

This parameter determines how many sensed cycles the programmer counts before it increases the Sensitivity setting to the next step.[45]

6. Close the Options window.

   The Perform Test window appears.

7. Review the temporary settings for the test parameters and reset any parameters that require it. Review the Additional Parameters (page 34) button to determine if these need to be reset. If necessary, select the Waveform Control button on the Rhythm Display to reset the waveform.

   To program the device to the temporary settings before the test begins, select the Start Temporary button.

8. To begin the test, select the Hold to Test button.

   The device senses at the starting Sensitivity setting for the programmed Number of Cycles/Step parameter. After the cycles have elapsed, the Sensitivity value is increased (mV value) to the next setting, until you remove your finger from the Hold to Test button or the device reaches the minimum sensed activity (maximum Sensitivity setting or 5 mV) and automatically ends the test.

9. Watch the ECG for loss of sensing. When this occurs, release the Hold to Test button.

   The This Session (page 33) window appears with the test results.

This Session

The This Session window contains the results of the Sense Test recorded during this programming session. You can view, change, or print the waveform like any Freeze Capture.

If the patient had insufficient rhythm to perform the test, the results are displayed as "None."

The window contains:

- A button for programming the A. Sensitivity (page 76) or V. Sensitivity[46] parameter (Increment A. Sense test or V. Sense Test)[47].
- The Safety Margin (ratio of the measured signal amplitude to the Sensitivity setting).
- The Sense Configuration setting.
- A "Sensing Lost" flag (Increment A. Sense Test or V. Sense Test) on the waveform at the programming step (vertical line) next to where the test was ended. If this flag is not correctly set, touch the strip where sensing was lost to reset the flag.
- The Amplitude Trend, a line graph of median weekly sense threshold measurements over time. The Trend displays the Sense Configuration (page 80) setting programmed at the time the weekly sample was taken.

Accessed From: Tests > Capture & Sense tab > Sense/Ventricle or Sense/Atrium button

Last Session

The Last Session window contains:

- The results of the last recorded Sense Tests.
- The Amplitude Trend, a line graph of median weekly sense threshold measurements over time. The Trend displays the Sense Configuration (page 80) setting programmed at the time the weekly sample was taken.

Accessed From: Tests > Capture & Sense tab > Sense/Ventricle or Sense/Atrium button > Last Session tab

Options

From the Options window, select a method to determine sense threshold. The options are:

- Automatic (page 35), automatically measures the signal amplitude and reports the results.
- Increment (page 35), manually reduces the A. Sensitivity or V. Sensitivity[48] setting during the test, reports the results, and suggests an A. Sensitivity or V. Sensitivity setting.
- **Number of Cycles/Step**. If the Increment method is selected, this parameter determines how many sensed cycles the programmer counts before it increases the Sensitivity setting[49] to the next step.[50]
- **Number of Measurements**. If the Automatic method is selected, this parameter determines how many times the system measures the signal amplitude before stopping the test. The Monitor setting allows the test to run for 120 cycles.

Accessed From: Tests > Capture & Sense tab > Sense/Ventricle or Sense/Atrium button > Perform Test tab > Options button

Additional Parameters

The Additional Parameters window temporarily sets other test parameters. Permanently programmed parameter settings are restored when the test ends or is canceled.

Accessed From: Tests > Capture & Sense tab > Sense/Ventricle or Sense/Atrium button > Perform Test tab > Additional Parameters button

---

[45] When the Sensitivity setting (mV) is increased, the actual sensitivity of the device decreases. Thus, as the test progresses, the device becomes less able to sense intrinsic activity.
[46] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[47] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[48] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[49] When the Sensitivity setting (mV) is increased, the actual sensitivity of the device decreases. Thus, as the test progresses, the device becomes less able to sense intrinsic activity.
[50] When the Sensitivity setting (mV) is increased, the actual sensitivity of the device decreases. Thus, as the test progresses, the device becomes less able to sense intrinsic activity.

AV Delays

The AV Delays window allows you to program the following parameters during a test:

- Paced AV Delay (page 70)
- Sensed AV Delay (page 70)

Accessed From: Tests > Capture & Sense tab > Sense-Ventricle or Sense-Atrium button > Perform Test tab > Paced/Sensed AV Delay "…" button

Follow-up EGM

The Follow-up EGM window is available if the AutoSense (page 75) parameter was On at any point prior to the programming session. The window contains:

- A **follow-up EGM** showing five complexes from the most recent out-of-clinic automatic P-wave or R-wave measurement (the complexes are shown chronologically from left to right).
- The **Amplitude Trend**, a line graph of median weekly sense threshold measurements over time. The Trend displays the Sense Configuration (page 80) setting programmed at the time the weekly sample was taken.
- The current programmed settings for the Sense Configuration and the Sensitivity (page 76) parameters (the green A symbol indicates automatic monitoring).
- Print button.
- Program button to change the Sensitivity setting (programmable only if Sensitivity is not autoprogrammed).

  Note

  If the tab is labeled "Today," the EGMs were recorded within the last 24 hours. Otherwise, the tab displays the date of the last recording.

  Only automatic, out-of-clinic measurements are saved in the Amplitude Trend. Measurements obtained during a programming session are noted in the trend with a green dot, but are not saved in memory.

Accessed From: Tests > Capture & Sense > Sense/Ventricle button or Sense/Atrium > Today/[Date] tab

Battery & Leads

The Battery & Leads window contains:

- **Battery** button. Shows the last measured battery voltage[51], a longevity gauge illustrating the time left to ERI (based on the current rate of usage and other data), and the date and duration of the last max charge[52]. Select this button to open the Battery Details (page 37) window[53].
- **Lead Impedance (page 38)** buttons, which include thumbnail views of the Lead Impedance trends for all leads (except the LV2 lead) and today's lead impedance measurements. A red button border indicates an alert, if, for example, the lead impedance measurements are beyond programmed limits. A green button border indicates no recent measurements in the last 30 days. A blue button indicates recent results. Select any of these buttons to open the Lead Impedance window for details on the lead impedance.
- **Ventricular HV Lead Impedance (page 39)** button[54], which includes a thumbnail view of the HV Lead Impedance Trend and today's lead impedance measurements. A red button border indicates an alert, if, for example, the lead impedance measurements are beyond programmed limits. A green button border indicates no recent measurements in the last 30 days. Select this button to open the Ventricular HV Lead Impedance window.
- **Update Leads** button. Select this button to measure lead impedance.
- **Include HV** check button[55]. Select or deselect this button to include or exclude the measurement of the high voltage lead impedance[56].
- **Real-Time Measurements** button. Opens the Real-Time Measurements (page 31) window.

Accessed From: Tests > Battery & Leads tab

Battery Details

The Battery Details window contains:

- The **Longevity Gauge**, which illustrates the time left to ERI. The longevity is based on calculations that factor the:
  - amount of time needed to consume the remaining battery capacity
  - current rate of battery consumption
  - anticipated or projected capacitor charges[57]
  - device duty cycle.

[51] Not available for devices with a Greatbatch Medical Model 2850 battery, Model 2753 battery, or Model 2950 battery.
[52] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[53] When the device estimates that ERI will occur in less than 90 days, the gauge will display in red and the message will read "ERI in <3 months."
[54] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[55] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[56] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[57] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

The calculation is made at the start of every session and whenever a programming change affects the estimate.

- **Battery Information**, including the Last Max Charge time and date[58], the last unloaded battery voltage measurement[59], the battery current, remaining capacity to ERI percentage[60], and the estimated longevity
- The **Voltage Trend**[61], which shows monthly samples of automatic, out-of-clinic battery voltage measurements for up to five years of data
- The **Ideal Battery Voltage Trend Thumbnail**[62]. This shows a lifetime voltage trend approximation for the battery for comparison purposes.
- The **Update Values** and **Print** buttons
- The **Clear ERI** button that appears when the device reports ERI[63] to the programmer and when the programmer determines that there is a potential for a false detection of ERI[64]. If you select this button, the programmer disables the ERI condition and allows you to reset the ERI Patient Notifier trigger (see Alert Triggers (page 133)).

Accessed From: Tests > Battery & Leads tab > Battery button

Magnet Rate

Magnet Rate (sometimes known as the Battery Test Rate) corresponds to the device's battery voltage and is an indicator of service life. As battery power is depleted, the Magnet Rate gradually declines from Beginning-of-Life (BOL) at 100 bpm to approximately 85 bpm, which indicates Elective Replacement Indicator (ERI) (page 312). Magnet Rates at 80.7 bpm indicate End-of-Life (page 313) (EOL). The following table lists representative Magnet Rates and the approximate corresponding battery voltage.

Note

When a magnet is applied to CRT-Ps (page 164), Dual-Chamber pacemakers (page 164), or Single-Chamber Pacemakers (page 164), the device paces at a Magnet Rate of 100 bpm unless the device is either:

- Interrogated by a programmer when the battery voltage is less than or equal to 2.95 V. The Magnet Rate correlates to the measured battery voltage as shown in the following table.

Available In: CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)

Table 16. Magnet rates between BOL and EOL and corresponding battery voltage values[65]

Magnet Rate (bpm)	Voltage
100 (BOL)	3.2
100	3.1
100	3.0
97.9	2.9
93.6	2.8
89.3	2.7
85.0 (ERI)	2.6
80.7 (EOL)	2.5

Lead Impedance

For each implanted lead, the Lead Impedance window shows the:

- One-year impedance trend
- Impedance trend of the last seven days of lead measurements
- Current pulse configuration
- Date and results of the first lead impedance measurement for each programmed pulse configuration
- Lifetime Range of lead impedance measurements for each programmed pulse configuration
- Lead Impedance Monitoring button, which lists the current Lead Monitoring setting, the Upper and Lower Limit settings. Select this button to open the Lead Monitoring Parameters (page 80) window
- Update Values button and Print buttons

Accessed From: Tests > Battery & Leads tab > Lead Impedance button

[58] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[59] Not available for devices with a Greatbatch Medical Model 2850 battery, Model 2753 battery, or Model 2950 battery.
[60] Devices with a Greatbatch Medical Model 2850, Model 2950, or Model 2753 battery only.
[61] Not available for devices with a Greatbatch Medical Model 2850 battery, Model 2753 battery, or Model 2950 battery.
[62] Not available for devices with a Greatbatch Medical Model 2850 battery, Model 2753 battery, or Model 2950 battery.
[63] Not available for devices with a Greatbatch Medical Model 2850 battery, Model 2753 battery, or Model 2950 battery.
[64] Devices with a Greatbatch Medical Model 2850, Model 2950, or Model 2753 battery only.
[65] Not all Magnet Rates are shown

Ventricular HV Lead Impedance

The Ventricular HV Lead Impedance window[66] shows the:

- One-year impedance trend and test configuration legend
- Impedance trend of the last seven days of lead measurements
- Current configuration
- Date and results of the first lead impedance measurement for each test configuration
- Lifetime Range of lead impedance measurements for each test configuration
- HV Lead Impedance Monitoring button, which lists the current Upper and Lower Limit settings. Select this button to open the Lead Monitoring Parameters (page 80) window
- Buttons to set the Test Configuration parameter
- Update Values button and Print buttons

Note

A report of "No Measurement" in the First Measurement and Lifetime Range data indicates that no measurement was taken or all measurements were out of range.

CAUTION

Defibrillation Lead Impedance. Do not implant the device if the acute high-voltage lead impedance is less than 20 Ω or if the lead impedance of a chronic lead is less than 15 Ω. The device may be damaged if high-voltage therapy is delivered into an impedance less than 15 Ω. A warning message appears after the device has delivered a shock if the measured impedance is less than 15 Ω.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Tests > Battery & Leads tab > Lead Impedance button

Capacitor

The Capacitor window contains the:

- **Initiate Maintenance** button. Select this button to dump all residual voltage and charge the capacitors to maximum voltage[67]. This is followed by a Charge Time optimization phase that lasts approximately 10 seconds.
- Listing of the **Voltage** (maximum voltage of therapy) and **Charge Time** (time needed for the most recent capacitor maintenance). These are blank if the Initiate Maintenance button is not selected during the session. The window displays a "---" if an arrhythmia or charge timeout occurred during the capacitor maintenance.
- **Date, duration, and reason** for the Last Max Charge
- **Charging Parameters** button, which opens the Capacitor Maintenance (page 122) parameters window.

When the unloaded battery voltage reaches a specific level, the Charge Interval setting changes to optimize the battery performance.

See also:

- Capacitor Maintenance Details (page 39).

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Tests button > Capacitor tab

Note

If the capacitor maintenance charge interval is decreased, the timer does not reset until after the next capacitor maintenance. Perform a manual capacitor maintenance to reset the charge interval.

Capacitor Maintenance Details

The charge time is normally less than 10 seconds. If an extended period of time elapses between high-voltage charges, the dielectric material within the high-voltage capacitors may become deformed. This can prolong the first charge time following a period of disuse. The device charges the high-voltage capacitors to their maximum voltage[68] if the Charge Interval (page 122) setting has passed without a charge for maximum-voltage therapy.

If an arrhythmia is detected while a capacitor maintenance charge is in progress or has been recently completed, the voltage of the therapy delivered is either the programmed voltage or the voltage remaining on the capacitors, whichever is greater. With voltage already on the capacitors, the charge time necessary to reach the therapy voltage is reduced.

Sensor

The Sensor window contains the Reset Auto Threshold (page 40) button.

[66] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[67] For 40J devices, the capacitors charge to the voltage equivalent to 36J.
[68] For 40J devices, the capacitors charge to the voltage equivalent to 36J.

This is a programmer-guided procedure to clear and recalculate the Measured Average Sensor data, which are used for setting automatic Threshold (page 63) settings. Measured Average Sensor data are derived from the patient's activity level over the previous 18-hour period.

Reset Auto Threshold

1. Select the Tests button.
2. Select the Sensor tab.
3. Select the Reset Auto Threshold button.
4. Have the patient rest quietly for the duration of the procedure or approximately 30 pacing cycles. The procedure may be delayed for over a minute following capacitor maintenance or therapy delivery.
5. Select the Start Procedure button.

   As the programmer clears the activity data from the device, the screen shows a countdown for approximately 30 s. The Done button appears when the procedure is complete.
6. Select the Done button.

   Note

   In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), a delay of about 60 seconds in the collection of sensor date may occur if the capacitors were recharged immediately before the Reset Auto Threshold procedure. This delay is not used in the on-screen countdown.

Timing Optimization/CRT Toolkit Tab

- **CRT ToolKit** tab (for devices with VectSelect Quartet LV Pulse Configuration Capability (page 194)), see: CRT Toolkit.
- **Timing Optimization** tab (For devices with QuickOpt Timing Optimization), see: QuickOpt™ Timing Cycle Optimization (page 48).

CRT Toolkit: Devices with Auto VectSelect Quartet™ Test capability

The CRT Toolkit window provides access to the following tools to assist in selecting and programming the device parameters for CRT pacing therapy. The window contents include:

- **Perform Auto VectSelect** button. For devices with Auto VectSelect Quartet™ LV Pulse Configuration capability (page 194). Select this button to begin a sequence of procedures that will aid in the selection of the LV Pulse Configuration and amplitude settings. The sequence begins with automatic measurement of RV-LV conduction times and proceeds to automatic tests for LV capture, followed by an option to choose the parameter settings selected by Auto VectSelect algorithm. See Instructions for the Auto VectSelect™ Quartet test (page 41).
- **Perform MPP Auto VectSelect** button. For devices with MultiPoint™ Pacing capability (page 189). Select this button to begin a sequence of procedures that will aid in the selection of the LV1 and LV2 Pulse Configuration and amplitude settings. The sequence begins with automatic measurement of RV-LV conduction times and proceeds to automatic tests for LV capture, followed by an option to choose the parameter settings selected by Auto VectSelect algorithm. See Instructions for the Auto VectSelect™ Quartet test (page 41).
- **Access MultiVector Tools** button. Select this button to open the VectSelect Quartet MultiVector Tools (page 42) window, where you can program Pulse Amplitude, Pulse Width, and Pulse Configuration for the quadripolar lead, test and record PNS (phrenic nerve stimulation), and perform capture tests.
- **Perform SyncAV™ CRT** button. For devices with SyncAV CRT capability (page 193). Select this button to open the SyncAV™ CRT Parameters window, where you can view, if automatically collected, the following parameters: Intrinsic AV Conduction Interval, SyncAV™ CRT Delta, Paced AV Delay, Sensed AV Delay, and Shortest AV Delay. If Intrinsic conduction measurements are not automatically collected, the SyncAV CRT Intrinsic Measurements window opens, where you can start the measurements test. See instructions for SyncAV CRT (page 46).
- **Perform QuickOpt™** button. Opens the QuickOpt™ Optimization Wizard that automatically measures the width of the sense and pace signals with pre-set test parameters and calculates optimal delay settings.
- **Manual Testing & Results** button. Opens the QuickOpt™ Optimization: Manual Test (page 49) window that allows you perform each portion of the delay optimization calculation manually with an ability to adjust the pre-set test parameters.

  WARNING

  For CRT-Ds, when any procedure in the CRT Toolkit is performed, tachycardia and fibrillation detection are suspended and no arrhythmia therapy is delivered.

  Note

  Parameter Availability. During temporary pacing, the Rate Responsive AV Delay (page 70), Hysteresis Rate (page 68), Ventricular Intrinsic Preference (VIP™) Parameter (page 71), Negative AV Hysteresis/Search (page 72), SyncAV CRT (page 46), Auto Mode Switch (page 86), PVC Response (page 85), PMT Response (page 85), AF Suppression™ Algorithm pacing (page 87), Rest Rate, (page 67) Rate Responsive PVARP/V Ref (page 81), V. Triggering (page 62), and rate-responsive pacing (Sensor (page 63)) are suspended.

Test Results. The measurements and test results are saved on the programmer only for the duration of the session. Results are cleared at the end of the session.

A Sense Configuration. During the QuickOpt procedure, the A Sense Configuration is programmed to Unipolar.

Available In: Devices with Auto VectSelect Quartet capability (page 194)

Accessed From: Tests button > CRT Toolkit tab

Auto VectSelect Quartet Test

The Auto VectSelect Quartet Test allows you to automatically measure RV-LV conduction times and automatically conduct capture tests for recommended LV Pulse Configuration settings.

Instructions for the Auto VectSelect Quartet Test

1. From the Main Menu, select Tests > CRT Toolkit tab and select the Perform Auto VectSelect button (for BiV pacing) or Perform MPP Auto VectSelect (for MPP Pacing).

   The Measure RV-LV Conduction Time (page 42) window opens.
2. If you want to change the parameters used for the test, select the Additional Parameters button under the heart diagram. This opens the RV-LV Conduction Time: Additional Parameters (page 43) window, a list of parameters that are temporarily programmed for the measurements.
3. Ensure that the temporary parameters are appropriate or select new settings. To test the temporary settings, select the Start Temporary button. When complete, close the window.
4. In the Measure RV-LV Conduction time window, select the Perform Measurements button.

   The programmer institutes the test settings and begins to measure the delay between sensing an RV signal and a signal from the four electrodes on the LV lead (Proximal4 to Can, Mid3 to Can, Mid2 to Can, Distal Tip1 to Can).
   When the measurements are complete, the Auto VectSelect Quartet Capture Test (page 43) window opens where you can begin capture threshold testing of any pulse configuration. Each available vector is provided with a check box to include it in the capture testing. When the window opens, up to four test vectors have been automatically checked by the Auto VectSelect algorithm as recommended test vectors.
5. From the Auto VectSelect Quartet Capture Test window, you can do any of the following:
   - Re-run the RV-LV measurements. Select the RV-LV Conduction time box to re-open the Measure RV-LV Conduction Time window.
   - Review and adjust the capture test temporary parameters. Select the Additional Parameters button to open the Auto VectSelect Quartet Capture Test: Additional Parameters (page 44) window.
   - Check or uncheck test vectors to add them to batch for capture testing.
   - Begin automatic capture testing of the selected test vectors. Select the Measure LV Thresholds button.
6. Once you have selected the Measure LV Thresholds button, the VectSelect Quartet MultiVector Tools (page 42) window opens while the automatic capture tests are conducted. To skip a test vector, select the Skip Current Vector button. Once the tests are complete, you can do any of the following:
   - Review the Test Results. Select the button in the Test Results capture column to see the EGM test result of each test. Test failures are labeled "n/a" but are viewable.
   - Re-run the RV-LV measurements. Select the RV-LV Conduction time box to re-open the Measure RV-LV Conduction Time window.
   - Perform a manual capture test on any vector. Select the Perform Manual Capture Testing button to open the Manual Capture Test window.
   - Repeat the automated capture test. Select the Perform Auto Capture test to re-open the Auto VectSelect Quartet Capture Test window.
   - Test the selected vectors for PNS. Select the Check PNS button to open the Phrenic Nerve Stimulation (PNS) Test window.
   - Print the test results. Select the Print button.
   - Program the LV pulse parameters suggested by the automated test. See Selection Method and Programmed Parameters below.

   Note

   Before finalizing your selection, it is recommended to perform the PNS test on each vector with a capture test result to obviate the occurrence of PNS.
7. **Selection Method and Programmed Parameters**.

   Following automatic and or manual capture testing, use these buttons to program an automatically batched set of parameters (Cap Confirm, Pulse Configuration, Pulse Amplitude, and Pulse Width). These settings are selected by the Auto VectSelect algorithm, based on the results of the RV-LV measurements and capture and phrenic nerve stimulation tests. Choose a Selection Method button to batch store the Programmed Parameters to the suggested programmed settings. The Selection Method choices are:

- **Programmed**. The currently programmed settings.
- **Latest Activation.** Settings that are based on the lowest capture threshold for the cathode with the longest RV-LV conduction time
- **Widest Spacing**. For devices with MultiPoint Pacing. Settings that represent the greatest anatomical separation between anode and cathode.
- **Earliest and Latest Activation**. For devices with MultiPoint Pacing. Settings that are based on the earliest RV-LV conduction time for LV1 and the latest conduction time for LV2.

8. If you want to change any of the settings, select the individual parameter to choose the desired setting.
9. If you want to switch the order of the LV1 and LV2 Pacing Pulse Configuration and associated pacing outputs, select the reverse button (double-arrow button).
10. Once you have selected the parameter settings you want, you can select Preview to see the changes that will occur or select Program to permanently program the parameters.

VectSelect Quartet™ MultiVector Tools

Note

Before using the VectSelect Quartet MultiVector tools, read the Instructions for the Auto VectSelect Quartet Test. (page 41)

The VectSelect Quartet™ MultiVector Tools window contains:

- **Dynamic heart diagram**. Highlights the LV electrodes currently selected for the LV Pulse Configuration. The arrow indicates the direction of the pulse (cathode to anode).
- **RV-LV Conduction Time**. Opens the Measure RV-LV Conduction Time (page 42) window and displays the results of previous RV-LV conduction time measurements.
- **Print** button. Creates the CRT Toolkit Report, which includes the results of the RV-LV Conduction Time, VectSelect Quartet™ MultiVector Testing, and QuickOpt™ Timing Cycle Optimization (see Test Results Settings (page 172)).
- **Perform Manual Capture Test**. Opens the Manual Capture Test window for manually testing the capture threshold for each test vector. (see instructions for VectSelect Quartet Manual Capture Test (page 44)).
- **Check PNS**. Opens the Phrenic Nerve Stimulation (PNS) test window to conduct tests on phrenic nerve stimulation for each selected vector.
- **Perform Auto Capture Test**. Opens the Auto VectSelect Quartet™ Capture Test window to begin automatic capture testing.
- **Test Results table**. Displays all the results of the Capture and PNS tests. Select a highlighted Capture test result button to open details of the test result.
- **Selection Method and Programmed Parameters:**
  Following automatic and/or manual capture testing, and optional PNS testing, use these buttons to program an automatically batched set of parameters (Cap Confirm, Pulse Configuration, Pulse Amplitude, and Pulse Width). These settings are selected by the Auto VectSelect algorithm, based on the results of the RV-LV measurements and capture and PNS tests. Choose a Selection Method button to batch store the Programmed Parameters to the suggested programmed settings. The Selection Method choices are:
  - **Programmed.** The currently programmed settings.
  - **Latest Activation.** Settings that are based on the lowest capture threshold for the cathode with the longest RV-LV conduction time.
  - **Widest Spacing.** For devices with MultiPoint Pacing. Settings that represent the greatest anatomical separation between anode and cathode.
  - **Earliest and Latest Activation.** For devices with MultiPoint Pacing. Settings that are based on the earliest RV-LV conduction time for LV1 and the latest conduction time for LV2.
- **Programmable Parameters**. Select each button to change the batched parameters suggested by the automatic testing. You can program the Pulse Configuration, Cap Confirm, Pulse Amplitude, and Pulse Width for LV. Select the reverse button (double-arrow button) to switch the order of the LV1 and LV2 pulse configurations(in devices with MultiPoint Pacing).
- **Program** and **Preview** buttons for new settings for the programmable parameters

Available In: Devices with Auto VectSelect Quartet™ Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Access MultiVector Tools button

Accessed From: Tests button > Capture and Sense tab > LV Capture test > MultiVector Testing button

Accessed From: Tests button > CRT Toolkit tab > Perform Auto VectSelect button or Perform MPP Auto VectSelect button > Auto VectSelect Capture Test window > Measure LV Thresholds button

Measure RV-LV Conduction Time

The Measure RV-LV Conduction Time window helps you determine the conduction time from the right ventricle to each of the four electrodes on the Quadripolar LV pacing lead. The test measures the delay between sensing an RV signal and a signal from the four

electrodes on the LV lead (Proximal4 to Can, Mid3 to Can, Mid2 to Can, Distal Tip1 to Can). You can change the measurement settings by selecting the Additional Parameters (page 43) button. The results are reported here and in the VectSelect Quartet™ MultiVector Tools window (page 42).

Perform Measurements button. Select this button to start the automatic conduction measurement. If you have accessed this window through the Perform Auto VectSelect button, when the measurements are complete, the Auto VectSelect Quartet™ Capture Test window opens, which allows you to test left ventricular capture thresholds. Otherwise, select the Perform Measurements button to open the VectSelect Quartet MultiVector Tools window or select the Close button to return to the previous window.

Available In: Devices with Auto VectSelect Quartet™ Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Perform Auto VectSelect button , Perform MPP Auto VectSelect button, or VectSelect Quartet MultiVector Tools window

Accessed From: Phrenic Nerve Stimulation (PNS) Test window, Manual Capture Test window or Auto VectSelect Quartet Capture Test window

RV-LV Conduction Time: Additional Parameters

The RV-LV Conduction Time: Additional Parameters window allows you to set the test parameters for the RV-LV Conduction Time measurements.

The two available test methods are:

- RV Pace. The programmer delivers a series of pulses from the RV lead and measures the conduction time to the LV electrode, within a window of 0 to 300 ms after the VP marker.
- RV Sense. The programmer measures the conduction time sensed between the right ventricle and the LV electrodes, within a window of 50 ms before to 200 ms after the VS marker.

Other parameters that may be temporarily set during the test include:

- Mode
- Base Rate
- Pacing AV Delay
- Sensed AV Delay
- PVARP
- V. Pace Refractory

Available In: Devices with VectSelect Quartet LV Pulse Configuration capability (page 194)

Accessed From: Tests button > CRT Toolkit tab > Perform Auto VectSelect button, Perform MPP Auto VectSelect button, or VectSelect Quartet MultiVector Tools window

Accessed from: Auto VectSelect Quartet Capture Test, Manual Capture Test, Phrenic Nerve Stimulation (PNS) Test

Auto VectSelect Quartet™ Capture Test

The Auto VectSelect Quartet™ Capture Test window allows you select any available LV Pulse Configuration for automatic capture threshold testing.

The window contains:

- **Dynamic heart diagram**. Highlights the LV electrodes currently selected for the LV Pulse Configuration. The arrow indicates the direction of the pulse (cathode to anode).
- **RV-LV Conduction Time**. Opens the Measure RV-LV Conduction Time window and displays the results of previous RV-LV conduction time measurements.
- **Additional Parameters**. Opens the Auto VectSelect Quartet Capture Test: Additional Parameters (page 45) window for conducting the automatic capture test.
- **Checkboxes**. Select a checkbox to test the pulse configuration. Preselected checkboxes are chosen based on the results of the RV-LV conduction time measurements and other criteria.
- **Measure LV Thresholds**. Once you have selected the pulse configurations you wish to test, select this button to begin capture threshold testing of each vector. The VectSelect Quartet MultiVector Tools (page 42) window opens to complete the testing.

See Instructions for the Auto VectSelect Quartet Test (page 41).

Available In: Devices with Auto VectSelect Quartet Test capability

Accessed From: Tests button > CRT Toolkit tab > Access MultiVector Tools button > Perform Auto Capture Test button

Accessed From: Tests button > Capture and Sense tab > LV Capture test > MultiVector Testing button > Perform Auto Capture Test button

Accessed From: Tests button > CRT Toolkit tab > Perform Auto VectSelect button or Perform MPP Auto VectSelect button > Measure RV-LV conduction time > Perform Measurements button

Auto VectSelect Quartet™ Capture Test: Additional Parameters

The Auto VectSelect Quartet™ Capture Test: Additional Parameters window allows you to set the test parameters for the Auto VectSelect Quartet Capture Test.

Available parameters that may be temporarily set during the test include:

- LV Pulse Width
- V. Pace Refractory
- Mode
- Base Rate
- BiVCap™ Confirm
- Paced AV Delay
- Sensed AV Delay

Available In: Devices with Auto VectSelect Quartet Test capability

Accessed From: Tests button > CRT Toolkit tab > Access MultiVector Tools button

VectSelect Quartet Manual Capture Test

The VectSelect Quartet Manual Capture Test window allows you to perform and record individual capture tests for any LV Pulse Configuration. The window contains:

- **Dynamic heart diagram**. Highlights the LV electrodes currently selected for the LV Pulse Configuration. The arrow indicates the direction of the pulse (cathode to anode).
- **RV-LV Conduction Time**. Opens the Measure RV-LV Conduction Time (page 42) window and displays the results of previous RV-LV conduction time measurements.
- **Additional Parameters**. Opens the MultiVector Testing: Additional Parameters (page 48) window for conducting the capture test.
- **Test Results table**. Displays the results of all Capture and PNS tests conducted in the current programming session. Select a highlighted Capture test result button to open details of the test result.
- **Test Vector Settings**. To manually test the capture threshold for a particular pulse configuration, use the buttons to select the test vector, Pulse Amplitude, and Pulse Width. Once you have select the correct settings, select the Start Manual Capture Test button to begin the test.

See Instructions for the VectSelect Quartet Manual Capture Test (page 44).

Available In: Devices with Auto VectSelect Quartet™Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Access MultiVector Tools button

Accessed From: Tests button > Capture and Sense tab > LV Capture test > MultiVector Testing button

Instructions for the VectSelect Manual Capture Test

The Manual Capture Test allows you to manually test the capture threshold of each possible LV Pulse Configuration.

1. If you wish to re-measure the RV-LV conduction time before testing, select the RV-LV Conduction Time window to open the Measure RV-LV Conduction Time (page 42) window.
2. If you wish to change any test parameters other than the Pulse Amplitude and Pulse Width, select the Additional Parameters button to open the MultiVector Testing: Additional Parameters (page 48) window.
3. To begin the test, select the test vector (right side of the screen) you would like to test. To choose the vector, you can:
   - Select the right or left arrows to move between vectors, or
   - Select the Test Vector button to see a list of all possible vectors.

   Each vector selected is shown in the Dynamic Heart Diagram on the right side of the screen.
4. Set the Pulse Amplitude and Pulse Width settings so that you can ensure capture. Select either the parameter button to see a range of settings or use the + and - buttons to increase or decrease the setting.
5. Select the Start Manual Capture Test button.

   The programmer initiates the temporarily programmed parameters.
6. Decrease the Pulse Amplitude setting using the - button until the devices loses capture.
7. Increase the Pulse Amplitude until capture is restored.
8. Select the Record Capture Loss button.

The test ends and the results are listed in the Test Results table.

9. You can choose another vector to test or close the test window.

Phrenic Nerve Stimulation (PNS) Test

The Phrenic Nerve Stimulation (PNS) Test window allows you to observe the occurrence of PNS during high voltage pulses at a particular LV Pulse Configuration and to record your results in the Test Results table. The window contains:

- **Dynamic heart diagram**. Highlights the LV electrodes currently selected for the LV Pulse Configuration. The arrow indicates the direction of the pulse (cathode to anode).
- **RV-LV Conduction Time**. Opens the Measure RV-LV Conduction Time (page 42) window and displays the results of previous RV-LV conduction time measurements.
- **Additional Parameters**. Opens the MutliVector Testing: Additional Parameters (page 48) window for conducting the PNS test
- **Test Results table**. Displays the results of all Capture and PNS tests conducted in the current programming session. Select a highlighted Capture test result button to open details of the test result.
- **Test Vector Settings**. To manually test the PNS for a particular LV Pulse Configuration, use the buttons to select the test vector, Pulse Amplitude, and Pulse Width. Once you have select the correct settings, select the Check PNS button to begin the test.

See Instructions for the Phrenic Nerve Stimulation (PNS) Test (page 45).

Available In: Devices with Auto VectSelect Quartet™ Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Access MultiVector Tools button

Accessed From: Tests button > Capture and Sense tab > LV Capture test > MultiVector Testing button

Instructions for the Phrenic Nerve Stimulation (PNS) Test

The Phrenic Nerve Stimulation (PNS) Test allows you to deliver a high voltage pulse to any LV Pulse Configuration to determine if PNS results. By recording your findings in the programmer, the Auto VectSelect algorithm can eliminate any vector that causes PNS and help pinpoint the suggested parameter set.

1. If you wish to re-measure the RV-LV conduction time before testing, select the RV-LV Conduction Time window to open the Measure RV-LV Conduction Time (page 42) window.
2. If you wish to change any test parameters other than the Pulse Amplitude and Pulse Width, select the Additional Parameters button to open the MultiVector Testing: Additional Parameters (page 48) window.
3. To begin the test, select the test vector (right side of the screen) you would like to test. To choose the vector, you can:
   - Select the right or left arrows to move between vectors, or
   - Select the Test Vector button to see a list of all possible vectors.

   Each vector selected is shown in the Dynamic Heart Diagram on the right side of the screen.
4. Set the Pulse Amplitude and Pulse Width settings to evaluate PNS. Select either the parameter button to see a range of settings or use the + and - buttons to increase or decrease the setting.
5. Select the Check PNS button.

   The programmer initiates the temporarily programmed parameters.
6. It is recommended that you assess the patient for signs of PNS. Change the Pulse Amplitude and Pulse Width settings as needed.
7. Select the Record PNS button if PNS is present or select the Record No PNS button if the patient does not report PNS. The findings are recorded in the Test Results column.
8. Repeat the process for each Test Vector of interest.
9. Close the test window to return to the VectSelect Quartet MultiVector Tools window.
10. Select one of the batched settings in the Selection Method column. Any vector that has PNS present will not be included in the selection.
11. You may wish to re-run the Automatic LV Capture Thresholds again, replacing any vector with PNS with vectors that have no PNS.

VectSelect Quartet™ Capture Results

The VectSelect Quartet Capture Results window shows the Capture Test waveform for a specific test vector recorded during the VectSelect Quartet™ MultiVector Testing. You can view, change, or print the waveform like any Freeze Capture.

The window also shows the tested LV Pulse Configuration, the Pulse Width and Pulse Amplitude of the LV capture, an results of any PNS test.

SyncAV™ CRT

The SyncAV™ CRT Parameters window allows you to view, and measure intrinsic AV conduction intervals. Intrinsic AV conduction intervals are measures of time from an atrial event to the detection of intrinsic right-ventricular activity and will be automatically collected if intrinsic activity occurs during a programmer session (for devices with SyncAV™ CRT Capability (page 193)).

Select the Perform SyncAV CRT button:

If intrinsic measurements were not automatically collected, the SyncAV CRT Intrinsic Measurements window opens, select the Start Measurement button.

If intrinsic measurements have been automatically collected, the SyncAV CRT Parameters window opens displaying the Intrinsic AV Conduction Interval measurements and SyncAV CRT Delta, Paced AV Delay, Sensed AV Delay, Shortest AV Delay parameters. Select the EGM button to show the Intrinsic AV Conduction Interval Results window.

Based on the intrinsic conduction interval you can adjust the SyncAV CRT Delta, Paced AV Delay, Sensed AV Delay, and Shortest AV Delay.

NOTE

Intrinsic measurements are not collected during AMS, VT/VF, or atrial noise.

NOTE

Enabling SyncAV CRT will disable Rate Responsive AV Delay.

Available In: Devices with SyncAV CRT capability.

Accessed From: Tests button > CRT ToolKit tab > Perform SyncAV CRT button

CRT Toolkit: Devices with VectSelect Quartet™ LV Pulse Configuration capability and without Auto VectSelect Quartet™ Test capability

The CRT Toolkit window provides access to the following tools:

- **Perform Measurements** button. This opens the Measure RV-LV Conduction Time (page 42) window, which measures and reports the conduction time between the right ventricle and each LV electrode.
- **Check LV Thresholds** button. This opens the VectSelect Quartet™ MultiVector Testing window, which allows you to perform and record manual capture tests and phrenic nerve stimulation tests for all vectors and to program the LV Pulse Configuration, LV Pulse Amplitude, and LV Pulse Width parameters.
- **Perform QuickOpt™** button. Opens the QuickOpt™ Optimization Wizard that automatically measures the width of the sense and pace signals with pre-set test parameters and calculates optimal delay settings.
- **Manual Testing & Results**. Opens the QuickOpt™ Optimization: Manual Test (page 49) window that allows you perform each portion of the delay optimization calculation manually with an ability to adjust the pre-set test parameters.

  WARNING

  For CRT-Ds, when any procedure in the CRT Toolkit is performed, tachycardia and fibrillation detection are suspended and no arrhythmia therapy is delivered.

  Note

  Parameter Availability. During temporary pacing, the Rate Responsive AV Delay, Hysteresis Rate, Ventricular Intrinsic Preference (VIP™) Parameter, Negative AV Hysteresis/Search, Auto Mode Switch, PVC Response, PMT Response, AF Suppression™ Algorithm pacing, Rest Rate, Rate Responsive PVARP/V Ref, V. Triggering, and rate-responsive pacing (Sensor) are suspended.

  Test Results. The measurements and test results are saved on the programmer only for the duration of the session. Results are cleared at the end of the session.

  A Sense Configuration. During the QuickOpt procedure, the A Sense Configuration is programmed to Unipolar.

Available In: Devices with VectSelect Quartet LV Pulse Configuration capability (page 194) and without Auto VectSelect Quartet Test capability

Accessed From: Tests button > CRT Toolkit tab

RV-LV Conduction Time Measurements

The Measure RV-LV Conduction Time window helps you determine the conduction time from the right ventricle to each of the four electrodes on the Quadripolar LV pacing lead. You can also change the measurement settings by selecting the Additional Parameters (page 43) button. The results are reported here and in the VectSelect Quartet™ MultiVector Testing window.

Perform Measurements button. Select this button to start the automatic conduction measurement.

Check LV Thresholds button. Select this button to open the VectSelect Quartet™ MultiVector Testing window.

Available In: Devices with VectSelect Quartet™LV Pulse Configuration capability (page 194) and without Auto VectSelect Quartet™ Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Perform Measurements button

RV-LV Conduction Time: Additional Parameters

The RV-LV Conduction Time: Additional Parameters window allows you to set the test parameters for the RV-LV Conduction Time measurements.

The two available test methods are:

- RV Pace. The programmer delivers a series of pulses from the RV lead and measures the conduction time to the LV electrode, within a window of 0 to 300 ms after the VP marker.
- RV Sense. The programmer measures the conduction time sensed between the right ventricle and the LV electrodes, within a window of 50 ms before to 200 ms after the VS marker.

Other parameters that may be temporarily set during the test include:

- Mode
- Base Rate
- Pacing AV Delay
- Sensed AV Delay
- PVARP
- V. Pace Refractory

Available In: Devices with VectSelect Quartet LV Pulse Configuration capability (page 194) and without Auto VectSelect Quartet Test capability)

Accessed from: Tests button > CRT Toolkit tab > Perform Measurements button > Additional Parameters button

VectSelect Quartet™ MulitVector Testing

The VectSelect Quartet™ MultiVector Testing window contains:

- **RV-LV Conduction Time**. Opens the Measure RV-LV Conduction Time (page 42) window and displays the results of previous RV-LV conduction time measurements.
- **Additional Parameters** (page 48) for conducting the capture test.
- **Start Manual Capture Test**. Measures and records the capture thresholds for each test vector (see Instructions for Conducting MultiVector Testing (page 47)).
- **Check PNS**. Delivers pulses to determine if the pacing output results in phrenic nerve stimulation (PNS) and records the results.
- **Test Pulse Amplitude and Pulse Width buttons**. Temporarily change these parameters during the test. Select the plus or minus buttons or the setting button to display the entire range of settings. Permanent settings are restored at the end of the test
- **Test Results table**. Displays all the results of the Capture and PNS tests. Select a highlighted Capture test result button to open details of the test result.
- **Programmable Parameters**. Permanently programs the LV2 Pulse Configuration, LV2 Pulse Amplitude, and LV2 Pulse Width parameters (available when the LVCap™ Confirm parameter is set to Monitor or Off).
- **Print** button. Creates the CRT Toolkit Report, which includes the results of the RV-LV Conduction Time, VectSelect Quartet™ MultiVector Testing, and QuickOpt™ Timing Cycle Optimization (see Test Results Settings (page 172)).
- **Program and Preview** buttons for new settings for the programmable parameters

Available In: Devices with VectSelect Quartet™ LV Pulse Configuration capability (page 194)

Accessed From: Tests button > CRT Toolkit tab > Check LV Thresholds button

Instructions for Conducting VectSelect Quartet™ MultiVector Testing

1. Open the VectSelect Quartet™ MultiVector Testing window.

   There are three ways to navigate to the window:
   - a) From the LV Capture Test window, select the MultiVector Testing button.
   - b) From the Main Menu, select Tools > CRT Toolkit tab > Check LV Thresholds button
   - c) From the Measure RV-LV conduction time window, select the Check LV Measurements button.

   The VectSelect Quartet™ MultiVector Testing window opens.
2. Select the RV-LV Conduction Time button on the left side of the window to perform the RV-LV Conduction Time Measurements (page 42) and select the Check LV Thresholds button when done.
3. Select the Test Vector you wish to test:
   - Select the Distal or Proximal arrows to choose the vector, or

- Select the Test Vector button, which opens a pop-up containing all available settings

4. Set the starting Test Pulse Amplitude and Pulse Width:
   - Toggle the + and - buttons to increase or decrease the settings, or
   - Select the Pulse Amplitude or Pulse Width button to see a pop-up of all available settings.
5. Select the Additional Parameters (page 48) button to change any other test parameter.
6. Select the Start Manual Capture Test button.
7. With the + and - buttons, adjust the Pulse Amplitude or Pulse Width settings until you see a change in the morphology on the real-time Rhythm Display indicating loss of capture.
8. Select the Record Capture Loss button, which records the findings in the Test Results column.

   Note

   After you record a capture test result, you can select the Results button in the Capture column of the Test Results table to open a Test Results window. This window contains a Freeze Capture and Print button to print the results.
9. Select the Check PNS button.
10. With the + and - buttons, adjust the Pulse Amplitude or Pulse Width settings until the patient notes the presence of PNS.
11. Select the Record PNS button if PNS is present or select the Record No PNS button if the patient does not report PNS. The findings are recorded in the Test Results column.
12. Repeat the process for each Test Vector of interest.
13. Based on your results, you may set the LV Pulse Configuration and the LV Pulse Amplitude and Pulse Width in the Programmable Parameters column on the right.
14. Print the test results. The CRT Toolkit report can also be printed with the Test Results Reports from the Wrap-Up Overview (see Test Results Settings (page 172)) and from the Print Menu (page 169) screen.

    Note

    Test Results. The QuickOpt Timing Cycle Optimization test results, MultiVector Testing results, and RV-LV Conduction Time measurements are saved on the programmer only for the duration of the session. Results are cleared at the end of the session.

MultiVector Testing: Additional Parameters

The VectSelect Quartet™ MultiVector Testing: Additional Parameters window allows you to set the test parameters for VectSelect Quartet™ MultiVector Testing.

Available parameters that may be temporarily set during the test include:

- LV Pulse Configuration
- LV Pulse Amplitude
- LV Pulse Width
- Mode
- Base Rate
- V. Pace Refractory
- Paced AV Delay
- Sensed AV Delay

Available In: Devices with Auto VectSelect Quartet™ Test capability (page 181)

Accessed From: Tests button > CRT Toolkit tab > Check LV Thresholds button

Accessed From: Tests button > Capture and Sense tab > LV Capture test > MultiVector Testing button

VectSelect Quartet™ Capture Results

The VectSelect Quartet Capture Results window shows the Capture Test waveform for a specific test vector recorded during the VectSelect Quartet™ MultiVector Testing. You can view, change, or print the waveform like any Freeze Capture.

The window also shows the tested LV Pulse Configuration, the Pulse Width and Pulse Amplitude of the LV capture, an results of any PNS test.

QuickOpt™ Timing Cycle Optimization

The QuickOpt™ Timing Optimization window allows you to optimize the settings for the Paced AV Delay (page 70), Sensed AV Delay (page 70), and Interventricular Delay (page 62) parameters. The procedure measures the width of the pace and sense signals using temporary parameter settings and calculates optimal settings. The optimization procedure is only available in DDD, DDI, and VVI modes.

The QuickOpt Timing Cycle Optimization window contains two buttons:

- **Perform Test.** Opens the QuickOpt™ Optimization Wizard that automatically measures the width of the sense and pace signals with pre-set test parameters and calculates optimal delay settings.
- **Manual Testing & Results.** Opens the QuickOpt™ Optimization: Manual Test (page 49) window that allows you perform each portion of the delay optimization calculation manually with an ability to adjust the pre-set test parameters.

Available in: Devices with QuickOpt Timing Cycle Optimization capability (page 192)

Accessed From: Tests button > CRT Toolkit tab (for devices with VectSelect Quartet LV Pulse Configuration capability)

Accessed From: Tests button > Timing Optimization tab (for devices without VectSelect Quartet LV Pulse Configuration capability)

WARNING

In CRT-Ds (page 163): When the QuickOpt Timing Cycle Optimization is performed, tachycardia and fibrillation detection are suspended and no arrhythmia therapy is delivered.

Note

Parameter Availability. During temporary pacing, the Rate Responsive AV Delay (page 70), Hysteresis Rate (page 68), Ventricular Intrinsic Preference (VIP™) Parameter (page 71), Negative AV Hysteresis/Search (page 72), SyncAV™ CRT (page 46) Auto Mode Switch (page 86), PVC Response (page 85), PMT Response (page 85), AF Suppression™ Algorithm pacing (page 87), Rest Rate (page 67), Rate Responsive PVARP/V Ref (page 81), V. Triggering (page 62), MultiPoint™ Pacing, and rate-responsive pacing (Sensor) are suspended.

Test Results. The measurements and test results are saved on the programmer only for the duration of the session. Results are cleared at the end of the session.

V Sense Configuration. During procedure, the V Sense Configuration is programmed to RV Bipolar.

A Sense Configuration. During procedure, the A Sense Configuration is programmed to Unipolar.

MultiPoint™ Pacing. The QuickOpt Timing Cycle Optimization test is not designed for MultiPoint Pacing. Recommendations for Ventricular Pacing do not include MultiPoint Pacing settings (RV - > LV1 - LV2 and LV1 - > LV2 - > RV)

QuickOpt ™ Optimization: Manual Testing & Results

The QuickOpt™ Timing Cycle Optimization window contains controls to measure the width of the atrial sense signals and to optimize the device's settings for Paced AV Delay (page 70), Sensed AV Delay (page 70), and Interventricular Delay (page 62). The window contains the following buttons and check-boxes:

- **Perform Test.** Select one of these buttons to open the manual measurement controls (QuickOpt™ Optimization: Manual Test (page 49)). The button also shows any previous QuickOpt measurements.
- **EGM.** After the signal is measured, select this button to open the QuickOpt™ Optimization Freeze Capture (page 50) of the measurement.
- **Check-boxes.** Select any of these to check (store for programming) or un-check (leave the parameter unchanged) the proposed setting. To permanently program the setting, select the Program Optimal Values button below.
- **Program Optimal Values.** After a successful measurement, select this button to permanently program the recommended settings.
- **Print Report.** After a successful measurement, select this button to print the results.

Accessed From: Tests button> CRT Toolkit tab > Manual Testing & Results button (for devices with VectSelect Quartet LV Pulse Configuration capability)

Accessed From: Tests button> Timing Optimization tab > Manual Testing & Results button (for devices without VectSelect Quartet LV Pulse Configuration capability)

QuickOpt™ Optimization: Manual Test

The QuickOpt™ Timing Cycle Optimization window shows:

- The **Start Test** button to begin measuring the width of the pace or sense signal. This toggles to the Stop Test button that appears after nine events have been measured.
- Additional buttons to change relevant parameters during the test.
- The **Cancel Temporary** button to cancel the measurement.

See Instructions for the QuickOpt Optimization Manual Measurement (page 50).

Accessed From: Tests > CRT Toolkit tab > Manual Testing & Results button > Perform Test buttons (for devices with VectSelect Quartet LV Pulse Configuration capability)

Accessed From: Tests > Timing Optimization tab > Manual Testing & Results button > Perform Test buttons (for devices without VectSelect Quartet LV Pulse Configuration capability)

Instructions for the QuickOpt™ Optimization Manual Measurement

1. From the Tests window, select the Timing Optimization tab.
2. Select the Manual Testing & Results button.

   The QuickOpt™ Timing Cycle Optimization window opens.
3. Select one of the Perform Test buttons.

   The QuickOpt Timing Cycle Optimization window opens for that measurement. Green buttons show temporarily programmed settings.
4. Select any available parameter button to temporarily change the setting during the test.

   To reveal the underlying rhythm, set low Base Rate and long Paced/Sensed AV Delay settings.
5. Select the Start Test button.

   The programmer institutes the temporary settings and begins to measure pace or sense signals. The procedure requires at least nine events to compute the optimal setting. The number of the measured cycles appears in the window. After nine events have been successfully measured, the Stop Test button is available. The measurements continue until you select the Stop Test button.
6. After nine events, select the Stop Test button.

   The QuickOpt Timing Cycle Optimization window appears. You can either reject the proposed settings (Step 7) or accept them (Step 8).
7. To reject the suggested setting, uncheck the box next to the parameter and select the X at the top right corner of the screen to close the screen and return to the QuickOpt™ Timing Cycle Optimization (page 48) window.
8. To accept any suggested setting, select any of the check-boxes. Then, select the Program Optimal Values button.

   If any other parameters are affected by this change, the Preview Changes (page 169) window appears with all proposed changes.
9. Select the Program button to program the new settings or the Discard Changes button to reject the proposed changes.

QuickOpt™ Optimization Freeze Capture

The QuickOpt Freeze Optimization Capture window contains up to the most recent 30 s of the EGM, Markers data, and Surface ECG of the QuickOpt Optimization measurement. The window is formatted like any Freeze Capture (page 14), where you can change various aspects of the screen display and print the results. The window also contains the average measurement, the eight measurements used, and the optimal values for all Delay parameters.

Accessed From: Tests > CRT Toolkit tab > Manual Testing & Results button > EGM button (for devices with VectSelect Quartet LV Pulse Configuration capability)

Accessed From: Tests > Timing Optimization tab > Manual Testing & Results button > EGM button (for devices without VectSelect Quartet LV Pulse Configuration capability)

Fibber & NIPS

The Fibber & NIPS window (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164)) allows you to conduct the Fibrillation Induction (Fibber) test and the Noninvasive Programmed Stimulation (NIPS) test and the NIPS window (CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164)) allows you to conduct the Noninvasive Programmed Stimulation (NIPS) test. These tests use the device's circuitry to introduce asynchronous electrical impulses to the myocardium at precise intervals in a predetermined pattern. The programmer disables arrhythmia detection and diagnosis during the test.

- **Fibber Test (page 51).** This test uses faster bursts of stimuli, shocks synchronized to T-waves, or continuous direct current (DC) to induce fibrillation. You can terminate arrhythmias induced with the V. Fibber Test with the Device-Based Testing (page 54) function.
- **NIPS Test** (page 55). This test is used to induce and/or terminate an arrhythmia. There are two methods: the Burst Test, in which you can manually apply a pacing burst to a chamber to induce an arrhythmia; or the Extrastimuli Test, in which you can program the length of the initial pacing burst followed by timed additional stimuli to induce an arrhythmia.

Accessed From: Tests button > Fibber & NIPS tab (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

CAUTION

RF Communication. While you are conducting the Fibber and NIPS tests, ensure that at least four telemetry strength indicator LEDs appear on the programmer and the Merlin™ Antenna. If fewer LEDs are lit, the device may lose its communication link when it charges or dumps the capacitors. If this occurs, the test ends and the device returns to its permanently programmed parameters. Perform the measures to optimize RF communication (listed in the section on Suboptimal RF Communication (page 165)), and then re-start the test.

Note

Telemetry Communication. During Fibber and NIPS tests, telemetry communication with the device must be maintained. If the telemetry link is broken during the test, the device returns to its permanently programmed parameters.

ERI. Fibber and NIPS testing are not available when the device reaches ERI.

Stopping the Test. When you communicate with the device via the inductive telemetry wand, you can stop the test by removing the wand. However, if you use RF communication, you must select the Cancel Test button to stop the test.

Fibber Test

From Fibber test window, you can:

- Choose the type of Fibber test to conduct (**Fibber Mode**).
  - Burst (page 51). Delivers bursts of stimuli at short cycle lengths with no extra stimuli.
  - DC (page 52). Delivers a single direct current pulse through the high-voltage electrodes (V. Fibber Test only).
  - Shock-on-T. Delivers overdrive pacing followed by a properly timed high-voltage shock (V. Fibber Test only).
- Set the Fibber Test Parameters (page 52).
- Set the Device-Based Testing (page 54) parameters for the ventricle(s). This allows you to program the device's first attempt to defibrillate the patient after an arrhythmia was induced.
- Review and adjust the DeFT Response™ Technology Settings (Shock Waveform) (page 114) parameter settings.
- View the **Time Since Last Induction**. The length of time that has elapsed since the end of the last arrhythmia induction. This timer resets each time an arrhythmia induction is initiated.
- Run the test (select the **Enable Fibber** button).
- View the test results when you select the **Display New Episodes** button. This opens the detail of the fibber test episode.

See also:

- Fibber Test Instructions (page 51)
- Device-Based Testing (page 54)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

WARNING

Always have a separate standby external defibrillator immediately available.

WARNING

Tachy Therapy Enable/Disable (page 168). Ventricular arrhythmia induction is not available if Tachy Therapy is disabled.

CAUTION

RF Communication. While you are conducting the Fibber and NIPS tests, ensure that at least four telemetry strength indicator LEDs appear on the programmer and the Merlin™ Antenna. If fewer LEDs are lit, the device may lose its communication link when it charges or dumps the capacitors. If this occurs, the test ends and the device returns to its permanently programmed parameters. Perform the measures to optimize RF communication (listed in the section on Suboptimal RF Communication (page 165)), and then re-start the test.

Note

Telemetry Communication. During Fibber test, telemetry communication with the device must be maintained. If the telemetry link is broken during the test, the device returns to its permanently programmed parameters.

Therapy. All antitachyarrhythmia therapies are right-ventricular only.

Atrial Burst Fibber Mode. Backup ventricular pacing is available when burst stimuli are delivered to the atrium (see V. Support Rate (page 54).)

Zone Configuration (page 89). When the Zone Configuration setting is Off, ventricular Fibber is not available.

Fibber Test Instructions

- Burst (page 51)
- DC (page 52)
- Shock-on-T

Burst

1. Establish telemetry between the device and the programmer.
2. Select the Tests button.
3. Select the Fibber & NIPS tab.
4. Select the Atrial or Ventricular Fibber button.

5. Set the Fibber Mode to Burst.
6. Set the Pulse Amplitude (page 53), Pulse Width (page 53), S1S1 (page 53), and V. Support Rate (page 54) (A. Fibber only) parameters.
7. For V. Fibbers, set the Device-Based Testing (page 54) parameters and the DeFT Response™ Technology Settings) (Shock Waveform) (page 114) and navigate back to the Fibber window.
8. Select the Enable Fib button.
9. Press and hold the Hold to Apply Burst button for the desired duration. The arrhythmia induction ends if the telemetry link is broken.
10. Release the Hold to Apply Burst button to end the test. The device delivers therapy after the arrhythmia induction. See Device Based Testing (page 54).
11. Repeat from step 6 if desired.

DC

1. Establish telemetry between the device and the programmer.
2. Select the Tests button.
3. Select the Fibber & NIPS tab.
4. Select the Ventricular Fibber button.
5. Set the Fibber Mode to DC
6. Set the Pulse Duration (page 53) setting.
7. Set the Device-Based Testing (page 54) parameters and the DeFT Response™ Technology Settings (Shock Waveform) (page 114) and navigate back to the Fibber window.
8. Select the Enable Fib button.
9. Select the Induce Fib button.

   The arrhythmia induction ends if the telemetry link is broken.
10. Repeat from step 6, if desired.

    The device delivers therapy after the arrhythmia induction. See Device-Based Testing (page 54).

Shock-on-T

1. Establish telemetry between the device and the programmer.
2. Select the Tests button.
3. Select the Fibber & NIPS tab.
4. Select the Ventricular Fibber button.
5. Set the Fibber Mode to Shock-on-T.
6. Set the Pulse Amplitude (page 53), S2 Shock Energy/Voltage (page 53), S1 Count (page 53), S1S1 (page 53), and S1S2 (page 53) parameters.
7. Set the Device-Based Testing (page 54) parameters and the DeFT Response™ Technology Settings (Shock Waveform) (page 114) and navigate back to the Fibber window.
8. Select the Enable Fib button.
9. Select the Induce Fib button.

   The arrhythmia induction ends if the telemetry link is broken.
10. Repeat from step 6, if desired.

    The device delivers therapy after the arrhythmia induction. See Device-Based Testing (page 54).

Fibber Test Parameters

See Fibber Test Instructions (page 51).

- Pulse Amplitude (page 53). This parameter is available for the A. Fibber Burst, V. Fibber Burst, and V. Fibber Shock-on-T tests.
- Pulse Width (page 53). This parameter is available for the A. Fibber Burst and V. Fibber Burst tests.
- Pulse Duration (page 53). This parameter is available for the V. Fibber DC test.
- S2 Shock Energy/Voltage (page 53). This parameter is available for the V. Fibber Shock-on-T test.
- S1 Count (page 53).This parameter is available for the V. Fibber Shock-on-T test.
- S1S1 (page 53). This parameter is available for the A. Fibber Burst and V. Fibber Burst and Shock-on-T tests.
- S1S2 (page 53). This parameter is available for the V. Fibber Shock-on-T test.

- V. Support Rate (page 54). This parameter is available for A. Fibber Burst test.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

Pulse Amplitude

The Pulse Amplitude parameter determines the delivered stimuli voltage.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

Pulse Width

The Pulse Width parameter determines the duration of the fibber stimuli.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

Pulse Duration

The Pulse Duration parameter determines the length of time that the direct-current (DC) pulse is delivered through the high-voltage electrodes.

See also:

- Parameter Availability and Settings

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

The Pulse Duration parameter determines the length of time that the direct-current (DC) pulse is delivered through the high-voltage electrodes.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

S2 Shock Energy/Voltage

The S2 Shock Energy/Voltage parameter determines the amount of energy delivered during the S2 Shock. It is delivered when a T-wave is detected for the V. Fibber Shock-on-T Test. When the Waveform Mode parameter is set to Tilt, the settings are Joules; then the Waveform Mode (page 114) parameter is set to Pulse Width, the settings are in Volts.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

S1 Count

The S1 Count parameter determines the number of stimuli delivered in the S1 drive cycle preceding a shock-on-T. The first stimulus is delivered synchronously with a sensed or paced event.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

S1S1

This parameter specifies the amount of time between all S1 stimuli in the Burst or Shock-on-T Fibber modes.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

S1S2

The S1S2 parameter specifies the amount of time that the device waits after the last S1 stimulus to deliver the high voltage S2 shock.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

V. Support Rate

The V. Support Rate parameter is the pacing rate of the stimulus delivered to the ventricle during A. Fibber (VOO pacing).

> CAUTION
>
> **Ventricular support pacing is delivered in the VOO (page 157) Mode. For more information, see VOO mode information.**

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular Fibber button

Device-Based Testing

The Device-Based Testing parameters allow you to select how to terminate any arrhythmias induced by the ventricular fibber tests. First, select the 1st Therapy Method (page 54) parameter to determine how you want to terminate the arrhythmia, then set the available parameters. For more information, see:

- 1st Therapy Method (page 54)
- 1st Therapy (page 54)
- Time to Therapy (page 55)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Tests button > Fibber & NIPS tab > Ventricular Fibber button

> WARNING
>
> **Tachy Therapy Enable/Disable (page 168). In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, Ventricular arrhythmia induction is not available if Tachy Therapy is disabled.**
>
> Note
>
> If the capacitors have not charged to the desired voltage by the time the therapy is scheduled or selected for delivery, the therapy is postponed until the desired voltage is reached.
>
> If the capacitors take longer than 32 s to reach the desired voltage, the device delivers the voltage present on the capacitors.

1st Therapy Method

The 1st Therapy Method parameter determines how the first therapy is delivered after the ventricular Fibber Test induces an arrhythmia. The settings are:

- **Automatic.** The device automatically detects, diagnoses, and treats an arrhythmia induced by the test. The method uses the currently programmed detection and therapy parameters. You can change these settings if you select the **Defib Therapy** button, which opens the ShockGuard™ Technology Settings (Zone Configuration Window) (page 89). This setting is not available when the Zone Configuration parameter is Off.
- **Timed.** The programmer automatically delivers the therapy (set by the 1st Therapy (page 54) parameter) after a timer has counted the time set by the Time to Therapy (page 55) parameter. For the Burst test, the timer starts when you release the Hold to Apply Burst button. For the DC and Shock-on-T tests, the timer starts after the programmer delivers the inducing shock.
- **Manual.** In the Manual method, after the arrhythmia induction, you can manually start the therapy when you select the **Deliver Therapy** button. The therapy energy or voltage is determined by the 1st Therapy (page 54) parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Ventricular Fibber button

1st Therapy

The 1st Therapy parameter determines the amount of energy or voltage that is delivered during the Timed or Manual therapy methods. Subsequent therapies are delivered according to the programmed Detection Criteria. This parameter is only available when the 1st Therapy Method (page 54) parameter is set to Timed or Manual.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Ventricular Fibber button

Time to Therapy

The Time to Therapy parameter determines the delay between the end of arrhythmia induction and delivery of the high-voltage therapy. This parameter is available only when the 1st Therapy Method (page 54) parameter is set to Timed.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Ventricular Fibber button

NIPS Test

The NIPS (Non-Invasive Programmed Stimulation) Test allows you to induce or terminate an arrhythmia by delivering trains of pacing bursts to the atrium or ventricle. From the NIPS window, you can:

- Choose the type of NIPS test to conduct (Extrastimuli (page 55) or Burst (page 51)).
  - The **Burst Test** allows you to manually apply a burst of low-voltage pulses to a chamber
  - The **Extrastimuli Test** allows you to apply a burst of low-voltage pulses to a chamber and to program the length of the initial pacing burst followed by timed additional stimuli.
- Set the NIPS Parameters (page 56).
- Set the NIPS Test Parameters (page 57).
- **Print** the current NIPS Test Parameters with the Print Settings button.
- **Run** the tests.
- **Display New Episodes**. Select this button to view the episode detail of any arrhythmia induced by extrastimuli. This button is not available if the extrastimuli has not induced an arrhythmia or for CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164).

See also:

- NIPS Test Instructions (page 55).

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

WARNING

Tachy Therapy Enable/Disable (page 168). In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), Ventricular arrhythmia induction is not available if Tachy Therapy is disabled.

CAUTION

RF Communication. While you are conducting the Fibber and NIPS tests, ensure that at least four telemetry strength indicator LEDs appear on the programmer and the Merlin™ Antenna. If fewer LEDs are lit, the device may lose its communication link when it charges or dumps the capacitors. If this occurs, the test ends and the device returns to its permanently programmed parameters. Perform the measures to optimize RF communication (listed in the section on Suboptimal RF Communication (page 165)), and then re-start the test.

CAUTION

Ventricular Backup Pacing is delivered in the VOO (page 157) Mode.

Note

Telemetry Communication. During NIPS tests, telemetry communication with the device must be maintained. If the telemetry link is broken during the test, the device returns to its permanently programmed parameters.

Therapy. In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), all antitachyarrhythmia therapies are right-ventricular only.

NIPS Test Instructions

- Extrastimuli (page 55)
- Burst (page 56)

Extrastimuli

Note

To print out the currently programmed NIPS parameters, select the Print settings button.

1. Establish telemetry between the device and the programmer.
2. Select the Tests button.

3. Select the Fibber & NIPS[69] or NIPS[70] tab.
4. Select the Atrial or Ventricular NIPS button.
5. Select the Extrastimuli radio button.
6. Set the NIPS Parameters (page 56) and the additional NIPS Test Parameters (page 57).
7. Select the Start NIPS button.

   The pulse train for the programmed S1 Count begins. The pulse train ends if the telemetry link is broken or if you select the Cancel Test button.

Burst

1. Establish telemetry between the device and the programmer.
2. Select the Tests button.
3. Select the Fibber & NIPS or NIPS tab.
4. Select the Atrial or Ventricular NIPS button.
5. Select the Burst radio button.
6. Set the S1S1 (page 53) parameter and set additional NIPS Test Parameters (page 57).
7. Press and hold the Hold to Apply Burst button for the desired duration.
8. Release the Hold to Apply Burst button to end the test.

NIPS Parameters

The availability of NIPS parameters depends on which method of NIPS you choose: Extrastimuli or Burst.

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

S1 Count

The S1 Count parameter specifies the number of S1 stimuli that the device will deliver during the NIPS test. This is only available with the Extrastimuli method.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

S1S1

This parameter is the amount of time that the device waits after the last paced/sensed event before delivering the first S1 stimulus and the amount of time between all subsequent S1 stimuli.

If you select the Fixed Mode, the S1S1 parameter remains at a fixed setting in ms. If you select the Adaptive Mode, the S1S1 parameter is calculated as a percentage of the last measured interval.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

S1S2

The S1S2 parameter is the amount of time that the device will wait after the last S1 stimulus to deliver the S2 NIPS stimulus. This is only available with the Extrastimuli method.

See also:

- Parameter Availability and Settings (page 197)

[69] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[70] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

S2S3

The S2S3 parameter is the amount of time that the device waits after the S2 stimulus to deliver the S3 NIPS stimulus. This is only available with the Extrastimuli method.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

S3S4

The S3S4 parameter is the amount of time that the device waits after the S3 stimulus to deliver the S4 NIPS stimulus. This is only available with the Extrastimuli method.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

NIPS Test Parameters

See NIPS and S1 Burst Test Instructions.

The NIPS test parameters include the following:

- Pulse Amplitude (page 57)
- Pulse Width (page 57)
- Pulse Configuration (page 58)
- Sinus Node Recovery Delay (page 58)
- V. Support Rate (page 58)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

Pulse Amplitude

The NIPS Pulse Amplitude the amount of voltage delivered to the myocardium during NIPS testing. It is independent of the current programmed setting for the Pulse Amplitude parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

Pulse Width

The NIPS Pulse Width parameter is the duration of the pulse during NIPS testing. It is independent of the current programmed setting for the Pulse Width parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

Pulse Configuration

The NIPS Pulse Configuration parameter sets the anode and cathode of the pulse during NIPS testing. The NIPS setting for this parameter is independent of the current programmed setting for the Pulse Configuration parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

Sinus Node Recovery Delay

The Sinus Node Recovery Delay parameter is the time allowed between the final atrial NIPS pulse and the resumption of normal atrial pacing. This delay provides a period with no external stimulation to allow time for the sinus node to recover from the stimuli.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

V. Support Rate

The V. Support Rate parameter is the pacing rate of the stimulus delivered to the ventricle during A. NIPS (VOO pacing). During the delivery of atrial NIPS, the V. Pulse Amplitude and V. Pulse Width parameters of the backup pacing are set at the current programmed settings.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Tests button > Fibber & NIPS tab > Atrial or Ventricular NIPS button (CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs)

Accessed From: Tests button > NIPS tab > Atrial or Ventricular NIPS button (CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers)

Temporary Pacing

From the Temporary Pacing window you can initiate temporary pacing. Temporary Pacing is also available through the Preview Changes window.

The window also contains the following buttons from which you can select settings for use during temporary pacing. These parameters can be adjusted while temporary pacing is ongoing. The new values are immediately in effect.

- Mode (page 61)
- Base Rate (page 66)
- Ventricular Pacing (page 61)
- LV Pulse Configuration (page 80)
- Paced AV Delay (page 70)
- Sensed AV Delay (page 70)
- Ventricular Pace Refractory (page 83)
- PVARP (page 81)
- Post-Ventricular Atrial Blanking (page 81)
- Pulse Amplitude
- Pulse Width

The following parameters are not selectable during temporary pacing and remain as selected:

- Atrial and Ventricular Sensitivity (page 76)
- Max Track Rate (page 67)
- Ventricular Safety Standby (page 84)

WARNING

In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164): During temporary pacing, tachycardia and fibrillation detection is suspended and no arrhythmia therapy is delivered.

Note

Parameter Availability. During temporary pacing, the Rate Responsive AV Delay (page 70), Hysteresis Rate (page 68), Ventricular Intrinsic Preference (VIP™) Parameter (page 71), Negative AV Hysteresis/Search (page 72), SyncAV™ CRT (page 46), Auto Mode Switch (page 86), PVC Response (page 85), PMT Response (page 85), AF Suppression™ Algorithm pacing (page 87), and rate-responsive pacing (Sensor (page 63)) are suspended.

Telemetry Communication. During temporary pacing, telemetry communication with the device must be maintained. The temporary pacing settings are in effect only when the Temporary Pacing window is shown and only during telemetry communication with the device. If telemetry communication between the device and the programmer breaks, temporary pacing ends and the permanent parameters are restored within two seconds.

Accessed From: Tests > Temporary Pacing

Brady Parameters

The Brady Parameters window shows most of the programmable brady parameters divided into groups. Select the appropriate button to change parameter settings. The buttons are:

- Basic Operation (page 61)
- Rates (page 66)
- Delays (page 69)
- Capture & Sense (page 73)
- Leads (page 79)
- Refractories & Blanking (page 80)
- AT/AF Detection & Response (page 86)
- Rates & Refractories (page 88) (single chamber devices only)

Accessed From: Parameters button > Brady tab

Basic Operation

From the Basic Operation window, you can change the settings for the following parameters:

- Mode (page 61)
- Ventricular Pacing
- V. Triggering (page 62)
- Interventricular Delay
- V. Noise Reversion Mode (page 63)
- Episodal Pacing Mode (page 63)
- Sensor (page 63)
- Threshold (page 63)
- Slope (page 63)
- Max Sensor Rate (page 64)
- Reaction Time (page 64)
- Recovery Time (page 64)
- Restore Last Settings (page 65)
- MultiPoint™ Pacing Settings (page 65)

Accessed From: Parameters button > Brady tab > Basic Operation button

Mode

The Mode parameter determines the basic pacing operation of the device.

For timing diagrams and mode description, see Mode Descriptions (page 153).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Ventricular Pacing

The Ventricular Pacing parameter determines which ventricles are paced and the order in which they are paced. When you select the LV—>RV or RV—>LV settings, you can also set the Interventricular Delay parameter.

In devices with MultiPoint™ Pacing Capability (page 189), you can enable MultiPoint Pacing by selecting either RV -> LV1 -> LV2 setting or the LV1 -> LV2 -> RV setting. You can set the both the first and second Delay when you program the Ventricular Pacing parameter.

If you program the Ventricular Pacing parameter to a setting other than RV -> LV1 -> LV2 or the LV1 -> LV2 -> RV, then MultiPoint Pacing is disabled.

NOTE

In order to enable MultiPoint Pacing when the RVCap Confirm or LVCap Confirm parameter is On, both RVCap Confirm and LV Cap Confirm pacing margins must be ≤1.0V.

MultiPoint Pacing is not available during Temporary Programming. If you temporarily program any parameters when MultiPoint Pacing is enabled, the Ventricular Pacing parameter is autoprogammed to either the RV -> LV or LV -> RV settings.

LVCap Confirm can be enabled while MultiPoint Pacing is enabled. However, the LVCap Confirm setting only applies to the LV1 Pulse Amplitude setting.

See also:

- MultiPoint Pacing (page 65)

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

V. Triggering

The V. Triggering parameter enables the device to send a pulse to the myocardium immediately following the detection of an intrinsic pulse. The V. Triggering parameter is only available when the Mode parameter is set to VVI(R) or DDI(R). Enabling this parameter changes the pacing mode to either VVT(R) or DDT(R).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Note

The Hysteresis Rate parameter is unavailable when the V. Triggering parameter is enabled.

In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), the Base Rate interval must be at least 30 ms longer than the longest tachycardia detection interval when both the V. Triggering parameter and tachycardia therapy are enabled.

The Max Trigger Rate (page 68) parameter sets the highest possible rate for the V. Triggering parameter.

You can enable or disable the V. Triggering parameter by re-setting the Mode parameter.

When both MultiPoint™ Pacing and V. Triggering are enabled, the RVCap™ Confirm and the LVCap™ Confirm setting "On" is not available. To program RVCap Confirm or LVCap Confirm On, disable either MulitPoint Pacing or V. Triggering.

Interventricular Delay

The Interventricular Delay parameter determines the interval between the pulses delivered to the ventricles when the Ventricular Pacing parameter is set to either LV–>RV or RV–>LV. The Interventricular Delay setting can be evaluated with the QuickOpt™ Timing Cycle Optimization (page 48) test.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button > Ventricular Pacing parameter button

Magnet Response

The Magnet Response parameter determines if the device recognizes a magnet when it is placed over the device.

In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), when the Magnet Response is Normal, a strong magnetic field suspends tachy detection and prevents delivery of tachyarrhythmia therapy. When the Magnet Response is Ignore, the device ignores the presence of a magnet and delivers therapy as usual. Bradycardia pacing is not affected by a magnet placed over a CRT-D, dual-chamber ICD, or single-chamber ICD.

In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), when Magnet Response is programmed to Battery Test and the magnet is placed over the device, the device paces asynchronously at the Magnet Rate, which is an indication of battery status. If Magnet Response is programmed Off and the magnet is placed over the device, the device will not respond to the placement of the magnet.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Note

Detection and Therapy. In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, a magnet placed over the device can be useful in the prevention of tachyarrhythmia detection and delivery of therapy if a programmer is not available to turn the device Off (page 123). See the device user's manual for more information on the use of magnets.

Paced AV Delay (page 70). In dual-chamber modes, the Paced AV Delay parameter is temporarily programmed to 120 ms during magnet application.

Episode Triggers (page 142). If the Magnet Response parameter is programmed On and the Magnet Response parameter is set to the Battery Test setting, the device stores the episode after a two-second delay and performs a Battery Test after a five-second delay.

V. Noise Reversion Mode

The V. Noise Reversion Mode algorithm prevents the device from sensing high-frequency noise on the ventricular channel as tachyarrhythmias. In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), when the V. Noise Reversion Mode algorithm is enabled the device sets the pacing rate to 50 bpm. In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), the device sets the pacing rate to the Base Rate (page 66).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Note

Mode (page 61). In CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs, the V. Noise Reversion Mode parameter is available in DDD(R), DDI(R), and VVI(R) pacing modes. In CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers, the V. Noise Reversion Mode parameter is available in DDD(R), DDI(R), DVI(R), VVI(R), and VDD(R) pacing modes.

Episodal Pacing Mode

The Episodal Pacing Mode parameter determines the pacing mode used during an episode. The device changes to the Episodal Pacing Mode setting after the third non-sinus interval and ends when the device redetects sinus.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Sensor

The Sensor parameter turns on rate-responsive pacing, which enables the device to increase or decrease its pacing rate based on activity sensor data.

When Passive is selected, the device does not activate rate-responsive pacing, but it records diagnostic data that can be read in the Rates (page 25) diagnostics.

Note

Elective Replacement Indicator (ERI). When the device reaches ERI, it automatically reprograms Sensor to Off, which disables rate-modulated pacing.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Threshold

The Threshold parameter determines the "trigger point" at which a certain level of activity affects the Sensor (page 63)-indicated rate. A lower Threshold setting allows the sensor to respond to lower levels of activity, while a higher setting makes the sensor respond only to higher activity levels.

The "Auto" settings allow the device to automatically adjust the Threshold parameter above or below the Measured Average Sensor (MAS) value, a calculation of the patient's activity over the previous 18 hours. Thus, a setting of Auto (+1.0) automatically sets the Threshold parameter to 3.0 if the MAS value is 2.0. The MAS value is continually updated with new sensor data.

The MAS value appears under the Threshold button.

To clear and recalculate the MAS value, select the Reset Auto Threshold button.

See also:

- Parameter Availability and Settings (page 197)

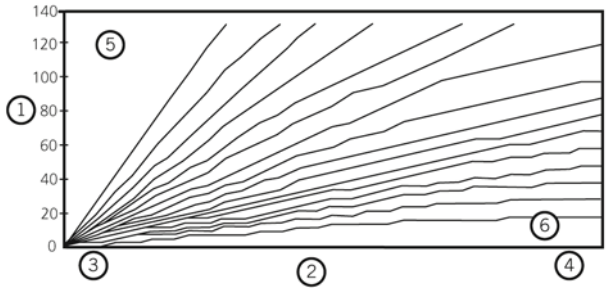
Accessed From: Parameters button > Brady tab > Basic Operation button

Slope

The Slope parameter assigns a flatter (low setting) or steeper (high setting) slope to the sensor rate-response. Lower settings, or flatter responses, limit the response to activity to small increases in the pacing rate. Higher settings, or steeper responses, allow the rate to increase to higher pacing rates. The figure below illustrates the various settings for the Slope parameter.

The "Auto" settings allow the device to automatically adjust the Slope parameter above or below the Measured Auto Slope, which is a calculation of the patient's activity over the previous seven days.

Figure 3. Slope



1. Increase in rate bpm
2. Sensor level
3. Low activity
4. High activity
5. Slope 16
6. Slope 1

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Max Sensor Rate

The Max Sensor Rate parameter is the fastest pacing rate allowed by the rate-responsive pacing. It is also the fastest Sensor (page 63)-indicated rate that can be recorded when the Sensor parameter is set to Passive.

In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), the Max Sensor Rate setting must be at least 30 ms longer than the longest programmed tachycardia detection interval to prevent arrhythmia detection at the Max Sensor Rate setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds, Dual-chamber ICDs, CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Basic Operation button

Accessed From: (Single-chamber ICDs, Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Reaction Time

The Reaction Time parameter controls how quickly increases in the Sensor (page 63)-indicated rate occur. A Very Fast setting allows for rapid rate increases, while a Slow setting only allows the rate to increase slowly.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Basic Operation button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Slope (page 63). Reaction Time increases are limited by the Slope setting.

Recovery Time

The Recovery Time parameter controls how quickly decreases in the Sensor (page 63)-indicated rate occur. A Fast setting allows for rapid rate decreases, while a Very Slow setting only allows the rate to decrease slowly.

For CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), the Recovery Time parameter also determines how quickly the device reduces the pacing rate from the Intervention Rate (page 69) setting to the Base Rate (page 66) setting following an advanced hysteresis intervention.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps, Dual-Chamber Pacemakers) Parameters button > Brady tab > Basic Operation button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers) Parameters button > Brady tab > Rates & Refractories button

Note

Slope (page 63). Recovery Time increases are limited by the Slope setting.

Sensor (page 63). The Sensor parameter does not have to be On to program the Recovery Time parameter.

Intervention Rate (page 69). The Recovery Time button is not active in the Rates window if the Intervention Rate parameter is Off.

Restore Last Settings

The Restore Last Settings button automatically restores all of the previous bradycardia and tachycardia parameter settings if the Mode (page 61) parameter is set to Pacing Off and/or the Zone Configuration (page 89) is set to Off.

In single-chamber pacemakers, dual-chamber pacemakers, and CRT-Ps, the Restore Last Settings button restores all previous bradycardia parameters when the Mode parameter is set to Pacing Off, AOO, VOO, or DOO. Changes to any parameter while in these Modes are reverted to the previous setting when you select the Restore Last settings button.

MultiPoint™ Pacing

From the MultiPoint™ Pacing window, you can change settings for the following parameters:

- Ventricular Pacing
- Delay 1 and Delay 2 (page 65)
- LV1 Pulse Configuration (page 58)
- LV2 Pulse Configuration (page 65)
- MultiPoint Post-Ventricular Atrial Blanking (page 66)

You can also select the Check LV Thresholds button, which opens the VectSelect Quartet™ MultiVector Tools (page 42) window (for devices with Auto VectSelect Quartet™ Test capability) or the VectSelect Quartet MultiVector Testing window (for devices without Auto VectSelect Quartet Test capability) help determine the capture thresholds.

Note

MultiPoint Pacing is only available at pacing rates of 110 **bpm** or less.

When MultiPoint Pacing is enabled and the V. Triggering or AMS V. Triggering parameters are enabled, then the MultiPoint Pacing enables triggered pacing.

MultiPoint Pacing is not available during Temporary Programming. If you temporarily program any parameters when MultiPoint Pacing is enabled, the Ventricular Pacing parameter is autoprogammed to either the RV -> LV or LV -> RV settings.

When both MultiPoint™ Pacing and V. Triggering are enabled, the RVCap™ Confirm and the LVCap™ Confirm setting "On" is not available. To program RVCap Confirm or LVCap Confirm On, disable either MulitPoint Pacing or V. Triggering.

Available in: Devices with MultiPoint™ Pacing Capability (page 189)

Accessed From: Parameters button > Brady tab > Basic Operation button > MultiPoint Pacing button

Delay 1 and Delay 2

The Delay parameter determines the interval between the pulses delivered to the right and left ventricles when MultiPoint™ Pacing is enabled (see Ventricular Pacing). The interval between each pulse is independently programmable.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button > MultiPoint Pacing button

NOTE

Oversensing. Oversensing may occur when high MultiPoint Pacing Pulse Amplitude settings and long MultiPoint Pacing Pulse Width settings are programmed along with long MultiPoint Pacing Delay settings and maximum Sensitivity settings.

RVCap Confirm and LV Cap Confirm. In order to enable MultiPoint Pacing when the RVCap Confirm or LVCap Confirm parameter is On, both RVCap Confirm and LV Cap Confirm pacing margins must be ≤1.0V

MultiPoint™ Pacing LV2 Pulse Configuration

The MultiPoint™ Pacing LV2 Pulse Configuration parameter determines the polarity of the second LV pacing pulse delivered. The first LV pacing pulse polarity is determined by the LV1 Pulse Configuration parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button > MultiPoint Pacing button

MultiPoint™ Pacing PVAB

In devices with MultiPoint™ Pacing Capability (page 189), the MultiPoint Pacing PVAB (Post-Ventricular Atrial Blanking) parameter establishes an atrial refractory period after ventricular paced and sensed events to prevent the atrial channel from detecting far-field R-waves when MultiPoint Pacing is enabled.

Atrial events falling within the MultiPoint Pacing PVAB period do not update the filtered atrial rate interval (FARI), nor are they used by the Rate Branch algorithm for dual-chamber SVT Discrimination Mode (see SVT Discrimination in Sinus Tach (page 94)). Events falling in this period are not counted in the AT/AF diagnostics.

Note

MultiPoint PVAB pacing is only available at pacing rates of 110 **bpm** or less.

MultiPoint PVAB pacing is only available when MultiPoint Pacing is enabled.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button > MultiPoint Pacing button

Rates

From the Rates window, you can change the settings for the following parameters:

- Base Rate (page 66)
- Rest Rate (page 67)
- Max Sensor Rate (page 64)
- Max Track Rate (page 67)
- Max Trigger Rate (page 68)
- Hysteresis Rate (page 68)
- Search Interval (page 68)
- Cycle Count (page 69)
- AMS Base Rate (page 87)
- 2:1 Block Rate (page 72)

You can also access the following:

- **AT/AF Settings.** Select the AT/AF Settings button to change the settings of the AT/AF Detection & Response (page 86) parameters.

For single-chamber devices, see Rates & Refractories (page 88).

Accessed From: Parameters button > Brady tab > Rates button

Base Rate

The Base Rate parameter sets the patient's minimum pacing rate. Typically, rates can fall lower than the Base Rate setting only if Hysteresis Rate (page 68), Rest Rate (page 67), or Post-Shock Base Rate (page 121) is enabled.

In DDD and atrial modes, the Base Rate interval is measured from an atrial stimulus to the next atrial stimulus without an intervening sensed atrial event. In VDD and ventricular modes (including DVI and DDI modes), the interval is from a ventricular stimulus to the next stimulus without an intervening sensed ventricular event (or an intervening sensed atrial event in VDD mode).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Rates tab > Basic Operation button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Elective Replacement Indicator (ERI). In CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers, when battery voltage decreases to ERI, the actual pacing interval is 100 ms longer than the programmed Base Rate interval. See Programmed Pacing Rates and Actual Pacing Rates at ERI (page 313).

Rest Rate

The Rest Rate parameter allows the device to decrease its pacing rate to a rate below the Base Rate (page 66) setting while the patient is asleep or in long periods of rest.

When the Rest Rate parameter is enabled, the device analyzes activity data over a seven-day period. When it detects that the patient has been inactive for more than 15 to 20 minutes, it switches the pacing rate from the Base Rate setting to the Rest Rate setting.

When the device senses activity, pacing is resumed at the Base Rate setting or at the Sensor (page 63)-indicated rate.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Testing. The Rest Rate parameter is disabled during a Capture & Sense (page 31) and NIPS Test (page 55).

Hysteresis Rate (page 68) and **Search Interval** (page 68). The Hysteresis Rate and Rate Hysteresis Search parameters are disabled when the Rest Rate parameter is enabled.

Mode Switch. While the device is operating at the AMS Base Rate (page 87) setting and the Rest Rate parameter is enabled, the Base Rate setting is used as the Rest Rate setting.

Base Rate (page 66). The available Rest Rate settings are limited by the Base Rate setting.

Max Track Rate

The Max Track Rate (MTR) parameter is the maximum ventricular pacing rate allowed by the device. If the device in DDD(R) or VDD(R)[71] mode senses an atrial rhythm faster than the MTR setting, the Sensed AV Delay (page 70) interval is extended to ensure that the ventricular paced rate does not exceed the MTR setting. Occasional pauses (Wenckebach behavior) may occur in accord with normal upper rate behavior.

As an aid to programming, when the Max Track Rate parameter is programmed, the programmer shows the intrinsic atrial rate at which 2:1 AV block occurs.

In CRT-Ds (page 163) and Dual-Chamber ICDs (page 163), to prevent arrhythmia detection due to pacing at the MTR setting, the MTR cycle length must be at least 30 ms longer than the longest programmed tachycardia cycle length and is limited by the programmed Paced AV Delay, Sensed AV Delay, and PVARP settings.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds, Dual-Chamber ICDs, CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates button

Note

Max Sensor Rate (page 64). The Max Track Rate setting can be exceeded if the Max Sensor Rate setting is programmed higher than the Max Track Rate setting.

Detection Interval/Rate (page 90). The Max Track Rate setting must be at least 30 ms longer than the longest Detection Interval/Rate setting[72].

Paced AV Delay (page 70), **Sensed AV Delay**, and **PVARP** (page 81). The Max Track Rate setting is limited by the programmed Paced AV Delay, Sensed AV Delay, and PVARP settings.

High Tracking Rates. When programming Maximum Tracking Rates of 190, 200, or 210 bpm, ensure that these rates are appropriate for the patient.

Interactions with Algorithms. The interaction of a number of algorithms may allow the device to override the Max Track Rate and Max Sensor Rate settings. These include all ventricular-based algorithms and the AF Suppression™ Algorithm (page 87), Ventricular Intrinsic Preference (VIP™) Parameter (page 71), Negative AV Hysteresis/Search (page 72), SyncAV™ CRT (page 46), and Ventricular Safety Standby (page 84) algorithms. This interaction is more likely to occur in cases where the operational Paced AV Delay (page 70) setting is significantly different than the patient's conduction time. For more information on upper rate behavior, contact Technical Support (page 163).

[71] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[72] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Max Trigger Rate

The Max Trigger Rate parameter is the pacing rate at which the V. Triggering (page 62) parameter is disabled.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Basic Operation button

Hysteresis Rate

The Hysteresis Rate parameter is a rate below the Base Rate (page 66) setting that is used when the patient's intrinsic rhythm is preferred to pacing. When the Hysteresis Rate parameter is enabled, the device decreases the pacing rate from the Base Rate setting to the Hysteresis Rate setting when it senses intrinsic activity. If the device fails to sense intrinsic activity, the device switches back to the Base Rate setting.

Operation at the Hysteresis Rate setting is triggered by a P-wave in atrial-based modes [DDD(R), AAI(R) and VDD(R)[73]] and an R-wave in ventricular-based modes [DDI(R), VVI(R) and DVI(R)[74]].

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Rate-Responsive Modes. The Hysteresis Rate parameter is disabled if the Sensor (page 63) parameter is set to On and the device detects sensor activity.

AF Suppression™ Algorithm (page 87) **Pacing.** The Hysteresis Rate parameter is auto-selected Off when the AF Suppression algorithm is enabled.

Rest Rate (page 67). The Rest Rate parameter takes precedence over the Hysteresis Rate parameter.

Post-Shock Base Rate (page 121). The Post-Shock Base Rate[75] parameter takes precedence over the Hysteresis Rate parameter.

Ventricular Pacing. Hysteresis Rate is not available if the Ventricular Pacing parameter is set to the Simultaneous (RV + LV) setting and the Mode parameter is set to the VVI setting.

Hysteresis Tracking Rate

When VDD(R) mode is programmed, the Hysteresis Tracking Rate nonprogrammable parameter is the minimum intrinsic atrial rate at which P-waves can be tracked. This rate interval equals the sum of currently programmed Hysteresis Rate interval and the Sensed AV Delay (page 70).

When VDD(R) mode is programmed, the Hysteresis Tracking Rate value appears on the programmer screen below the Hysteresis Rate button.

Accessed From: (CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates button

Advanced Hysteresis Functions

Up to five additional parameters are available in some devices when the Hysteresis Rate parameter is enabled. The parameters include:

- Search Interval (page 68)
- Cycle Count (page 69)
- Intervention Rate (page 69)
- Intervention Duration (page 69)
- Recovery Time (page 64)

Search Interval

The Search Interval parameter tells the device to periodically extend the pacing interval by the programmed number of minutes to search for intrinsic activity. Thus, if you select "5," the device reduces the pacing rate to the Hysteresis Rate (page 68) setting every five minutes to search for intrinsic activity.

[73] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[74] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[75] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

If the device senses an intrinsic beat during the search, it reduces the rate to the programmed Hysteresis Rate setting. If no intrinsic beat is sensed during the Hysteresis Rate interval, the device delivers a pulse at the end of the interval and begins pacing at the Base Rate (page 66) setting. If a native beat occurs between searches, the device operates at the Hysteresis Rate setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Rates tab > Rates button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Cycle Count

The Cycle Count parameter determines the number of cycles the device searches for intrinsic activity when Hysteresis Rate is enabled.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Hysteresis Rate (page 68). The Cycle Count parameter is available only when the Hysteresis Rate parameter is enabled.

Intervention Rate

Use this function to "intervene" if the patient's intrinsic rate falls below the Hysteresis Rate (page 68) setting and needs to be quickly restored to a higher pacing rate.

When the Intervention Rate parameter is enabled, the device begins pacing at the Intervention Rate setting when the pacing rate falls below the Hysteresis Rate (page 68) setting for a period longer than the Cycle Count (page 69) setting. The Intervention Rate setting stays in effect for the time set by the Intervention Duration (page 69) parameter. The rate then returns to the Base Rate (page 66) setting along a time line described by the Recovery Time (page 64) parameter.

If the Intervention Rate parameter is programmed Off, the device paces at the programmed Base Rate setting if the intrinsic rate drops below the Hysteresis Rate setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Rates button

Note

Episodes. If the Intervention Rate parameter is enabled, it autoprograms the Advanced Hysteresis Trigger On in devices with that function[76].

Intervention Duration

The Intervention Duration parameter is the number of minutes that the device operates at the Intervention Rate (page 69) setting. After this time period, the device decreases the rate according to the programmed Recovery Time (page 64) parameter until the Base Rate (page 66) setting or Sensor-indicated rate is reached and normal Hysteresis Rate operation resumes.

The Intervention Duration parameter is not programmable if the Intervention Rate parameter is Off.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Rates button

Delays

From the Delays window, you can change the settings for the following parameters:

- Paced AV Delay (page 70)
- Sensed AV Delay (page 70)
- Rate Responsive AV Delay (page 70)
- Shortest AV Delay (page 71)

[76] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

- Ventricular Intrinsic Preference (VIP™) Parameter (page 71)
- Negative AV Hysteresis/Search (page 72)
- SyncAV™ CRT Delta (page 72)
- 2:1 Block Rate (page 72)

You can also access the following:

- VIP™ Parameter Settings (page 73). Select the VIP Settings button to change the VIP™ Extension (page 73), Search Interval (page 73), and Search Cycles (page 73) parameters.

Accessed From: Parameters button > Brady tab > Delays button

Paced AV Delay

The Paced AV Delay parameter is the interval between a paced atrial event and a paced ventricular event.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Base Rate (page 66). The longest programmable Paced AV Delay interval is determined by the Base Rate, AMS Base Rate, or Post-Shock Base Rate settings. The maximum Paced AV Delay settings for all programmed Base Rate, AMS Base Rate, and Post-Shock Base Rate settings are shown in the following table.

Table 17. Maximum Paced AV Delay settings

AMS Base Rate, Post-Shock Base Rate, or Base Rate (bpm)[77]	Maximum Paced AV Delay (ms)
30–90	350
95-100	300
105	250
110	225
115-120	200
125	180
130-160	170
170	160

Sensed AV Delay

The Sensed AV Delay parameter is the interval between a sensed atrial event and a paced ventricular event.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Paced AV Delay (page 70). The longest programmable Sensed AV Delay setting is determined by the Paced AV Delay setting. The Sensed AV Delay setting must be shorter than or equal to the Paced AV Delay setting.

Rate Responsive AV Delay

The Rate Responsive AV Delay parameter increases or decreases the Paced AV Delay (page 70) or Sensed AV Delay (page 70) setting in relation to changes in the Sensor (page 63)-indicated rate, AF Suppression™ Algorithm (page 87) pacing rate, or sensed intrinsic atrial rate. A Low setting changes the Paced/Sensed AV Delay setting by one ms for each one-**bpm** change in the Sensor-indicated rate, AF Suppression pacing-driven rate, or sensed intrinsic atrial rate. A High setting changes the Paced/Sensed AV Delay setting by three ms for each one-**bpm** change in the Sensor-indicated rate, AF Suppression pacing-driven rate, or sensed intrinsic atrial rate. Thus as pacing rates rise, the device decreases both the Paced and Sensed AV Delay settings until the Max Sensor Rate (page 64), Max Track Rate (page 67), or Shortest AV Delay (page 71) setting is reached.

For devices with Enhanced Rate Responsive Pacing capability (page 187), the algorithm begins to operate when the rate exceeds either 60 **bpm** or a Base Rate set above 60 **bpm**. When the Sensor-indicated rate or sensed intrinsic atrial rate falls below 60 **bpm,** the algorithm terminates.

[77] Rates > 100 are only available in CRT-Ps and dual-chamber pacemakers.

For all other devices, the algorithm begins to operate when the rate exceeds either 90 **bpm** or a Base Rate set above 90 **bpm**. When the Sensor-indicated rate or sensed intrinsic atrial rate falls below 90 **bpm,** the algorithm terminates.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Post-Shock Duration[78]. The Rate Responsive AV Delay parameter is disabled during the Post-Shock Duration.

Ventricular Noise Reversion. The Rate Responsive AV Delay parameter is disabled during Ventricular Noise Reversion. See V. Noise Reversion Mode (page 63).

Ventricular Episode[79]. The Rate Responsive AV Delay setting is disabled during a ventricular episode.

Shortest AV Delay

The Shortest AV Delay parameter is the minimum AV delay for the Rate Responsive AV Delay (page 70), Negative AV Hysteresis/Search (page 72),and SyncAV™ CRT (page 46) settings. The Shortest AV Delay must be shorter than the programmed Paced AV Delay (page 70) setting. It can, however, be longer than the programmed Sensed AV Delay (page 70) setting. In that case, no shortening of the Sensed AV Delay interval will occur.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Rate Responsive AV Delay (page 70) and **Mode** (page 61). The Shortest AV Delay parameter is only available when the Rate Responsive AV Delay parameter is enabled and the Mode setting is DDD(R), DDIR, VDD(R)[80] or DVI(R)[81].

Rate Responsive AV Delay (page 70), Negative AV Hysteresis/Search (page 72), and SyncAV™ CRT Delta (page 72). For CRT-Ds (page 163) and CRT-Ps (page 164), the Shortest AV Delay parameter is available when the Rate Responsive AV Delay parameter is disabled but the Negative AV Hysteresis/Search, or SyncAV CRT Delta (page 72) parameter is enabled. This defines the lower limit of delay-shortening by the Negative AV Hysteresis/Search,or the SyncAV CRT Delta (page 72) parameter.

Ventricular Intrinsic Preference (VIP™) Parameter

The Ventricular Intrinsic Preference (VIP™) parameter enables an algorithm which allows the device to search for intrinsic conduction that is slower than the programmed Sensed AV Delay (page 70) setting. If intrinsic conduction is sensed, the Sensed AV Delay and Paced AV Delay settings are extended to allow the intrinsic conduction to continue.

See also:

- VIP Extension (page 73)
- Search Interval (page 73)
- Search Cycles (page 73)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Pacing Mode. The VIP algorithm is available only when Mode is DDD(R) or VDD(R).[82] See Mode Descriptions.

Conditions for Operation. The VIP algorithm cannot be enabled:

- When the Base Rate (page 66) setting is >110 **bpm** and the Rate Responsive AV Delay (page 70) parameter is enabled
- When the Ventricular Pacing mode is not RV Only
- When the Negative AV Hysteresis/Search (page 72) parameter or the SyncAV™ CRT (page 46) parameter is enabled

VIP suspends operation:

- When the intrinsic atrial rate or Sensor (page 63)-indicated rate is ≥ 110 **bpm**

[78] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[79] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[80] Available in CRT-Ps and dual-chamber pacemakers.
[81] Available in CRT-Ps and dual-chamber pacemakers.
[82] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.

- During a Capture or Sense test
- Following the delivery of a high-voltage shock during the Post-Shock Duration interval if the Post-Shock Mode parameter is enabled.[83]
- When mode-switching occurs. See Auto Mode Switch (page 86).

PVCs have no effect on this feature.

Negative AV Hysteresis/Search

The Negative AV Hysteresis/Search parameter enables the device to decrease the Paced AV Delay (page 70) and Sensed AV Delay (page 70) settings whenever an R-wave is detected in order to discourage intrinsic conduction and encourage ventricular pacing. The settings are the amount the Paced/Sensed AV Delay is decreased after an R-wave detection.

When the Negative AV Hysteresis/Search parameter is enabled, a detected R-wave shortens the Paced/Sensed AV Delay setting. This remains in effect for 31 cycles after R-wave detection. If another R-wave is not detected in that time, the permanently programmed Paced/Sensed AV Delay setting is restored. If another R-wave is detected during the 31-cycle period, the shortened Paced/Sensed AV Delay setting remains in effect for 255 cycles.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

Note

Mode (page 61). The Negative AV Hysteresis/Search parameter is only available when the Mode parameter is set to DDD(R).

Sensor (page 63). Sensor-driven increases in the pacing rate or the Rate Responsive AV Delay (page 70) setting can override or further shorten the Paced/Sensed AV Delay interval beyond the setting for the Negative AV Hysteresis/Search parameter.

Shortest AV Delay (page 71). The Negative AV Hysteresis/Search parameter cannot reduce the Paced/Sensed AV Delay setting below the Shortest AV Delay setting.

Ventricular Intrinsic Preference (VIP™) Parameter (page 71). The Negative AV Hysteresis/Search parameter cannot be turned on if the VIP algorithm is enabled.

SyncAV™ CRT Delta

The SyncAV™ CRT Delta parameter enables a feature that allows the device to dynamically adapt the Paced AV Delay (page 70) and Sensed AV Delay (page 70) settings in order to discourage intrinsic conduction and encourage ventricular pacing. Three intrinsic AV conduction intervals will trigger SyncAV™ CRT to shorten the Paced/Sensed AV Delay.The SyncAV CRT Delta parameter defines the amount the Paced/Sensed AV delay is decreased from the measured AV conduction time.

When the SyncAV CRT Delta parameter is enabled, the third detected intrinsic AV conduction interval shortens the Paced/Sensed AV Delay setting. This remains in effect for 31 cycles. If another three intrinsic AV conduction intervals are not detected in that time, the permanently programmed Paced/Sensed AV Delay setting is restored. If another three intrinsic AV conduction intervals are detected at the end of the 31-cycle period, the shortened Paced/Sensed AV Delay setting remains in effect for 255 cycle.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

NOTE

Mode (page 61). The SyncAV CRT Delta parameter is only available when the Mode parameter is set to DDD(R).

Sensor (page 63). Sensor-driven increases in the pacing rate or the Rate Responsive AV Delay (page 70) setting can override or further shorten the Paced/Sensed AV Delay interval beyond the setting for the SyncAV CRT Delta parameter.

Rate Responsive AV Delay (page 70). Should be OFF when the SyncAV CRT Delta parameter is set to a non-OFF value.

Shortest AV Delay (page 71). The SyncAV CRT Delta parameter cannot reduce the Paced/Sensed AV Delay setting below the Shortest AV Delay setting.

Ventricular Intrinsic Preference (VIP™) Parameter (page 71). The SyncAV CRT Delta cannot be turned on if the VIP algorithm is enabled.

2:1 Block Rate

The programmer displays the intrinsic atrial rate at which 2:1 AV block will occur in DDD(R) mode.

[83] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button

VIP™ Parameter Settings

From the VIP™ Settings window, you can change the settings for the following parameters:

- Ventricular Intrinsic Preference (VIP™) Parameter (page 71)
- VIP™ Extension (page 73)
- Search Interval (page 73)
- Search Cycles (page 73)

See also:

- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)

Accessed From: Parameters button > Brady tab > Delays button > VIP™ Settings button

VIP™ Extension

The VIP™ Extension parameter determines the length of time the device extends the Sensed AV Delay (page 70) interval to search for intrinsic conduction.

If an R-wave is sensed during the extension, the ventricular pulse is inhibited and the extended Sensed AV Delay interval remains in effect until the Search Interval (page 73) times out. If an R-wave is not sensed during the extension, the programmed Sensed AV Delay setting is restored until the Search Interval times out.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button > VIP™ Settings button

Search Interval

The Search Interval parameter determines how frequently the device extends the Sensed AV Delay (page 70) interval to search for intrinsic conduction.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button > VIP™ Settings button

Search Cycles

The Search Cycles parameter determines the number of cycles the device extends the Sensed AV Delay (page 70) interval to search for intrinsic conduction.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Delays button > VIP™ Settings button

Capture & Sense

From the Capture & Sense window, you can change the following settings used for pacing and sensing:

- Cap Confirm/V. AutoCapture™ parameter (page 73)
- Pulse Amplitude (page 75)
- Pulse Width (page 75)
- AutoSense (page 75)
- Sensitivity (page 76)
- Cap Confirm/V. AutoCapture™ Settings (page 76)
- SenseAbility™ Sensing Algorithm Settings (page 77)

Accessed From: Parameters button > Brady tab > Capture & Sense button

Cap Confirm/V. AutoCapture™ parameter

The Cap Confirm/V. AutoCapture™ parameter periodically measures the capture threshold and automatically sets the Pulse Amplitude (page 75) setting above the measured threshold. The device measures the capture threshold when the Cap Confirm/V. AutoCapture

Capture Test (page 32) is conducted and every eight or 24 hours, depending on the setting of the Search Interval (page 76) parameter (accessed from the Cap Confirm/V. AutoCapture Settings (page 76) window).

The capture threshold is measured with the "threshold search" algorithm, in which the device decreases the Pulse Amplitude 0.25 V below the last measured capture threshold. If this results in a loss of capture, the device emits a 5.0 V backup safety pulse and increases the Pulse Amplitude in steps of 0.125 V to search for a new capture threshold. When the threshold is found, the device sets a new Automatic Pulse Amplitude by adding a safety margin to the capture threshold measurement.

To operate the Cap Confirm/V. AutoCapture function, you must:

- For ACap™ Confirm, RVCap™ Confirm, and V. AutoCapture parameters, implant a low polarization, bipolar pacing lead in the appropriate chamber
- For LVCap™ Confirm, implant a low polarization lead, either unipolar or bipolar
- For RVCap Confirm, LVCap Confirm, and V. AutoCapture parameters, run the Cap Confirm/V. AutoCapture Setup test (see Capture Test (page 32))

The Cap Confirm/V. AutoCapture parameter has up to four settings:

- **Setup**. This setting is available when there are no valid Cap Confirm/V. AutoCapture setup test results (not available for ACap Confirm). If you choose this setting, the programmer asks if you want to start the Capture Test (page 32).
- **On.** The devices measures the threshold, automatically adjusts the Automatic Pulse Amplitude setting, and records the threshold measurement in the **Threshold Trend**, a graph of all threshold measurements (available on the This Session (page 33) and Follow-up EGM (page 34) windows).
- **Monitor.** The devices measures and records the capture threshold in the Threshold Trend but does not adjust the Pulse Amplitude setting (not available for V. AutoCapture parameters).
- **Off.** The device does not measure or record the capture threshold and does not automatically adjust the Pulse Amplitude setting.

When the Cap Confirm/V. AutoCapture parameter is programmed to the On or Monitor settings, a number of programming changes occur:

- When set to On, the programmer shows the Automatic Pulse Amplitude and additional V. AutoCapture/Cap Confirm parameters; Pulse Amplitude becomes unavailable.
- The programmer displays the Backup Pulse Configuration (page 76) and Search Interval (page 76) parameters for later programming.
- The device adds a safety margin to the last measured capture threshold.

Safety Margins for each parameter:

- For the RVCap Confirm and LVCap Confirm parameters, the Automatic Pulse Amplitude parameter is set to the last measured ventricular capture threshold plus the setting of the Pacing Margin (page 76) parameter. Thus, the Cap Confirm pulse amplitude = measured threshold + Pacing Margin setting. If the capture threshold has not been measured, the Automatic Pulse Amplitude parameter is set to 5.0 V.
- For the V. AutoCapture parameter, the Automatic Pulse Amplitude parameter is set to the last capture threshold plus 0.25 V.
- For the ACap Confirm parameter, the safety margin setting depends on the size of the measured atrial capture threshold, as described in this table.

Table 18. Amount of Pulse Amplitude increase over the measured atrial capture threshold

Atrial Capture Threshold (V)[84]	Additional Amplitude (V)
≤ 1.5	1.0[85]
1.625 — 2.25	1.5
2.375 — 3.0	2.0
3.125 — 3.875	Fixed at 5.0 V

The Pulse Width (page 75) setting does not change when the Cap Confirm/V. AutoCapture parameter is programmed to On or Monitor.

When the Cap Confirm/V. AutoCapture parameter is programmed to Off or Monitor, the Pulse Amplitude parameter is set to twice the measured capture threshold (maximum 5.0 V, minimum 2.0 V).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button

Note

High Base Rate Settings. The ACap Confirm function does not operate at intrinsic atrial rates or Base Rate settings at or above 120 bpm. If the device detects these high rates, it attempts capture measurement an hour later.

MultiPoint™Pacing. LVCap Confirm can be enabled while MultiPoint Pacing is enabled. However, the LVCap Confirm setting only applies to the LV1 Pulse Amplitude setting.

[84] In steps of 0.125V.
[85] At the 1.125 and 1.375 settings, the additional increase in the pulse amplitude is 1.125.

In order to enable MultiPoint Pacing when the RVCap Confirm or LVCap Confirm parameter is On, both RV Cap Confirm and LVCap Confirm pacing margins must be ≤1.0V.

When both MultiPoint™ Pacing and V. Triggering are enabled, the RVCap™ Confirm and the LVCap™ Confirm setting "On" is not available. To program RVCap Confirm or LVCap Confirm On, disable either MulitPoint Pacing or V. Triggering.

Threshold Search Delays. The device delays a scheduled threshold search if one of the following conditions exist:

- Auto Mode Switch (page 86) entry (ACap Confirm only)
- VT or VF episode[86]
- Automatic P- and R-wave measurement (see Sense Tests (page 34)) (all)
- Lead Monitoring measurement (see Lead Impedance (page 38))
- Threshold search in another chamber.

Pulse Amplitude

The Pulse Amplitude parameter determines how much electrical potential is applied to the myocardium during the pacing stimulus. The Pulse Amplitude setting can be evaluated with the Capture & Sense (page 31) test.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button

NOTE

LV2 Pulse Amplitude. For devices with MultiPoint™ Pacing Capability, the LV2 Pulse Amplitude parameter determines the setting of the LV2 pacing pulse.

Oversensing. Oversensing may occur when high LV1/LV2 Pulse Amplitude settings and long LV1/LV2 Pulse Width settings are programmed along with long MultiPoint Pacing Delay settings and maximum Sensitivity settings.

Pulse Width

The Pulse Width parameter determines how long the Pulse Amplitude (page 75) is applied to the myocardium. The Pulse Width setting can be evaluated with the Capture & Sense (page 31) test.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button

NOTE

LV2 Pulse Width. For devices with MultiPoint™ Pacing Capability, the LV Pulse Width parameter determines the setting of the LV2 pacing pulse.

Oversensing. Oversensing may occur when high LV1/LV2 Pulse Amplitude settings and long LV1/LV2 Pulse Width settings are programmed along with long MultiPoint Pacing Delay settings and maximum Sensitivity settings.

AutoSense

The AutoSense parameter enables an algorithm that adjusts the atrial and ventricular[87] sensitivity for optimal sensitivity. For a full explanation, see AutoSense Function (page 78).

- When the AutoSense parameter is set to On, the atrial sensitivity automatically adjusts as the amplitude of the atrial complex changes.
- When the atrial AutoSense parameter is set to Off, the atrial sensitivity remains fixed at the programmed atrial Sensitivity (page 76) setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button

Note

Sensing. Ventricular sensing only occurs in the right ventricle.

[86] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[87] Available only when the right ventricular Sense Configuration is set to Bipolar.

Sensitivity

The Sensitivity parameter determines the threshold above which the device responds to sensed events. The Auto setting turns autosensing on or off (see AutoSense Function (page 78)).

Although the setting for V. Sensitivity is always set to Auto in CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), you can adjust sensing for the RV chamber by adjusting the parameters in the SenseAbility™ Sensing Algorithm Settings (page 77) window. The device does not sense LV events, except during testing.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button

> **Note**
>
> **Oversensing.** Oversensing may occur when high LV1/LV2 Pulse Amplitude settings and long LV1/LV2 Pulse Width settings are programmed along with long MultiPoint™ Pacing Delay settings and maximum Sensitivity settings.

Cap Confirm/V. AutoCapture™ Settings

From the Cap Confirm/V. AutoCapture™ Settings window, you can change the settings of the following parameters:

- Cap Confirm/V. AutoCapture™ parameter (page 73)
- Backup Pulse Configuration (page 76)
- Search Interval (page 76)
- V. AutoCapture™/Cap Confirm Paced/Sensed AV Delay parameter (page 76)
- Pacing Margin (page 76)

Backup Pulse Configuration

The Backup Pulse Configuration parameter allows you to program the polarity configuration of the backup safety pulse for the Cap Confirm/V. AutoCapture™ parameter (page 73) parameter to either the bipolar or unipolar settings.

Accessed From: Parameters button > Brady tab > Capture & Sense button > Cap Confirm Settings button

Search Interval

The Search Interval parameter selects the timing of automatic threshold searches when the Cap Confirm/V. AutoCapture™ parameter (page 73) is set to Monitor or On.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > Cap Confirm Settings button

V. AutoCapture™/Cap Confirm Paced/Sensed AV Delay parameter

When the RVCap™ Confirm, LVCap™ Confirm, or V. AutoCapture™ parameter is selected, the V. AutoCapture/Cap Confirm Paced/Sensed AV Delay parameter sets the Paced AV Delay and Sensed AV Delay parameters used when the device performs a Threshold Search.

> **Note**
>
> The recommended setting for this parameter is 50/25. Fusion is more likely with longer delays and may cause inaccurate threshold search results.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > Cap Confirm Settings button

Pacing Margin

When either the RVCap™ Confirm or LVCap™ Confirm parameter is enabled, the Pacing Margin parameter is the extra voltage that is to be added to the measured threshold in determining the Automatic Pulse Amplitude. Thus, the Cap Confirm pulse amplitude = measured threshold + Pacing Margin setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > Cap Confirm Settings button

SenseAbility™ Sensing Algorithm Settings

From the SenseAbility™ Sensing Algorithm Settings window, you can change the settings for the following parameters:

- Max Sensitivity (page 77)
- Decay Delay (page 77)
- Threshold Start (page 78)
- Select Nominals (page 78)
- Advanced Settings (page 79) (Low Frequency Attenuation (page 79))

See also:

- AutoSense Function (page 78)

Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button

Note

Low-amplitude Signals. Changing any of these parameters may affect the ability to sense low-amplitude signals.

Nominal Settings. Nominally, these Sensing Parameters are set close to their most sensitive settings. Change them only if there is a specific need to do so.

Max Sensitivity

The Max Sensitivity parameter is the highest sensitivity the device can achieve. You can set the Max Sensitivity parameter independently for:

- **Atrial Max Sensitivity** is the maximum atrial sensitivity to which the atrial threshold can decay.
- In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), **Ventricular Pacemaker Max Sensitivity** is the maximum sensitivity to which the ventricular pacemaker threshold can decay.
- In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), **Ventricular Max Sensitivity** is the maximum sensitivity to which the ventricular pacemaker threshold can decay.
- In CRT-Ds, dual-chamber ICDs, and single-chamber ICDs, **Ventricular Defibrillator Max Sensitivity** is the maximum sensitivity to which the ventricular defibrillator threshold can decay.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button

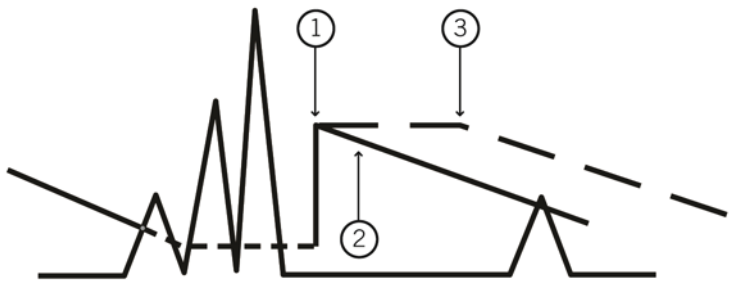
Note

Oversensing. The Ventricular Pacemaker Max Sensitivity setting should only be changed from the nominal setting if oversensing of low-level signals cannot be eliminated by adjusting the Decay Delay (page 77), Threshold Start (page 78), and Atrial Pace Refractory (page 82) parameters.

Decay Delay

The Decay Delay parameter determines the amount of time after the sensed or paced refractory period that the threshold remains at the programmed Threshold Start (page 78) setting before beginning its decay. Increasing the Decay Delay may prevent oversensing of P-waves and T-waves.

Figure 4. An example of Decay Delay



1. Threshold Start
2. Decay Delay of 0 ms
3. Decay Delay of 60 ms

When the ventricular Post-Paced Decay Delay is set to Auto, the device automatically adjusts the Decay Delay used after a ventricular paced pulse to compensate for QT-interval shortening associated with fast pacing rates.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button

Note

Low-amplitude Signals. Changing the Decay Delay setting may affect the ability to sense low-amplitude signals.

AutoSense (page 75). The atrial AutoSense parameter must be enabled for the Decay Delay parameter to be programmable in the atrium.

Threshold Start

The Threshold Start parameter determines the maximum peak amplitude that is sensed during the refractory period for a sensed event. Threshold Start can be used to prevent oversensing of P-waves and T-waves.

- **Post-Sensed Threshold Start.** After a sensed event, the device determines the maximum amplitude signal detected during the Atrial Sense Refractory (page 83) and Ventricular Sense Refractory (page 83) periods. Upon expiration of the sensed refractory period, the sensing threshold automatically adjusts to the higher of either the Threshold Start setting or a percentage of that maximum amplitude with an absolute maximum value of 6 mV in the ventricle or 3 mV in the atrium. This percentage is known as the Post-Sensed Threshold Start.
- **Post-Paced Threshold Start.** After a paced event, when the Atrial Pace Refractory (page 82) or Ventricular Pace Refractory (page 83) period expires, the sensing threshold automatically adjusts to the programmed Post-Paced Threshold Start value.

With Ventricular Post-Paced Threshold Start set to Auto, the device automatically adjusts the Threshold Start used for a ventricular paced pulse to provide increased sensitivity at fast pacing rates.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button

Note

Low-amplitude Signals. Changing the Threshold Start setting may affect the ability to sense low-amplitude signals.

AutoSense (page 75). The A. AutoSense parameter must be enabled for the A. Threshold Start parameter to be programmable.

Select Nominals

The Select A. Nominals and Select V. Nominals buttons restore the atrial and ventricular Max Sensitivity (page 77), Decay Delay (page 77), and Threshold Start (page 78) parameters to their nominal values.

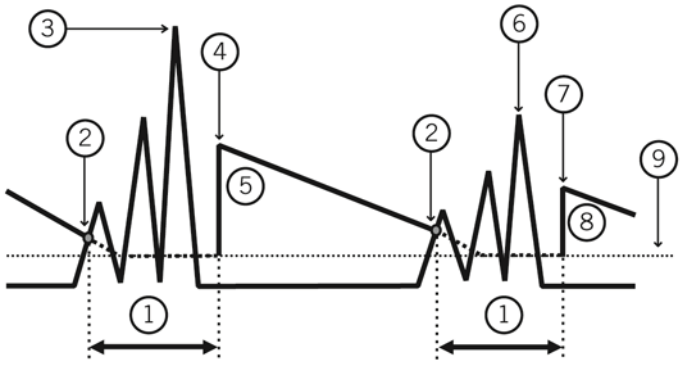
Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button

AutoSense Function

The AutoSense feature automatically adjusts the device's sensitivity to cardiac signal to more accurately sense in both the atrium and the right ventricle over a wide range of signal strengths. Sensing is controlled by a number of parameters working in concert: Max Sensitivity (page 77), Decay Delay (page 77) (Post-Paced and Post-Sensed), Threshold Start (page 78) (Post-Paced and Post-Sensed), and Paced and Sensed Refractory Period (Post-Paced and Post-Sensed). In the example in the figure below, the device senses the maximum signal from an R-wave at 6 mV. The sense channel begins to measure R-waves at the Post-Sensed Decay Delay setting (in this example, 50% of maximum measured signal or approximately 3 mV). It maintains this gain level for the duration of the Decay Delay setting (in this example, 0 ms) and then linearly increases the gain (reduces the mV setting) until the next sensed beat or until it reaches the Max Sensitivity setting (1 mV in this example). When an R-wave is sensed, it begins its Refractory Period and restarts the cycle when the Refractory Period ends.

The AutoSense features works in a similar manner for atrial post-sensed and post-paced signals and for ventricular post-paced signals. The function automatically adjusts various parameter settings in the presence of extremely strong or weak signals so that all signal strengths can be adequately detected and classified.

Figure 5. Automatic sensitivity control in the right ventricle



1. Sense refractory
2. R-wave is sensed
3. Max R-wave amplitude measured at 6 mV
4. Threshold Start set to 3 mV
5. 3 mV
6. Max R-wave amplitude measured at 4 mV
7. Threshold Start set to 3 mV
8. 2 mV
9. Max Sensitivity Threshold

Advanced Settings

From the SenseAbility™ Advanced Settings window, you can change the settings for the following parameters:

- Low Frequency Attenuation (page 79).

Low Frequency Attenuation

The Advanced Settings button enables you to turn the Low Frequency Attenuation filter On or Off. The Low Frequency Attenuation filter increases the R to T wave amplitude ratio, which may enhance sensing performance and may reduce oversensing T waves. Turning the Low Frequency Attenuation filter On or Off changes the device's sensing performance. This may include slight changes in waveform shape, resulting in small differences in R wave measurements or slight changes in VF waveform shape. The Morphology Template is unaffected. For more information on how turning the Low Frequency Attenuation filter On or Off affects the sensing ability of the device, contact Technical Support (page 163).

Accessed From: Parameters button > Brady tab > Capture & Sense button > SenseAbility™ Settings button > Advanced Settings button

Leads

From the Leads window, you can change the settings for the following parameters:

- Lead Type (page 79)
- Lead Chamber (page 79)
- Pulse Configuration (page 80)
- Sense Configuration (page 80)
- Lead Monitoring. Select the Lead Monitoring button to change the settings of the Lead Monitoring Parameters (page 80)
- SecureSense™ RV Lead Noise Discrimination. Select this button to open the SecureSense™ Settings (page 90) window to change the settings of the SecureSense™ RV Lead Noise Discrimination feature.

Accessed From: Parameters button > Brady tab > Leads button

Lead Type

The Lead Type parameter determines the type of implanted lead.

See also:

- Parameter Availability and Settings (page 197)

Note

"Plugged" Port Setting.

- The "Plugged" setting available in devices with Plugged Port Lead Type Capability (page 191) automatically restricts the availability of certain pacing modes and Tests that require an active lead in the plugged receptacle. Thus, setting the Atrial Lead parameter to Plugged will eliminate all atrial-based Tests and modes.
- The Plugged setting is only available for the Atrial and LV Lead Types.

Lead Chamber

The Lead Chamber parameter determines the chamber in which the lead of a single-chamber pacemaker (page 164) is implanted.

See also:

- Parameter Availability and Settings (page 197)

Pulse Configuration

The Pulse Configuration parameter determines the polarity of the pacing pulse.

See also:

- Parameter Availability and Settings (page 197)

NOTE

MultiPoint™ Pacing LV2 Pulse Configuration Parameter (page 65). For devices with MultiPoint Pacing Capability (page 189), the LV Pulse Configuration parameter determines the polarity of the second LV pacing pulse.

Sense Configuration

The Sense Configuration parameter determines how sensing occurs.

See also:

- Parameter Availability and Settings (page 197)

Lead Monitoring Parameters

From the Lead Monitoring window, you can change the settings for the following parameters:

- Lead Monitoring (page 80)
- Lower Limit (page 80)
- Upper Limit (page 80)
- HVLI Monitoring Lower Limit (page 80)
- HVLI Monitoring Upper Limit (page 80)

Accessed From: Parameters button > Brady tab > Leads button > Lead Monitoring button

Lead Monitoring

The Lead Monitoring parameter enables automatic monitoring of lead impedance values and automatic switching[88] of the Pulse Configuration (page 80) and Sense Configuration (page 80) settings if a lead measurement is above the range set by the Lower Limit (page 80) and Upper Limit (page 80) parameters. The programmer displays an alert if the Lead Monitoring parameter has automatically changed the lead configuration and one of the Lead Impedance Alert Triggers (page 133) has been delivered.

See also:

- Parameter Availability and Settings (page 197)

Lower Limit

The Lower Limit parameter determines the lower limit to the range of acceptable pacing lead impedance measurements.

See also:

- Parameter Availability and Settings (page 197)

Upper Limit

The Upper Limit parameter determines the upper limit to the range of acceptable pacing lead impedance measurements.

See also:

- Parameter Availability and Settings (page 197)

HVLI Monitoring Lower Limit

The HVLI Monitoring Lower Limit parameter determines the lower limit to the range of acceptable high-voltage lead impedance measurements.

See also:

- Parameter Availability and Settings (page 197)

HVLI Monitoring Upper Limit

The HVLI Monitoring Upper Limit parameter determines the upper limit to the range of acceptable high-voltage lead impedance measurements.

See also:

- Parameter Availability and Settings (page 197)

Refractories & Blanking

From the Refractories & Blanking window, you can change the settings for the following parameters:

- PVARP (page 81)

[88] Not available in high-voltage devices and CRT-Ps with VectSelect Quartet™ LV Pulse Configuration capability.

- Post-Ventricular Atrial Blanking (page 81)
- Rate Responsive PVARP/V Ref (page 81)
- Shortest PVARP/V Ref (page 82)
- Atrial Pace Refractory (page 82)
- Atrial Sense Refractory (page 83)
- Ventricular Pace Refractory (page 83)
- Ventricular Sense Refractory (page 83)
- SenseAbility™ Sensing Algorithm Settings (page 77)
- Additional Settings, PVC & PMT (page 83)

For single-chamber devices, see Rates & Refractories (page 88).

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

PVARP

The Post Ventricular Atrial Refractory Period (PVARP) parameter sets the amount of time that the device is unresponsive to signals from the atrial sensing circuit to avoid inappropriate response to stimuli. The PVARP parameter is intended to prevent non-physiologic or retrograde P-waves from inhibiting the atrial stimulus.

The PVARP period begins after an intrinsic R-wave, PVC, or a ventricular paced pulse in DDI(R) or DDD(R) modes.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

Post-Ventricular Atrial Blanking

The Post-Ventricular Atrial Blanking parameter establishes an atrial refractory period after ventricular paced and sensed events to prevent the atrial channel from detecting far-field R-waves.

Atrial events falling within the Post-Ventricular Atrial Blanking period do not update the filtered atrial rate interval (FARI), nor are they used by the Rate Branch (page 94) algorithm[89] for dual-chamber SVT Discrimination Mode[90] (see SVT Discrimination in Sinus Tach (page 94)). Events falling in this period are not counted in the AT/AF (page 28) diagnostics.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

Note

SVT Discriminators (page 93) and Auto Mode Switch (page 86). Use the Post-Ventricular Atrial Blanking parameter with caution as it may have adverse effects on atrial sensing, and indirectly, SVT discriminators and the Auto Mode Switch function.

SVT Discrimination Mode (page 92), Mode (page 61), Post-Shock Mode (page 121). The Post-Ventricular Atrial Blanking parameter is only available when the SVT Discrimination mode is set to the Dual Chamber setting or when the Mode or Post-Shock Mode parameter is set to the DDIR or DDD(R) setting.

MultiPoint™ Pacing PVAB (page 66). For devices with MultiPoint Pacing Capabilities, the Post-Ventricular Atrial Blanking and MultiPoint Pacing PVAB parameters are independently programmable.

MultiPoint Pacing PVAB (page 66) is only available at pacing rates of 110 **bpm** or less.

Rate Responsive PVARP/V Ref

The Rate Response PVARP/V Ref parameter automatically changes the Ventricular Pace Refractory (page 83) and PVARP (page 81) settings in response to increases or decreases in the AF Suppression™ Algorithm (page 87) rate, Sensor (page 63)-indicated rate, or the filtered atrial rate in DDD(R) mode.

For devices with Enhanced Rate Responsive Pacing capability (page 187), a Low setting changes the Post-Paced Refractory Period and PVARP settings:

- If the Sensor is On, to preserve a 10% atrial alert period at the Maximum Sensor Rate
- If the Sensor is Off, to preserve a 10% atrial alert period at the Maximum Tracking Rate
- In single-chamber modes, a one ms change is made for each one-**bpm** change in the pacing rate

A Medium setting changes the Post-Paced Refractory Period and PVARP settings to preserve a 20% atrial alert period at the maximum rate. A High setting changes the Post-Paced Refractory Period and PVARP settings to preserve a 30% atrial alert period at the maximum rate.

[89] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[90] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

For all other devices, a Low setting changes the ventricular Post-Paced Refractory Period and PVARP settings by one ms for each one-**bpm** change in the pacing rate. A High setting changes the ventricular Post-Paced Refractory Period and PVARP settings by three ms for each one-**bpm** change in the pacing rate.

Thus as pacing rates rise, the device decreases both the ventricular Post-Paced Refractory Period and PVARP settings until the Max Sensor Rate (page 64), Max Track Rate (page 67), or Shortest PVARP/V Ref (page 82) setting is reached.

For devices with Enhanced Rate Responsive Pacing capability (page 187), the algorithm begins to operate when the intrinsic rate or pacing rate exceeds 60 **bpm or** Base Rate (page 66), whichever rate is higher. When the rate falls below 60 **bpm or Base Rate**, the algorithm is suspended.

For all other devices, the algorithm begins to operate when the intrinsic rate or pacing rate exceeds 90 **bpm**. When the rate falls below 90 **bpm**, the algorithm is suspended. The pacing rate is determined by whichever rate is highest: Base Rate, Sensor-indicated rate, AMS Base Rate (page 87), or AF Suppression™ Algorithm-driven rate.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Refractories & Blanking button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Rate Responsive Atrial Refractory Period and Mode (page 61). When the Mode parameter is set to AAI(R) or AAT(R), the Rate Responsive PVARP/V Ref parameter is renamed Rate Responsive Atrial Refractory Period.

Rate Responsive Ventricular Refractory Period and Mode. When the Mode parameter is set to VVI(R), the Rate Responsive PVARP/V Ref parameter is renamed Rate Responsive Ventricular Refractory Period.

Ventricular Noise Reversion. The Rate Responsive PVARP/V Ref parameter is disabled during Ventricular Noise Reversion. See V. Noise Reversion Mode (page 63).

Ventricular Episode. The Rate Responsive PVARP/V Ref parameter is disabled during a ventricular episode.

Mode. The Rate Responsive PVARP/V Ref parameter is available in DDD(R), VDD(R), DDI(R), VVI(R), and AAI(R) modes.

Shortest PVARP/V Ref

The Shortest PVARP/V Ref parameter sets the shortest allowable interval for the Rate Responsive PVARP/V Ref (page 81) parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Refractories & Blanking button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Shortest Atrial Refractory Period and **Mode** (page 61). When the Mode parameter is set to AAI(R) or AAT(R), the Shortest PVARP/V Ref parameter is renamed Shortest Atrial Refractory Period.

Shortest Ventricular Refractory Period and **Mode** (page 61). When the Mode parameter is set to VVI(R), the Shortest PVARP/V Ref parameter is renamed Shortest Ventricular Refractory Period.

Ventricular Pace Refractory (page 83). The Shortest PVARP/V Ref setting must be shorter than or equal to the Ventricular Pace Refractory period setting.

Atrial Pace Refractory

The Atrial Pace Refractory period parameter is the amount of time that the device is unresponsive to atrial signals from the sensing circuits following an atrial paced event. It allows the device to avoid inappropriate responses to stimuli. Events occurring in the Atrial Pace Refractory period are not counted in the Filtered Atrial Rate (FARI) or in the Rate Branch average.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

Note

Sensing Anomalies. Increasing the Atrial or Ventricular Pace Refractory period decreases the sensing time available between paced events.

Mode. Atrial Pace Refractory is programmable only when the Mode is set to AAT or AAI.

Atrial Sense Refractory

The Atrial Sense Refractory period parameter is the amount of time that the device is unresponsive to atrial signals from the sensing circuits following an atrial sensed event to avoid inappropriate responses to stimuli. Events occurring in the Atrial Sense Refractory period are not counted in the Filtered Atrial Rate (FARI) or in the Rate Branch average.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button

Ventricular Pace Refractory

The Ventricular Pace Refractory parameter is a refractory period that occurs after a paced event. The refractory period is initiated by a ventricular paced event and either ends when the period times out or is reset when another ventricular paced event occurs.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Refractories & Blanking button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Note

Sensing Anomalies. Increasing the Atrial or Ventricular Pace Refractory period decreases the sensing time available between paced events.

Ventricular Sense Refractory

The Ventricular Sense Refractory parameter is a refractory period that occurs after a sensed event. The refractory period is initiated by a ventricular sensed event and either ends when the period times out or is reset when another ventricular sensed event occurs.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: (CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Refractories & Blanking button

Accessed From: (Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)) Parameters button > Brady tab > Rates & Refractories button

Additional Settings, PVC & PMT

From the Additional Settings, PVC & PMT window, you can change the settings for the following parameters:

- Ventricular Blanking (page 83)
- Ventricular Safety Standby (page 84)
- Arrhythmia Unhiding (page 84)
- PVC Response (page 85)
- PMT Response (page 85)
- PMT Detection Rate (page 85)

For single-chamber devices, see Rates & Refractories (page 88).

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Ventricular Blanking

The Ventricular Blanking parameter determines an absolute refractory period in the ventricular channel immediately following an atrial output pulse in dual-chamber modes. This absolute refractory period minimizes the chances of the ventricular channel sensing the atrial output and inappropriately inhibiting the ventricular output.

In DDD(R) and DDI(R) pacing, an atrial output pulse initiates ventricular blanking, but a P-wave that inhibits the atrial pulse does not.

The "Auto" setting, available in dual chamber pacemakers and CRT-Ps, employs sensing of ventricular signals following the atrial pacing pulse and automatically increases the initial blanking period if ventricular signals are sensed. Continued sensing of ventricular signals increases the blanking periods until a maximum of 52 ms is reached or until the device senses no ventricular signals.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Ventricular Safety Standby

The Ventricular Safety Standby algorithm prevents the device from inappropriately sensing crosstalk that would inhibit the ventricular pulse output. If crosstalk is sensed, a ventricular pulse is delivered 120 ms after the atrial pulse. Signals sensed outside of the detection window inhibit the ventricular pulse.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Note

Interactions. If the Sensed AV Delay (page 70) parameter or the Rate Responsive AV Delay (page 70) parameter is programmed shorter than 120 ms, the ventricular pulse is delivered at that interval.

Crosstalk occurs when atrial output signals are sensed by the ventricular channel and results in the inhibition of the ventricular pulse. Clinically, crosstalk can usually be identified by atrial pacing with no ventricular channel output. Crosstalk typically occurs with:

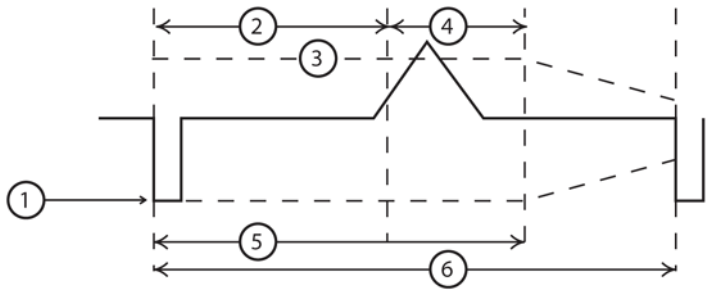
- high Atrial Pulse Amplitude or Pulse Width settings
- low Ventricular Sensitivity settings (greater sensitivity)
- rapid pacing rates

To minimize crosstalk, decrease the atrial Pulse Amplitude (page 75) or Pulse Width (page 75) setting and/or increase the Ventricular Pacemaker Max Sensitivity (page 77) setting (that is, decrease the device's sensitivity). Even if crosstalk is not sensed, the Ventricular Safety Standby parameter can prevent the inappropriate inhibition of ventricular output.

Arrhythmia Unhiding

The Arrhythmia Unhiding parameter[91] enables an adaptive relative refractory period to search for arrhythmias hidden by pacing. This may happen when fast atrial rates are tracked or when sensor-driven pacing rates shorten alert periods. As shown in the figure below, Arrhythmia Unhiding increases the alert period (through an adaptive relative refractory period or ARRP) to unmask arrhythmias hidden by pacing. An ARRP is enabled when the ventricular pacing cycle length is less than two times the longest tachycardia Detection Interval/Rate (page 90) or two times the pacing refractory period, whichever is shorter.

Figure 6. Arrhythmia Unhiding



1. Pace pulse
2. Pacing interval/2 - 30 ms
3. Defib sensitivity
4. ARRP
5. Pace refractory period
6. Current pacing interval

If a sensed event occurs during the ARRP and the next event is paced, then the ARRP is enabled again. If no sensed event occurs during the ARRP or the next event is not paced, then the pace refractory period returns to normal. Once the number of intervals specified by Arrhythmia Unhiding have occurred consecutively with a sensed event during the ARRP, the pacing cycle length is extended for six cycles in an attempt to reveal the arrhythmia.

If no arrhythmia is revealed during the extended pacing interval, the ARRP is not re-enabled for 10 cycles in order to prevent unnecessary extension of the pacing interval.

[91] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Note

Zone Configuration (page 89) and **Mode** (page 61). Arrhythmia Unhiding is only available when the Zone Configuration is not Off (page 123) and the Mode is VVIR, DDIR, or DDD(R).

PVC Response

The PVC Response parameter detects and responds to premature ventricular contractions (PVCs) when the device is in DDD(R) mode. The PVC Response algorithm detects a PVC if: (1) an R-wave is not preceded by an atrial event; or (2) a P-wave is detected in the relative refractory portion of the PVARP (page 81) period but is not followed by an R-wave within 280 ms of the atrial event.

The Atrial Pace setting is a response to a PVC confirmation. The response consists of a continuous extension of the PVARP setting to 475 ms, followed by an atrial alert period of 330 ms until a P-wave is tracked outside the extended PVARP period.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Note

Diagnostics. The Rates (page 25) window reports the total number of PVCs detected by the device.

Atrial Diagnostics. An Atrial Pace response can result in the appearance of fast atrial rates in atrial diagnostics such as the Atrial Heart Rate Histogram (page 25).

PMT Response

The PMT Response parameter has three settings:

- **Off.** No PMTs are detected.
- **Passive.** PMTs are detected as described below and counted in the diagnostics, but the device does not respond to stop the PMT.
- **Atrial Pace.** PMTs are detected as described below and the Atrial Pace response is started to end to the PMT.

When you set the PMT Response parameter to either Passive or Atrial Pace, you can select the PMT Response button in the Refractories & Blanking (page 80) window to open the PMT window to set the PMT Detection Rate (page 85) parameter.

Detection. If the device detects eight consecutive P–P intervals above the PMT Detection Rate, the device calculates the stability of the eight VP-AS intervals. If the device determines that the VP-AS intervals are stable, then for the ninth interval, the device:

- Shortens the Sensed AV Delay (page 70) interval by 50 ms (if the AS-VP interval is ≥100 ms)
- Increases the Sensed AV Delay interval by 50 ms (if the AS-VP interval is < 100 ms)

If the tenth VP-AS interval is nearly equal to the ninth VP-AS interval, the device concludes that PMT is present and begins its response. If the ninth and tenth intervals differ by more than 16 ms, then the device concludes that PMT is not present and the detection algorithm is repeated after 256 cycles.

Note

If the intrinsic rate is equal to the Max Track Rate during detection, then the Sensed AV Delay is increased by 50 ms, rather than decreased.

Response. The device suspends the ventricular output and delivers an atrial pulse 330 ms after the detected retrograde P-wave, followed by normal operation.[92]

Note

Auto Mode Switch (page 86). The PMT algorithm is suspended during an Auto Mode Switch.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

PMT Detection Rate

The PMT Detection Rate parameter determines at what rate the device becomes alert to the presence of pacemaker-mediated tachycardia (PMT) when the PMT Response (page 85) parameter is enabled. The settings begin at 90 bpm (or higher if the Base Rate (page 66) parameter is programmed above 90 bpm) and do not exceed the Max Track Rate (page 67) parameter.

See also:

- Parameter Availability and Settings (page 197)

[92] The atrial pulse may be inhibited if a P-wave is detected during an alert period.

Accessed From: Parameters button > Brady tab > Refractories & Blanking button > Additional Settings button

Note

Base Rate. The PMT Detection Rate setting cannot be slower than the Base Rate setting, and is auto-selected to a setting 10 bpm faster than the Base Rate setting if you attempt to set the PMT Detection Rate parameter equal to or slower than the Base Rate setting.

Max Track Rate (MTR). The PMT Detection Rate setting cannot be faster than the MTR parameter, and is auto-selected to equal to the MTR setting if you attempt to set the MTR setting faster than the PMT Detection Rate setting.

AT/AF Detection & Response

From the AT/AF Detection & Response window, you can change the settings for the following parameters:

- Auto Mode Switch (page 86)
- AMS V. Triggering (page 86)
- Atrial Tachycardia Detection Rate (page 87)
- AMS Base Rate (page 87)
- AMS Max Trigger Rate (page 87)
- AF Suppression™ Algorithm Pacing (page 87)
- Overdrive Pacing Cycles (page 88)
- Maximum AF Suppression™ Rate (page 88)

See also:

- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

Note

Mode (page 61). The AT/AF Detection & Response button is not available when the pacing mode is set to AOO(R), VOO(R), or DOO(R).

Auto Mode Switch

The Auto Mode Switch (AMS) parameter prevents atrial-based timing modes from tracking atrial tachycardias and causing pacemaker-mediated tachycardia (PMT). The Auto Mode Switch algorithm switches the mode from DDD(R) to a ventricular-timing mode (DDI, DDIR, DDT, DDTR, VVT, VVTR, VVI, or VVIR)[93] when the atrial rate surpasses the Atrial Tachycardia Detection Rate (page 87) (ATDR) setting. At mode-switch, the device paces in the ventricle at the AMS Base Rate (page 87) setting.

Rather than use the actual atrial rate, which cannot always distinguish between sustained tachycardia and intermittent fast cycles, AMS uses the Filtered Atrial Rate Interval (FARI), which is based on a comparison of the current atrial rate to a continually updated average rate.

When the tachyarrhythmia subsides and the FARI falls below the AF Suppression™ Algorithm (page 87) pacing-driven rate setting, Max Track Rate (page 67) setting, or the Sensor (page 63)-indicated rate (whichever is faster), the device switches back to the DDD(R) or VDD(R) mode.

Diagnostic data on mode switching can be found in the Mode Switch and AT/AF (page 26) diagnostic.

In devices with Ventricular Triggering Capability (page 194), the DDT(R) and VVT(R) settings enable V. Triggering (page 62) while the device is mode-switched. Auto Mode Switch is not available when the Mode parameter is set to DDT or VVT. These settings also enable the AMS V. Triggering (page 86) parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

AMS V. Triggering

The AMS V. Triggering parameter enables the device to operate the V. Triggering (page 62) function (DDT (page 155) or VVT (page 159) modes) while the device is mode-switched. You can autoprogram this parameter to On by selecting the either the DDT(R) or VVT(R) settings for Auto Mode Switch.

The AMS V. Triggering parameter is automatically disabled when the pacing rate reaches the AMS Max Trigger Rate (page 87) to prevent triggering if the ventricular rate gets too fast during an AMS episode.

See also:

- Parameter Availability and Settings (page 197)

[93] DDT(R) and VVT(R) modes are only available in devices with Ventricular Triggering Capability.

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

Atrial Tachycardia Detection Rate

The Atrial Tachycardia Detection Rate (ATDR) parameter sets the atrial rate at which the device mode-switches when the Auto Mode Switch (page 86) parameter is enabled. A mode-switch occurs when the Filtered Atrial Rate Interval (FARI) exceeds the programmed ATDR setting. The device switches back to DDD(R) pacing when the FARI falls below the AF Suppression™ Algorithm (page 87) pacing-driven rate, Max Track Rate (page 67) setting, or the Sensor (page 63)-indicated rate. The ATDR parameter is always available because it is also used to classify events in atrial tachycardia and trigger EGM storage. Atrial events at rates greater than the ATDR setting are recorded in the AT/AF (page 28) and Rates (page 25) diagnostics.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

> **Note**
>
> **PVARP** (page 81). During a mode switch, the PVARP parameter is set to 82 ms[94]. When the atrial rate falls below the AF Suppression pacing-driven rate, Max Track Rate setting, or the Sensor-indicated rate, the device reverts to the programmed PVARP setting.

AMS Base Rate

The AMS Base Rate parameter sets the ventricular pacing rate when the device has switched from DDD(R) mode to the programmed Auto Mode Switch (page 86) pacing mode. When the device returns to DDD(R) mode, the device resumes pacing at the programmed Base Rate (page 66) setting. The AMS Base Rate parameter is only available when the Auto Mode Switch parameter is enabled.

Unless the Mode Switch Base Rate parameter is set to a specific setting, it is auto-selected to equal the permanently programmed Base Rate setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

AMS Max Trigger Rate

The AMS Max Trigger Rate parameter is the rate at which the AMS V. Triggering (page 86) function is disabled. When the ventricular pacing reaches this rate, the Mode switches to DDI(R) or VVI(R). The parameter becomes available when the AMS V. Triggering parameter is set to On.

The device maintains the AMS Max Trigger Rate setting at least 5 bpm above the Base Rate and AMS Base Rate settings and at least 30 ms above the Atrial Tachycardia Detection Rate (page 87).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

AF Suppression™ Algorithm

The AF Suppression™ algorithm enables the device to pace the atrium at rates faster than the intrinsic atrial rate in order to overdrive and suppress paroxysmal or persistent atrial fibrillation (AF). The AF Suppression algorithm is available in AAI(R) and DDD(R) modes.

When the algorithm detects two P-waves in a 16-cycle window, the device increases the pacing rate to overdrive the intrinsic conduction. After pacing at the AF Suppression Algorithm (page 87) pacing-driven rate for the number of cycles set by the Overdrive Pacing Cycles (page 88) parameter, the device steps down its rate until it senses an additional two P-waves. If two P-waves are sensed, it resumes overdrive pacing. If two P-waves are not sensed, it resumes operation at the Base Rate (page 66) setting, the Rest Rate (page 67) setting, or the Sensor (page 63)-indicated rate.

Diagnostic data on the AF Suppression algorithm can be found in the Rates (page 25) diagnostic.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

> **Note**
>
> **Auto Mode Switch** (page 86). If a mode-switch occurs, the AF Suppression algorithm is disabled, and the rate is set to the Base Rate, AMS Base Rate (page 87), or Sensor-indicated rate.

[94] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Hysteresis Rate (page 68). When the AF Suppression algorithm is enabled, the Hysteresis Rate parameter is auto-selected to Off and the pacing rate immediately increases to the Sensor-indicated rate when the Sensor-indicated rate is greater than the current AF Suppression pacing-driven rate.

Maximum AF Suppression Rate (page 88). The maximum AF Suppression pacing-driven rate cannot exceed the Max AF Suppression Rate setting.

Rate-Responsive Stimulation. The paced rate increases to the Sensor-indicated rate when it is greater than the current AF Suppression pacing-driven rate.

Rate Responsive AV Delay (page 70) and **Rate Responsive PVARP/V Ref** (page 81). When the AF Suppression algorithm is enabled, the Rate Responsive AV Delay and Rate Responsive PVARP/V Ref parameters are auto-selected to Medium, if the parameters are set to Off or Low.

Ventricular Episode. The AF Suppression algorithm is disabled during a ventricular episode.

Overdrive Pacing Cycles

The Overdrive Pacing Cycles parameter is the number of cycles the device overdrives the pacing rate before the AF Suppression™ algorithm begins to decrease the rate to the Base Rate (page 66) setting, the Rest Rate (page 67) setting, or the Sensor (page 63)-indicated rate.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

Maximum AF Suppression™ Rate

The Maximum AF Suppression™ Rate parameter determines the fastest rate that the device can pace the atrium in response to the AF Suppression algorithm.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Brady tab > AT/AF Detection & Response button

Note

Base Rate (page 66). The Base Rate setting cannot exceed the Maximum AF Suppression Rate setting.

Rates & Refractories

From the Rates & Refractories window, you can change the settings for the following parameters:

- Base Rate (page 66)
- Rest Rate (page 67)
- Max Sensor Rate (page 64)
- Arrhythmia Unhiding (page 84)
- Ventricular Pace Refractory (page 83)
- Ventricular Sense Refractory (page 83)
- Rate Responsive PVARP/V Ref (page 81)
- Shortest PVARP/V Ref (page 82)
- SenseAbility™ Sensing Algorithm Settings (page 77)
- Hysteresis Rate (page 68)
- Search Interval (page 68)
- Cycle Count (page 69)

Accessed From: Parameters button > Brady tab > Rates & Refractories button

Tachy Parameters

The Tachy Parameters window contains a summary of information on the device's current ShockGuard™ Technology settings. Select any of these buttons to open windows to change these settings:

- ShockGuard Technology Settings (Zone Configuration Window) (page 89)
- DeFT Response™ Technology Settings (Shock Waveform) (page 114)
- Redetection & Post Detection Criteria (page 119)
- Post-Shock Pacing (page 121)
- Capacitor Maintenance (page 122)
- Tachy Therapy Detailed Descriptions (page 123)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab

ShockGuard™ Technology Settings (Zone Configuration Window)

The ShockGuard™ Settings window (Zone Configuration) shows the device's current ShockGuard Technology settings for the number of tachy zones selected for therapy, the tachycardia detection criteria, the SVT discrimination option and details, and the therapy to be delivered to each zone. Select the parameter buttons to change the settings. For more information, select one of the following links:

- Zone Configuration (page 89)
- Detection Criteria (page 89)
- SVT Discrimination (page 91)
- SVT Discrimination Details (page 92)
- Zone Therapy (page 105)
- DeFT Response™ Settings. Select this button to open the DeFT Response Technology Settings (Shock Waveform) (page 114) window
- Morphology Scoring. Select this button to open the Morphology Scoring Window (page 104)
- SecureSense™ RV Lead Noise Discrimination. Select this button to change the settings of the SecureSense™ Settings feature[95]

See also:

- Zone Descriptions (page 123)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

Zone Configuration

The Zone Configuration parameter determines the number of rate zones the device recognizes for detection, diagnosis, and therapy delivery.

See also:

- Tachy Therapy Enable/Disable (page 168)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

Detection Criteria

You can program the following Detection Criteria parameters independently for each rate zone:

- Detection Interval/Rate (page 90)
- No. Intervals (page 90)

See also:

- Tachyarrhythmia Detection Description (page 123)
- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

[95] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

Detection Interval/Rate

The Detection Interval/Rate parameter is the interval/rate that must be exceeded within each rate zone to be counted toward detection of a tachyarrhythmia. The Detection Interval/Rate is independently programmable in each rate zone.

See also:

- Tachyarrhythmia Detection Description (page 123)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

Note

Zone Configuration (page 89). The Detection Interval/Rate setting in each rate zone reverts to the nominal setting when the Zone Configuration setting changes.

Detection Interval. Each detection interval must be at least 30 ms longer than the next fastest detection interval.

No. Intervals

The No. Intervals parameter sets the number of binned intervals within each rate zone that must be shorter than the Detection Interval/Rate (page 90) for detection of a tachyarrhythmia. The number of binned intervals required for detection is independently programmable in each rate zone.

See also:

- Tachyarrhythmia Detection Description (page 123)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

Note

Time for Detection. Programming a lower No. Intervals setting may shorten the time for the detection of a tachyarrhythmia. Programming a greater No. Intervals setting may increase the time for the detection of a tachyarrhythmia. See Tachyarrhythmia Detection Description (page 123).

SecureSense™ Settings

The SecureSense Settings window allows you to program the SecureSense™ algorithm to help prevent inappropriate therapy delivered due to the presence of noise generated by a V or RV lead failure.

You can program the following parameters from this window:

- SecureSense™ (page 90)
- Far Field MD™/SecureSense™ Configuration (page 91)
- SecureSense™ Timeout Until Therapy (page 91)
- Trigger Alert for Non-sustained RV Oversensing (NSO) (page 91)

Available In: Devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

Accessed From: Parameters button > Alert Notification tab > SecureSense button

Accessed From: Parameters button > Brady tab > Leads button > SecureSense button

SecureSense™

When programmed to On, the SecureSense™ parameter enables an algorithm to (1) detect RV or V lead noise, (2) inhibit therapy when lead noise is detected, and (3) detect non-sustained lead noise that has an insufficient number of intervals to meet VT/VF detection thresholds but can still be identified as lead noise. The SecureSense algorithm utilizes a far field sensing or “Discrimination” channel to detect lead noise, and its configuration is set by the Far Field MD™/SecureSense™ Configuration parameter.

The algorithm operates by comparing the rate of sensed events on the primary sensing channel (V Sense Amp) to the rate of sensed events on the Discrimination channel. If the device detects a fast rate on the primary channel and sinus rates on the Discrimination channel, the device classifies the signals as noise and inhibits VT/VF therapy.

When programmed to Passive, the algorithm detects noise and provide diagnostics and EGMs, but does not inhibit VT/VF therapy. The algorithm also detects short episodes of noise that are not long enough to cause VT/VF detection.

From the Alert Triggers window, you can program the device to trigger an alert and vibratory patient notifier when lead noise or non-sustained lead noise is detected. You can also program the device (from the Episode Triggers window) to record an episode (store a EGM)

when non-sustained lead noise is detected. Finally, from both the Alert Triggers and Episode Triggers windows, you can program the device to trigger an alert and record an episode if the SecureSense algorithm classifies a rhythm as a non-sustained RV lead noise event.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

Far Field MD™/SecureSense™ Configuration

The Far Field MD™/SecureSense™ Configuration parameter sets the electrode configuration of the far-field (Discrimination) channel used in both the SecureSense™ algorithm and the Far Field MD™ Morphology Discrimination algorithm (see Morphology Type). The signal from this far field vector channel is compared to the near field vector on the primary sensing channel in order to diagnose RV Lead Noise. This parameter also controls what configuration is displayed when the Discrimination channel is shown in EGMs or Stored EGMs.

Ideally, the Discrimination channel should have an R-wave amplitude greater than 1 mV with no noticeable myopotentials. The nominal setting (RVcoil-Can) is the appropriate choice for most patients. If you have a concern about the integrity of the RV coil or if you are using integrated bipolar leads, the RVtip - Can setting may be preferable.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

SecureSense™ Timeout Until Therapy

The SecureSense™ Timeout Until Therapy sets a limit on the amount of time the device can inhibit the delivery of therapy while detecting RV or V lead noise through the SecureSense algorithm.

When the diagnosis of lead noise is first made, the Timeout algorithm begins counting. If the algorithm reaches the programmed setting but the device continues to detect noise, then the device delivers ATP therapy or charging for therapy begins on the next R-wave diagnosed as VT/VF. If no lead noise is detected at the end of the Timeout period, then the device withholds therapy.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

Trigger Alert for Non-sustained RV/V Oversensing (NSO)

The Trigger Alert for Non-sustained RV/V Oversensing (NSO) parameter defines the number of non-sustained oversensing episodes that the device needs to detect before triggering an NSO clinical alert or patient notification.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

SVT Discrimination

The SVT Discrimination parameters define the upper limit at which the device will not classify a tachyarrhythmia or deliver therapy unless the SVT Discriminators (page 93) classify the rhythm as VT according to the Diagnosis (page 94). The SVT Discrimination setting is a rate overlap zone that spans the VT (or VT-1) zone or both the VT-1 and VT-2 zones.

To enable or disable the VT, VT-1, or VT-2 SVT Discrimination, select the On/Off button for SVT discrimination on the ShockGuard™ Technology Settings (Zone Configuration Window) (page 89). In the 3 Zones (page 123) configuration, when SVT discrimination is disabled in the VT-1 zone, it is also disabled in the VT-2 zone.

You can also program a specific rate limit for the SVT Discrimination Zone with the SVT Upper Limit (page 93) parameter. When the SVT Upper Limit parameter is used to define the SVT Discrimination Zone, the programmed setting is displayed within the SVT Discrimination Zone button in the corresponding rate zone.

See also:

- SVT Discrimination Details (page 92)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

> **Note**
>
> **Diagnosis**. The SVT discriminators only affect the initial diagnosis of an episode. They do not influence redetection after a failed first therapy.
>
> **Rate Crossover** is a condition where the maximum rate of a supraventricular rhythm can exceed the slowest ventricular tachyarrhythmia detection rate. In patients not expected to have rate crossover, disable the SVT Discriminators (page 93) so that they do not affect diagnosis and delivery of therapy.

SVT Discrimination Details

The SVT Discrimination Details window is available when the Zone Configuration (page 89) parameter is set to 2 Zone or 3 Zone. (When the Zone Configuration parameter is set to Off or 1 Zone, then the Morphology Scoring (page 105) parameter is available as a means to help diagnose SVT when manually reviewing EGMs). From this window, you can program the following:

- SVT Discrimination Mode (page 92)
- SVT Discrimination Timeout (page 92)
- Therapy After Timeout (page 93)
- SVT Upper Limit (page 93)
- SVT Discriminators (page 93), which include:
  - Rate Branch (page 94) (CRT-Ds and Dual-Chamber ICDs only)
  - Morphology (page 95)
  - Interval Stability (page 101)
  - Arrhythmia Onset/Sudden Onset Window (page 102)
  - Diagnosis (page 94)

See also:

- Rate Zone Legend (page 124)
- SVT Discrimination Timeout Description (page 131)
- SVT Discrimination Description (page 124)
- SVT Discrimination Criteria Programming Guidelines (page 126)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

SVT Discrimination Mode

The SVT Discrimination mode defines the sensing method used to discriminate between ventricular tachycardias (VT) and supraventricular tachycardias (SVT) within the SVT Discrimination (page 91).

Only rhythms with running interval averages that fall within the SVT Discrimination Zone are evaluated by the SVT Discriminators (page 93).

Use the Ventricular Only setting (CRT-Ds and Dual-Chamber ICDs) when an atrial lead is not present or when atrial sensing is unavailable.

See also:

Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

Note

Diagnosis. The dual chamber SVT Discrimination mode uses both atrial and right-ventricular information from the SVT discriminators in making a diagnosis, whereas the Ventricular Only SVT Discrimination mode only uses right-ventricular information.

Rhythm Classification. When the SVT Discrimination mode is set to Dual Chamber and SVT discriminators are enabled, the device is more likely to classify a rhythm as VT. When the SVT Discrimination mode is set to Ventricular Only and SVT discriminators are enabled, the device is less likely to classify a rhythm as VT.

Rate Branch (page 94). When the SVT Discrimination mode is set to Ventricular Only, the Rate Branch discriminator is disabled. The diagnostic data are still reported and can be accessed from various diagnostic screens. See Diagnostics (page 25).

SVT Discrimination Timeout

The SVT Discrimination Timeout parameter is the amount of time to diagnose a rhythm as SVT before therapy is delivered.

SVT Discrimination Timeout is available only if at least one of these SVT Discriminators (page 93) (SVT Upper Limit (page 93), Morphology (page 95), Sudden Onset (page 103), or Interval Stability (page 101)) is enabled or the SVT Discrimination Mode (page 92) is set to Dual Chamber.

As protection against delivering SVT Discrimination Timeout-directed therapy into a **bigeminal rhythm**, the device must detect more tachyarrhythmia intervals than sinus intervals before it delivers therapy.

See also:

- Therapy After Timeout (page 93)
- SVT Discrimination Timeout Description (page 131)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

Therapy After Timeout

The Therapy After Timeout parameter determines the first therapy delivered after the SVT Discrimination Timeout (page 92) timer expires. The Therapy After Timeout parameter is available only if the SVT Discrimination Timeout parameter is available and enabled.

See also:

- SVT Discrimination Timeout Description (page 131)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

SVT Upper Limit

The SVT Upper Limit parameter determines the specific detection interval/rate to which the SVT Discrimination (page 91) extends. The SVT Discrimination Zone extends from the VT or VT-1 detection rate up to (but not including) the SVT Upper Limit. When SVT Discriminators (page 93) are programmed On, the device will not classify a rhythm as VT, VT-1, or VT-2 nor will the device deliver therapy for a rhythm falling into this SVT Discrimination Zone unless those discriminators classify the rhythm as VT according to the programmed Diagnosis (page 94).

If the SVT Upper Limit is programmed Off, arrhythmia diagnosis is not affected by the SVT discriminators.

You can also enable or disable the VT, VT-1, or VT-2 SVT Discrimination Zone with the On/Off buttons for SVT discrimination on the ShockGuard™ Technology Settings (Zone Configuration Window) (page 89).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

> **Note**
>
> **Zone Configuration** (page 89). The SVT Upper Limit is available only in the 2 Zones (page 123) and 3 Zones (page 123) configurations.
>
> **Rate Crossover** is a condition where the maximum rate of a supraventricular rhythm can exceed the slowest ventricular tachyarrhythmia. In patients not expected to have rate crossover, the SVT Discriminators (page 93) should be disabled so that they do not affect diagnosis and delivery of therapy.

SVT Discriminators

The SVT Discriminators are a set of programmable tools that can analyze the current rhythm to distinguish VT/VF from sinus or atrial tachycardias. To use these tools, the Zone Configuration (page 89) parameter must be set to 2 Zone or 3 Zone. Rhythms subjected to analysis are initially classified by the Rate Branch (page 94) parameter, which sends the rhythm to one of three different "branches" for further analysis, with a final diagnosis made according to the criteria of the Diagnosis (page 94) parameter[96].

When the SVT Discrimination Mode (page 92) parameter is set to Ventricular Only and the Zone Configuration parameter is set to 2 Zone or 3 Zone, the Rate Branch discriminator is unavailable, and the discrimination begins when a rhythm is analyzed by the Additional Discriminators.

You can also disable a discriminator to skip an analysis.

When the Zone Configuration parameter is set to Off or 1 Zone, then SVT Discriminators are not available, but the Morphology Scoring (page 105) parameter can be used to help retrospectively diagnose SVT using EGMs.

Select any button to choose the parameter setting or to open a window to program additional discrimination settings.

The SVT discriminators include:

- Rate Branch (page 94) (Dual Chamber SVT Discrimination only)
- Diagnosis (page 94)
- Additional Discriminators
  - Morphology (page 95)
  - Interval Stability (page 101)
  - Arrhythmia Onset/Sudden Onset (page 103)

See also:

- SVT Discrimination Description (page 124)
- SVT Discrimination (page 91)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

[96] If the Rate Branch analysis determines that the rhythm is VT or VF, no additional analysis is made; the device immediately begins therapy.

Note

Rhythm Classification. When the SVT Discrimination Mode (page 92) parameter is set to Dual Chamber and SVT discriminators are enabled, the device is more likely to classify a rhythm as VT. When the SVT Discrimination Mode parameter is set to Ventricular Only and SVT discriminators are enabled, the device is less likely to classify a rhythm as VT.

SVT Discriminators. At least one of the SVT Discriminators must be programmed On in each rate branch.

SVT Discriminators that are set to Passive do not influence Tachycardia Diagnosis Criteria.

Rate Branch

The Rate Branch SVT discriminator compares the current ventricular rhythm to the atrial rate. This parameter is only available when the SVT Discrimination Mode (page 92) parameter is set to Dual Chamber. This discriminator then classifies the rhythm into one of three branches, utilizing any discriminators that are On or Passive:

- **V<A** -- Typically, atrial fibrillation or atrial flutter (AF/AFL). The rhythm's EGM complex can then be checked against the current morphology template (Morphology Template (page 103)) and the Interval Stability (page 101) criteria and diagnosed according to the criteria set by the Diagnosis (page 94) parameter.
- **V=A** -- Typically, sinus tachycardia (Sinus Tach). Select this button to open the Sinus Tach Rate Branch Control (page 94) window. If the SVT Discrimination in Sinus Tach (page 94) parameter is On, the stability of the rhythm is analyzed by comparing the second longest and second shortest AV intervals (see the AV Interval Delta (page 95) parameter). The complex can be compared to the template for similarities in morphology. Then, it can be tested to determine if the onset was sudden or gradual (see Sudden Onset (page 103)) and which chamber the rhythm onset started first (Chamber Onset (page 102)). Finally, the rhythm is diagnosed according to the criteria set by the Diagnosis parameter.
- **V>A** -- Typically, V Tach or V Fib (VT/VF). If the ventricular rate is greater than the atrial rate, no further discrimination is needed and the device begins to deliver therapy.

The AF/AFL and VT/VF rate branches are always On. The Sinus Tach rate branch is enabled by the SVT Discrimination in Sinus Tach (page 94) parameter.

See also:

- Rate Branch Detailed Description (page 124)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

Diagnosis

The Diagnosis parameter determines the number of SVT Discriminators (page 93) that must classify a rhythm as VT before the device diagnoses VT. The settings include:

- **If Any**. Only one discriminator must classify the rhythm as VT before VT is diagnosed.
- **If All**. All the enabled discriminators must classify the rhythm as VT before VT is diagnosed.
- **If 2 of 3**. This setting is available when the SVT Discrimination Mode (page 92) parameter is set to Ventricular Only and all of the SVT Discriminators are set to On.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button

Sinus Tach Rate Branch Control

You can program the following parameters from the Sinus Tach Rate Branch Control window:

- SVT Discrimination in Sinus Tach (page 94)
- AV Interval Delta (page 95)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Details Details button > Sinus Tach button

SVT Discrimination in Sinus Tach

The SVT Discrimination in Sinus Tach parameter enables the V=A -- Sinus Tach Rate Branch (page 94). If this parameter is Off and ventricular rhythm equals the atrial rhythm (V=A), the event is classified as VT/VF and the device initiates therapy.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Details Details button > Sinus Tach button

AV Interval Delta

The AV Interval Delta parameter sets the maximum difference between the second longest and second shortest AV interval in the complexes found during detection. If the rhythm is V=A, but the difference between the AV intervals is greater than the setting for the AV Interval Delta parameter, then the rhythm is immediately diagnosed as ventricular tachycardia and Morphology and Sudden Onset/Chamber Onset are not evaluated. If the difference is less than the AV Interval Delta setting, the rhythm can be analyzed further for diagnosis of SVT.

The larger the difference between the long and short AV intervals, the more likely the rhythm is "dissociated," that is, not associated with a stable AV interval, a characteristic of VT or VF. If the AV intervals vary only a small amount, the rhythm is more likely to have a stable AV association, often characteristic of Sinus Tach or SVT.

See also:

- Rate Branch Detailed Description (page 124)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Details Details button > Sinus Tach button

Note

SVT Discrimination Mode (page 92). The AV Interval Delta parameter is available only when the SVT Discrimination Mode parameter is set to Dual Chamber.

Concurrent VTs and SVTs. The AV Interval Delta parameter may be useful for patients who have VTs concurrent with SVTs for which therapy is erroneously inhibited by the Rate Branch (page 94) discriminator.

Rhythm Classification. When the AV Interval Delta parameter is set to a shorter interval, it is more likely that a rhythm is classified as VT.

Morphology Window

From the Morphology window, you can acquire a new morphology template, evaluate the existing template, or program one of the following Morphology discriminator parameters:

- Morphology (page 95)
- Morphology in AF/A Flutter (V<A Rate Branch: Morphology) (page 95)
- Morphology in Sinus Tach (V=A Rate Branch: Morphology) (page 96)
- % Match (page 96)
- Template Match Criteria (page 96)
- Morphology No. of Matches (page 96)
- Morphology Window Size (page 97)
- Template Auto Update (page 97)
- Morphology Template (page 103)
- Morphology Template Pacing Hysteresis (page 97)
- Far Field MD™/SecureSense™ Configuration (page 91)
- Advanced Settings (page 98)

See also:

- Morphology Detailed Description (page 125)
- Details of the Template Auto Update (page 98)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Morphology

The Morphology parameter enables the device to compare the shape of a characteristic sinus rhythm complex (morphology template) to an arrhythmia's complexes. The Passive setting allows the device to store diagnostic information but does not affect the diagnosis of VT.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Morphology in AF/A Flutter (V<A Rate Branch: Morphology)

The Morphology in Sinus Tach (V=A Rate Branch: Morphology) parameter enables the device to compare the shape of a characteristic sinus rhythm complex (morphology template) to an arrhythmia's complexes in the V=A Rate Branch when the SVT Discrimination Mode

(page 92) is set to Dual Chamber. The Passive setting allows the device to store diagnostic information but does not affect the diagnosis of VT.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Morphology in Sinus Tach (V=A Rate Branch: Morphology)

The Morphology in AF/A Flutter (V<A Rate Branch: Morphology) parameter enables the device to compare the shape of a characteristic sinus rhythm complex (morphology template) to an arrhythmia's complexes in the V<A Rate Branch when the SVT Discrimination Mode (page 92) parameter is set to Dual Chamber. The Passive setting allows the device to store diagnostic information but does not affect the diagnosis of VT.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

% Match

The % Match parameter is the degree of similarity that must exist between a complex and the template for it to be considered a match. Complexes with scores equal to or exceeding the percentage match are classified as matching the template. If the Morphology parameter is programmed On or Passive, a check mark appears on real-time EGMs under each complex that matches the template. An "x" marks complexes that do not match the template.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Note

Rhythm Classification. When the % Match parameter is set to a higher setting, it is more likely that a rhythm is classified as VT.

Rate Branch (page 94). For CRT-Ds and Dual-Chamber ICDs, the % Match parameter is not independently programmable in the AF/AFL and Sinus Tach rate branches.

Template Match Criteria

The Template Match Criteria consists of two parameters: the Morphology No. of Matches (page 96) and the Morphology Window Size (page 97). Used together, these parameters set the number of template matches within a specified limit of R-wave complexes (Morphology Window size) that must match the morphology template with a score greater than or equal to the % Match (page 96) setting before a diagnosis of VT is made. Thus, with the Morphology No. of Matches parameter, you can set the number of complexes that come within a percentage of a match to the established morphology (template) of a sinus complex. With the Morphology Window Size parameter, you can set the number of complexes to compare against the template.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Morphology No. of Matches

The Morphology No. of Matches parameter is the number of R-wave complexes within a limit of R-wave complexes (the Morphology Window Size (page 97) parameter) that must match the template for the Morphology (page 95) discriminator to classify the rhythm as SVT. If the observed number of matches is less than the programmed number of matches, the Morphology discriminator classifies the rhythm as VT. If the number of observed matches is equal to or greater than the programmed number, the discriminator classifies the rhythm as SVT.

See also:

- Morphology Detailed Description (page 125)

- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Note

Rate Branch (page 94). For CRT-Ds and Dual-Chamber ICDs, the Morphology No. Matches parameter is not independently programmable in the AF/AFL and Sinus Tach rate branches.

Rhythm Classification. When the % Match parameter is set to a higher setting, it is more likely that a rhythm is classified as VT.

Morphology Window Size

The Morphology Window Size parameter is the number of complexes prior to detection used to determine the origin of a rhythm (SVT or VT) based on the morphology of the rhythm. The Window Size must be less than the programmed number of intervals for any tachycardia detection (VT, VT-1, or VT-2) within the SVT Discrimination (page 91).

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Template Auto Update

The Template Auto Update parameter is the amount of time between automatic evaluations of the active morphology template. The device periodically checks to see that the active morphology template is still similar enough to the baseline complex. If the template is not similar enough, the device attempts to update it.

When the Template Auto Update timer expires, the device determines if the baseline rhythm is suitable for sampling. Conditions that disqualify the rhythm include:

- the average interval is less than 500 ms or the current VT/VT-1 detection cycle length setting
- noise reversion is ongoing
- NIPS or Fibber test is operating
- a potential VT/VF episode is ongoing.

If any of these conditions are detected, the device postpones the update for a period designated by the parameter setting. If, however, the conditions are not present, the device updates the template.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Morphology Template Pacing Hysteresis

In devices with Far Field MD Morphology Discrimination Capability (page 187), the Morphology Template Pacing Hysteresis parameter enables the device to temporarily adjust certain pacing parameters to reduce ventricular pacing and to allow intrinsic activity to be sensed. This improves the possibility of successfully acquiring a potential morphology template out-of-clinic. When the device has not been able to update the template for the past seven days, it adds 100 ms to the programmed Paced AV Delay setting and disables the Negative AV Hysteresis/Search algorithm. If the Mode is set to DDI or VVI, the Base Rate is also temporarily reduced to a minimum of 40 **bpm**. When the template is acquired, the programmed settings revert.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button

Far Field MD™/SecureSense™ Configuration

The Far Field MD™/SecureSense™ Configuration parameter sets the electrode configuration of the far-field (Discrimination) channel used in both the SecureSense™ algorithm and the Far Field MD™ Morphology Discrimination algorithm (see Morphology Type). The signal from this far field vector channel is compared to the near field vector on the primary sensing channel in order to diagnose RV Lead Noise. This parameter also controls what configuration is displayed when the Discrimination channel is shown in EGMs or Stored EGMs.

Ideally, the Discrimination channel should have an R-wave amplitude greater than 1 mV with no noticeable myopotentials. The nominal setting (RVcoil-Can) is the appropriate choice for most patients. If you have a concern about the integrity of the RV coil or if you are using integrated bipolar leads, the RVtip - Can setting may be preferable.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SecureSense button

Advanced Settings

The Advanced Settings window allows you to specify the Morphology Type parameter to enable either the Far Field MD Morphology Discrimination or Original MD settings.

Available In: Devices with Far Field MD™ Morphology Discrimination Capability (page 187)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button > Advanced Settings button

Morphology Type

The Morphology Type parameter specifies the algorithm used to obtain the characteristic sinus rhythm template used for morphology discrimination. You can choose either Original MD (RVtip-RVring EGM vector) or Far Field (the EGM vector specified by the Far Field MD/SecureSense™ Configuration parameter).

The Original MD setting obtains R-wave morphologies based on the near-field RVtip-RVring sense amp channel signal and uses that data to compute morphology match scores. The Far Field MD setting uses the near-field RVtip-RVring channel to align R-waves, but compares the R-wave morphologies and computes match scores based on the signal from the far-field channel, which is set by the Far Field MD/SecureSense Configuration parameter.

When the Morphology Type parameter is set to Far Field, the morphology template cannot be acquired manually. See Instructions for Acquiring a Morphology Template.

Note

When the Morphology Type setting is changed, the Episodes, Stored EGMs, and the active morphology template are all cleared from the device.

See also:

- Morphology Detailed Description (page 125)
- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Morphology button > Advanced Settings button

Details of the Template Auto Update

The figures below show how the Template Auto Update evaluates the current active template.

Figure 7. Template Auto Update in devices without Far Field MD Morphology Discrimination Capability

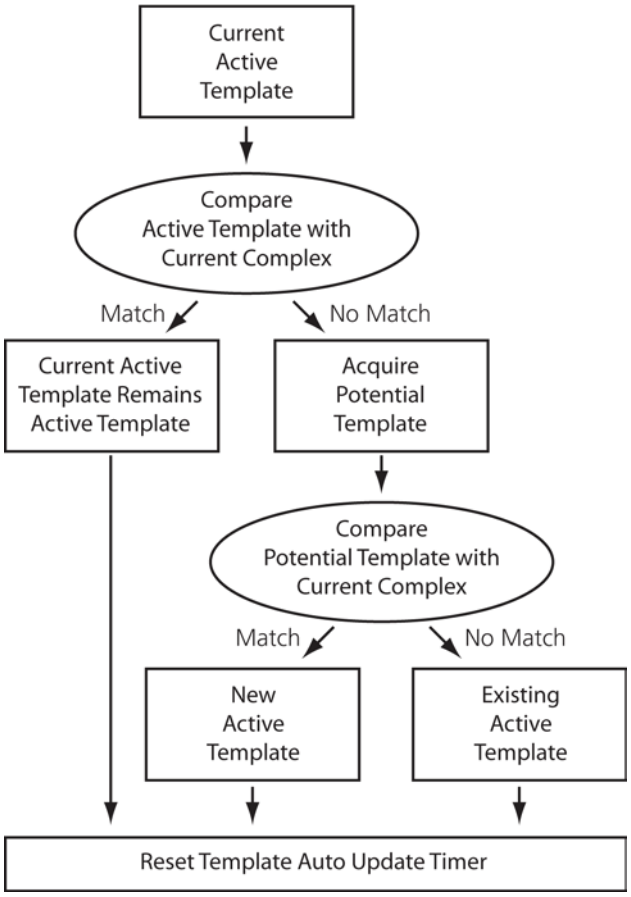
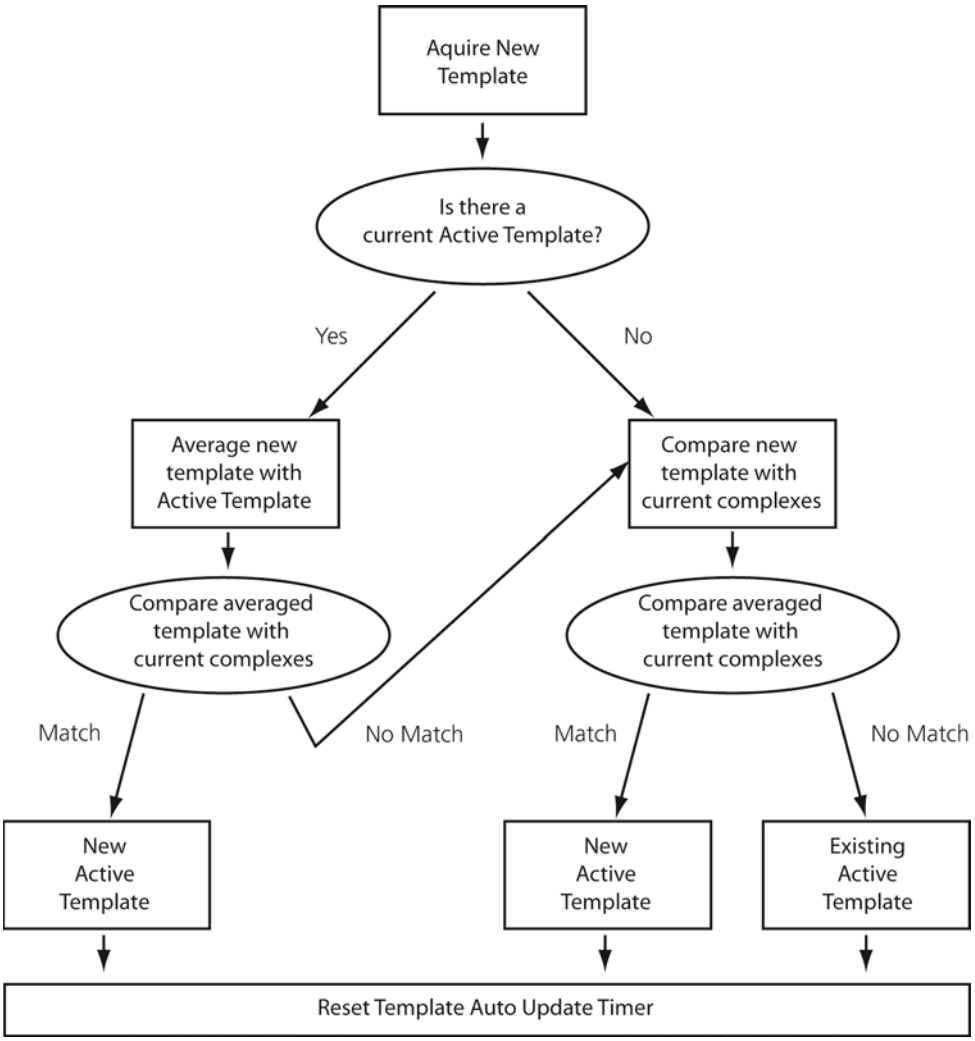


Figure 8. Template Auto Update in devices with Far Field MD Morphology Discrimination Capability (page 187)



See Morphology Template (page 103).

Interval Stability Window

From the Interval Stability window, you can program the following Interval Stability discriminator parameters:

- Interval Stability (page 101)
- Stability Delta (page 101)
- AV Association (page 101) Delta[97]
- SIH (page 101) Count[98]
- Interval Stability Window Size (page 102)

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

[97] Only available for Dual Chamber SVT Discrimination.
[98] Only available for Ventricular Only SVT Discrimination.

Interval Stability

The Interval Stability parameter enables a discriminator that distinguishes between atrial fibrillation (AF) (more rate-variability) and VT (less rate-variability). When the Interval Stability parameter is enabled, the Stability Delta (page 101), AV Association Delta (page 101) or SIH Count (page 101), and Interval Stability Window Size (page 102) parameters are enabled.

- When the SVT Discrimination Mode (page 92) parameter is set to Dual Chamber and the Interval Stability (page 101) parameter is set to On w/AVA (AV association), the AV Association Delta (page 101) parameter is available.
- When the SVT Discrimination Mode parameter is set to Ventricular Only and the Interval Stability parameter is set to On w/SIH (sinus interval history), the SIH Count (page 101) parameter is available.

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

Stability Delta

The Stability Delta parameter defines the acceptable difference between the second longest and the second shortest ventricular intervals in a recent group of intervals defined by the Interval Stability Window Size (page 102).

- When the measured Stability Delta interval is equal to or longer than the programmed Stability Delta setting, the Interval Stability (page 101) discriminator classifies the rhythm as SVT.
- When the measured Stability Delta interval is shorter than the programmed Stability Delta setting, the Interval Stability discriminator classifies the rhythm as VT.

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

Note

Rhythm Classification. When the Stability Delta parameter is set to a longer interval, it is more likely that a rhythm is classified as VT.

AV Association Delta

The AV Association Delta (AVA Delta) parameter defines the acceptable difference between the second longest and the second shortest AV interval in a recent group of intervals defined by the Interval Stability Window Size (page 102).

- When the measured AVA Delta interval is shorter than the programmed AVA Delta setting, the Interval Stability (page 101) discriminator classifies the rhythm as SVT. When the Interval Stability parameter is set to On w/AVA and the Interval Stability discriminator classifies the rhythm as SVT, the measured AV Association Delta interval is not checked.
- When the measured AVA Delta interval is longer than or equal to the programmed AVA Delta setting, the Interval Stability (page 101) discriminator classifies the rhythm as VT.

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

Note

Rhythm Classification. When the AV Association Delta parameter is set to a shorter interval, it is more likely that a rhythm will be classified as VT.

SVT Discrimination Mode (page 92). The AV Association Delta parameter is available when the SVT Discrimination mode is set to Dual Chamber.

SIH Count

The SIH (Sinus Interval History) Count parameter defines the number of sinus intervals or average intervals of a rhythm that can occur during detection of a rhythm classified as VT.

- When the number of sinus intervals or the average intervals of a rhythm is greater than or equal to the SIH Count, the Interval Stability (page 101) discriminator classifies the rhythm as SVT. The rhythm may be regularized AF.
- When the number of sinus intervals or the average intervals of a rhythm is less than the SIH Count, the Interval Stability discriminator classifies the rhythm as VT.

The SIH Count parameter is available when the SVT Discrimination Mode (page 92) is set to Ventricular Only.

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

Note

Rhythm Classification. When the SIH Count parameter is set to a larger number of intervals, it more likely that a rhythm will be classified as VT.

Interval Stability Window Size

The Interval Stability Window Size parameter determines the number of intervals prior to the detection of an arrhythmia that are used to evaluate the stability of an arrhythmia. The Interval Stability Window Size setting must be less than or equal to the selected No. Intervals (page 90) for any tachycardia detection rate zone (VT, VT-1, or VT-2) within the SVT Discrimination (page 91).

See also:

- Interval Stability Detailed Description (page 125)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Interval Stability button

Sudden Onset Window

For CRT-Ds and dual-chamber devices with Chamber Onset Discrimination Capability (page 184) and with the following criteria selected, this window is titled “Arrhythmia Onset.”

Criteria:

- SVT Discrimination setting = Dual Chamber
- Sinus Tach V=A = On

For CRT-Ds and dual-chamber devices, this window is titled "Sudden Onset."

Otherwise, this window is titled “Sudden Onset.”

From this window, you can program the following Arrhythmia Onset/Sudden Onset discriminator parameters:

- Chamber Onset (page 102) (Arrhythmia Onset window only)
- Sudden Onset (page 103)
- Onset Delta (page 103)

See also:

- Sudden Onset Description (page 126)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Sudden Onset button

Chamber Onset

The Chamber Onset parameter helps discriminate between VT and SVT by determining which chamber is driving an abrupt rate increase. If the Chamber Onset algorithm determines that the atrial rate has increased prior to the ventricular rate, then the arrhythmia is determined to be an SVT. If the ventricular rate is found to increase prior to the atrial rate, the arrhythmia is determined to be VT. The algorithm also factors in how quickly the ventricular rate changed (see Sudden Onset), and will also diagnose an SVT based on that criterion.

The Chamber Onset parameter is available in the V=A Rate Branch during dual chamber discrimination, where either Sudden Onset or Chamber Onset can be enabled.

The On” setting initiates the Chamber Onset algorithm and turns off the Sudden Onset parameter. The “Off” setting shifts the function from the Chamber Onset algorithm to the Sudden Onset algorithm. When set to the “Passive” setting, the device analyzes the rhythms and collects data but does not contribute to the SVT discrimination.

See also:

- Arrhythmia Onset/Sudden Onset Detailed Description
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Arrhythmia Onset button

Sudden Onset

The Sudden Onset parameter enables a discriminator that distinguishes between VT (abrupt onset) and sinus tachycardia (gradual onset) in patients whose maximum sinus rates can exceed their slowest ventricular tachyarrhythmia rates (**"rate overlap"**).

See also:

- Sudden Onset Description (page 126)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Sudden Onset button

Onset Delta

The Onset Delta parameter determines the abruptness of a tachycardia's onset. If the measured Onset Delta interval is equal to or greater than the programmed Onset Delta setting, the Sudden Onset discriminator classifies the rhythm as VT. If the measured difference is less than the delta, the discriminator classifies the rhythm as SVT. The Onset Delta parameter can be programmed as a specific change in the interval (Fixed) or as a percentage of change in the interval (Adaptive).

See also:

- Sudden Onset Description (page 126)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > SVT Discrimination Details button > Sudden Onset button

Note

Rhythm Classification. When the Onset Delta parameter is set to a shorter interval or smaller percentage, it is more likely that a rhythm is classified as VT.

Sudden Onset (page 103). The Sudden Onset discriminator uses abruptness of onset to discriminate between sinus rhythms and ventricular tachycardias. The results of a stress test may be helpful in selecting an appropriate Onset Delta setting.

Detection Interval/Rate (page 90). The Onset Delta setting cannot be less than the difference between the VT/VT-1 detection interval and the fastest pacing interval.

Morphology Template

The following buttons are available on the Morphology Template window:

- **Automatic** button**.** Select this button to automatically acquire an active morphology template.
- **Manual** button. Select this button to manually acquire a potential morphology template[99].
- **Acquire** button. Initiates the morphology template maintenance algorithm.
- **Template window(s)**. This window shows a snapshot of the Active Template (currently in use) and the date and time of its acquisition. When you select the Manual template acquisition method, the window also shows both the Active and Potential Template snapshots, the date and time of the acquisition, buttons to select the template to score, and a button to activate the Potential Template. At the bottom of the window, the text "scoring..." indicates that the device is comparing the active template to the currently measured complexes.

You can also temporarily program the following parameters from the Morphology Template window to ensure the appearance of intrinsic rhythm:

- Mode
- Base Rate
- Paced AV Delay
- Sensed AV Delay

See also:

- Morphology Scores (page 104)
- Template Auto Update (page 97)
- Instructions for Acquiring a Morphology Template (page 104)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Acquire/Evaluate Template button

Note

Disabling Morphology Scoring. When you disable the Morphology Scoring (page 105) parameter or the Morphology (page 95) parameter, the active template is retained in the device.

[99] Not available when the Morphology Type parameter is set to Far Field.

Instructions for Acquiring a Morphology Template

Automatic

1. From the Zone Configuration window, select the SVT Details button or the Morphology Scoring button.
2. From the SVT Details window or the Morphology Scoring window, select the Acquire/Evaluate Template button.

   The button text presents the current template status (Active template Present or No Active Template).
3. On the Morphology Template page, select the Automatic button.
4. Set any of the pacing parameters to optimize sensing of sinus rhythm. Select the Start Temporary button when complete.
5. Select the Acquire button.

   If the device successfully senses intrinsic rhythm and a usable active template is available, the programmer asks if you want to keep the current active template or clear and update the template. If you select the Keep Template button, the programmer shows the snapshot of the complex in the Active Template window and uses that complex to compare against new complexes. If you select the Clear and Update Template button, the device restarts its sensing routine, and upon completion, the programmer shows the snapshot of the complex in the Active Template window and uses that complex to compare against new complexes.
6. If the waveform does not appear representative, repeat the procedure or use the Manual acquisition method.

Manual

1. From the Zone Configuration window, select the SVT Details button or the Morphology Scoring button[100].
2. From the SVT Details window or the Morphology Scoring window, select the Acquire/Evaluate Template button.

   The button text presents the current template status (Active template Present or No Active Template)
3. On the Morphology Template page, select the Manual button.

   If an active template is available, windows for both the Potential and Active templates appear.
4. Set any of the pacing parameters to optimize sensing of sinus rhythm. Select the Start Temporary button when complete.
5. Select the Acquire button.

   If the device is unable to sense intrinsic rhythm, the programmer asks you to adjust the pacing parameters and try again.
   If the device successfully senses intrinsic rhythm and a usable active template is available, the programmer shows snapshots of the complexes in the Potential and Active Template windows. You have three options:
   - - To continue to use the Active Template for scoring (that is, to compare the Active Template to the currently sensed complex), select the Active button.
   - - To use the potential button for scoring, select the Potential button.
   - - To replace the Active Template with the Potential Template, select the Activate Potential button.
6. If the waveform does not appear representative, repeat the procedure.

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Acquire/Evaluate Template button

Morphology Scores

Morphology scores indicate the percentage of similarity of the current rhythm to the template. Morphology Markers appear on the marker channel on the Rhythm Display when:

- An active template exists and is used for scoring.
- A potential template exists and is used for scoring. These scores are only generated and appear on the Rhythm Display (page 5) when the Morphology Template window is displayed.

When the Morphology discriminator is set to On or Passive, a check mark appears on Rhythm Display below each complex that matches the active template and an "X" is placed below each complex that does not match the active template, based on the % Match (page 96) setting. High Morphology Scores and check marks indicate that the current rhythm matches the template. Low scores and "X's" indicate mismatches.

Morphology Scoring Window

From the Morphology Scoring window, you can enable the following parameters:

- Morphology Scoring (page 105)
- Template Auto Update (page 97)

See also:

- Morphology Template (page 103)
- Morphology Scores (page 104)

[100] Not available when the Morphology Type parameter is set to Far Field.

Morphology Scoring

The Morphology Scoring parameter enables scoring of the sensed R-waves during VF episodes against the active template. An active template must exist to enable Morphology Scoring. Active and potential templates are not cleared when Morphology Scoring is disabled.

See also:

- Morphology Template (page 103)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Morphology button

> **Note**
>
> **Zone Configuration** (page 89). Morphology Scoring is available only when the Zone Configuration is set to Off and 1 Zone (page 123).

Zone Therapy

The Zone Therapy window allows you to program therapies for each active rate zone. A table in the top right indicates which rate zones are programmed and their current limits. The buttons on the window include:

- Active/Monitor button. This button, which is available for VT-1 Therapy (3 Zones) or VT Therapy (2 Zones), toggles between two settings:
  - Active. Delivers the programmed therapy at the current settings.
  - Monitor. Withholds therapy in the VT-1 or VT rate zone but records all activity in the Diagnostics.
- VT Therapy Timeout (page 105)
- Timeout Trigger (page 105)
- Therapy (page 106) buttons
- ATP Prior to Charging (page 107)
- ATP While Charging (page 107)
- ATP Details (page 108)

See also:

- Rate Zone Legend (page 124)
- VT Therapy Timeout Description (page 132)
- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button

VT Therapy Timeout

The VT Therapy Timeout parameter determines the amount of time the device can deliver tachycardia therapy. When the VT Therapy Timeout setting expires, the device abandons tachycardia therapies and delivers VF therapy.

The VT Therapy Timeout parameter is available only in the 2 Zones (page 123) or 3 Zones (page 123) configuration.

As protection against delivering VT Therapy Timeout directed therapy into a **bigeminal rhythm**, the device must detect more tachyarrhythmia intervals than sinus intervals before it delivers therapy.

See also:

- VT Therapy Timeout Description (page 132)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button

Timeout Trigger

The Timeout Trigger parameter determines the therapy that must be delivered to initiate the VT Therapy Timeout (page 105) timer. The Timeout Trigger parameter is only available in the 2 Zones (page 123) or 3 Zones (page 123) configuration.

The available settings depend on the programmed Zone Configuration (page 89) settings.

See also:

- VT Therapy Timeout Description (page 132)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button

Therapy

From the Zone Therapy window, you can program successive therapies for each available rate zone. In each rate zone, Therapy 1 is delivered before Therapy 2, and so on, until the device reaches Therapy 4. You can program up to four therapies in the VT zones and three or four[101] therapies in the VF zone (for a total of up to seven delivered therapies in the VF zone).

The tables below show the therapies available within the rate zones and the energy/voltage settings available for CVRT and Defib therapies.

Table 19. Therapies available[102]

Therapy Number	Rate Zone		
	VT/VT-1	VT-2	VF
Therapy 1	Off[103] ; ATP; CVRT	ATP; CVRT	Defib
Therapy 2	Off[104]; ATP; CVRT	Off[105]; ATP; CVRT	Defib
Therapy 3	Off[106]; CVRT	Off[107]; CVRT	Defib x 4
Therapy 4	Off; CVRT; CVRT x 2	Off; CVRT; CVRT x 2	N/A

Table 20. Therapies available for devices with ATP Therapy Prior to Charging and ATP Therapy While Charging (page 181) Capability[108]

Therapy Number	Rate Zone		
	VT/VT-1	VT-2	VF
Therapy 1	Off[109]; ATP; CVRT	ATP; CVRT	Defib; ATP Prior to Charging; ATP While Charging
Therapy 2	Off[110]; ATP; CVRT	Off[111]; ATP; CVRT	Defib
Therapy 3	Off[112]; CVRT	Off[113]; CVRT	Defib[114]; Defib x 4[115]
Therapy 4	Off; CVRT; CVRT x 2	Off; CVRT; CVRT x 2	Defib x 4[116]; N/A[117]

Table 21. CVRT and Defib therapy settings[118]

Device	Detection Zone		
	VT/VT-1/VT-2/VF (Therapy 1)	VT/VT-1/ VT-2 (Therapy 2, 3, 4); VF (Therapy 2[119])	VF (Therapy 3[120])
Tilt[121] (J)			
40 J Devices (Battery Model 2753 (page 183) and Battery Model 2850 (page 183))	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; … 40.0	17.5; 20.0; … 30.0; 32.0; … 40.0
36 J Devices (Battery Model 2555 (page 182))	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0	17.5; 20.0; … 27.5; 30.0; 32.0; 34.0; 36.0
36 J Devices (Battery Model 2950 (page 183))	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0	17.5; 20.0; … 27.5; 30.0; 32.0; 34.0; 36.0
30 J Devices(Battery Model 2356 (page 182))	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0	0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0	15.0; 17.5; … 30.0

[101] Available with ATP Prior to Charging or ATP While Charging On.
[102] Once a CVRT or Defib setting has been selected in a zone, subsequent therapies must be greater than or equal to the setting for the previous therapy.
[103] Also turns off subsequent therapies within the rate zone.
[104] Also turns off subsequent therapies within the rate zone.
[105] Also turns off subsequent therapies within the rate zone.
[106] Also turns off subsequent therapies within the rate zone.
[107] Also turns off subsequent therapies within the rate zone.
[108] Once a CVRT or Defib setting has been selected in a zone, subsequent therapies must be greater than or equal to the setting for the previous therapy.
[109] Also turns off subsequent therapies within the rate zone.
[110] Also turns off subsequent therapies within the rate zone.
[111] Also turns off subsequent therapies within the rate zone.
[112] Also turns off subsequent therapies within the rate zone.
[113] Also turns off subsequent therapies within the rate zone.
[114] Available with ATP Prior to Charging or ATP While Charging On.
[115] Available with ATP Prior to Charging or ATP While Charging Off.
[116] Available with ATP Prior to Charging or ATP While Charging On.
[117] Available with ATP Prior to Charging or ATP While Charging Off.
[118] This is the full range of settings displayed by the programmer. Depending on other parameter settings, the programmer may not allow all settings to be programmed.
[119] For devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability, also applicable for VF Therapy 3 when ATP Prior to Charging or ATP While Charging is enabled.
[120] For devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability, also applicable for VF Therapy 4 when ATP Prior to Charging or ATP While Charging is enabled.
[121] Available energy settings depend on the configuration of the DeFT Response™ Technology Settings (Shock Waveform).

Table 21. CVRT and Defib therapy settings[118]

Device	Detection Zone		
	VT/VT-1/VT-2/VF (Therapy 1)	VT/VT-1/ VT-2 (Therapy 2, 3, 4); VF (Therapy 2[119])	VF (Therapy 3[120])
Pulse Width (V)			
40 J Devices (Battery Model 2753 (page 183))	50; 100; … 800; 830	50; 100; … 800; 830; 875	700; 750; 800; 830; 875
40 J Devices (Battery Model 2850 (page 183))	50; 100; … 800; 845	50; 100; … 800; 845; 890	700; 750; 800; 845; 890
36 J Devices (Battery Model 2950 (page 183))	50; 100; … 800	50; 100; … 800; 875	700; 750; 800; 875
36 J Devices and 30 J Devices (Battery Model 2555 (page 182) and Battery Model 2356 (page 182))	50; 100; … 800; 830	50; 100; … 800; 830	700; 750; 800; 830

See also:

- ATP Parameters (page 108)
- Tachyarrhythmia Therapy Description (page 131)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button

Note

Energy to Voltage Conversion. When the Waveform Mode (page 114) is set to Tilt, the conversion between energy and voltage depends on the current settings of the Waveform parameter and the 1st Phase Tilt parameters. At some tilt settings, high energy values may convert to voltage levels that are not achievable. If this occurs, the programmer selects the highest energy value that can be achieved.

ATP Prior to Charging

The ATP Prior to Charging feature enables the device to deliver a single sequence of ATP therapy before the device charges for HV delivery in the VF zone. After you choose the ATP Prior to Charging parameter, program the Upper Rate Cutoff, which is the upper rate that ATP will be delivered in the VF zone.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > VF Therapy 1 > ATP Prior to Charging/ATP While Charging/Defib

ATP While Charging

The ATP While Charging feature enables the device to deliver a single sequence of ATP therapy while the device charges for HV delivery in the VF zone. After you choose the ATP While Charging parameter, program the Upper Rate Cutoff, which is the upper rate that ATP will be delivered in the VF zone.

Note

In Ellipse devices, the ATP While Charging parameter is disabled at ERI.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > VF Therapy 1 > ATP Prior to Charging/ATP While Charging/Defib

ATP Details

The ATP Details window shows a summary of the antitachycardia pacing (ATP) settings for each rate zone and therapy. Select a summary button to program the ATP Parameters (page 108) for that rate zone and therapy. You can program different ATP therapies for each Zone.

Note

For ATP settings in the VF Zone[122], settings from Therapy 1 in the adjacent VT zone are used. If ATP is Off in the adjacent VT zone, the ATP settings are nominal.

For more information, select one of the following links:

- ATP Pulse Amplitude (page 108)
- ATP Pulse Width (page 108)

A table in the top right indicates which rate zones are programmed and their current limits. See Rate Zone Legend (page 124).

See also:

- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button > ATP Details button

ATP Pulse Amplitude

The ATP Pulse Amplitude parameter determines how much electrical potential is applied to the myocardium during the ATP pacing stimulus.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button > ATP Details button

ATP Pulse Width

The ATP Pulse Width parameter determines how long the ATP Pulse Amplitude (page 108) is applied to the myocardium.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button > ATP Details button

ATP Upper Rate Cutoff

Use the ATP Upper Rate Cutoff parameter to specify the rate in bpm above which ATP therapy in the VF zone will not be delivered. If the intrinsic rate is above the parameter setting, the device does not attempt ATP therapy. The setting for the ATP Upper Rate Cutoff cannot be equal to or slower than the VF Detection Rate\Interval.

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Zone Therapy button > ATP Details button

ATP Parameters

The ATP Details window allows you to program parameters that control the timing and delivery of antitachycardia pacing (ATP). For information on setting these parameters and their interactions, see ATP Therapy Configurations (page 111). These parameters include:

- Number of Bursts (page 109)
- Number of Stimuli (page 109)
- Add Stimuli Per Burst (page 109)
- Burst Cycle Length (page 109)
- Minimum Burst Cycle Length (page 110)
- Readaptive (page 110)
- Scanning (page 110)
- Scan Step (page 110)
- Max Step (page 111)
- Ramp (page 111)
- Ramp Step (page 111)

See also:

- Rate Zone Legend (page 124)
- Parameter Availability and Settings (page 197)

[122] For devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Number of Bursts

The Number of Bursts parameter determines the maximum number of pacing bursts delivered during ATP.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Number of Stimuli

The Number of Stimuli parameter determines the number of stimuli (pulses) delivered in each burst.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

> **Note**
>
> **Surface ECG**. In Current, Current RF, Promote, and Promote RF devices, the first stimulus is delivered synchronously with a sensed event. Since the stimulus is synchronized to the downslope of the bipolar EGM, the surface ECG typically shows the stimulus to be the calculated first pulse interval plus 40 to 80 ms after onset of the QRS complex. The remaining stimuli in the burst are delivered as VOO pacing at the programmed Burst Cycle Length (page 109) interval, regardless of the intrinsic rhythm.
>
> In all other devices, the first stimulus of the ATP pulse train is also delivered synchronously with a sensed event and is equal to the first calculated Burst Cycle Length following the intrinsic event on which the VT/VF diagnosis was made. Thus, if Burst Cycle Length is set to 85% (Adaptive) and the VT cycle length is 400 ms, then the stimulus would equal 340 ms. The remaining stimuli in the burst are delivered as VOO pacing at the programmed Burst Cycle Length interval, regardless of the intrinsic rhythm.

Add Stimuli Per Burst

The Add Stimuli Per Burst parameter adds one additional stimulus per burst after the first burst. The total number of stimuli per burst is limited to 20 stimuli.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Burst Cycle Length

The Burst Cycle Length parameter determines the amount of time that each pacing stimuli in a burst is delivered. Readaptive (page 110), Scanning (page 110), and Ramp (page 111) can also affect this parameter. Program the Burst Cycle Length parameter to either of the following configurations:

- **Adaptive**. The initial burst cycle length is a percentage of the average tachycardia interval.
- **Fixed**. The device uses the programmed Burst Cycle Length setting, regardless of the cycle length of the tachycardia.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Minimum Burst Cycle Length (page 110). When the Burst Cycle Length parameter is set to Adaptive and the Minimum Burst Cycle Length interval is reached during a burst, the device delivers the remaining stimuli at the programmed Minimum Burst Cycle Length interval.

Minimum Burst Cycle Length

The Minimum Burst Cycle Length parameter determines the shortest cycle length delivered within a burst.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Readaptive (page 110), **Scanning** (page 110), **Ramp** (page 111), **or Burst Cycle Length** (page 109). When the Minimum Burst Cycle Length interval is reached during a burst, the device delivers the remaining stimuli at the Minimum Burst Cycle Length interval when the Readaptive, Scanning, or Ramp parameters are enabled, or when the Burst Cycle Length parameter is set to Adaptive.

Readaptive

The Readaptive parameter enables the recalculation of the initial burst cycle length based on the tachycardia interval average measured at each subsequent diagnosis. The burst cycle length is only recalculated when more than one burst is delivered in an episode. The Readaptive parameter may be useful in patients with more than one VT that falls within a single tachycardia zone.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Minimum Burst Cycle Length (page 110). When the Readaptive parameter is enabled and the Minimum Burst Cycle Length interval is reached during a burst, the device delivers the remaining stimuli at the programmed Minimum Burst Cycle Length interval.

Scanning

The Scanning parameter determines the initial cycle length between bursts. When the Scanning parameter is enabled, the initial burst cycle length of each burst decreases by the programmed Scan Step (page 110) from one burst to the next. When Scanning is disabled, the initial burst cycle length of each burst is the same.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Minimum Burst Cycle Length (page 110). When the Scanning parameter is enabled and the Minimum Burst Cycle Length interval is reached during a burst, the device delivers the remaining stimuli at the programmed Minimum Burst Cycle Length interval.

Scan Step

The Scan Step parameter determines the amount that the cycle length decreases from one burst to the next when the Scanning (page 110) parameter is enabled.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Max Step

The Max Step parameter determines the maximum difference between the first cycle length of the current burst and the first cycle length of the previous burst.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Readaptive (page 110) and Scanning (page 110). The Max Step parameter is available only when the Readaptive and Scanning parameters are both enabled.

Ramp

The Ramp parameter enables the successive decrease in intervals between stimuli within a burst.

When the Ramp parameter is enabled, each interval after the first in a burst is decremented by the programmed Ramp Step (page 111) interval. When the Ramp parameter is disabled, all of the stimuli in a burst are delivered at the same interval.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

Note

Minimum Burst Cycle Length (page 110). When the Ramp parameter is enabled and the Minimum Burst Cycle Length interval is reached during a burst, the device delivers the remaining stimuli at the programmed Minimum Burst Cycle Length interval.

Ramp Step

The Ramp Step parameter determines the amount by which each interval between stimuli within a burst is decremented when the Ramp (page 111) parameter is enabled.

See also:

- ATP Therapy Configurations (page 111)
- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Zone Configuration button > Therapy button > ATP Details button > ATP Details summary button

ATP Therapy Configurations

Eight ATP therapy configurations are available, depending on the settings for the Readaptive (page 110), Scanning (page 110), and Ramp (page 111) parameters.

Table 22. ATP Burst configurations and detailed description

Ramp	Readaptive	Scanning	Detailed Description
Off	Off	Off	ATP Therapy Detail A (page 112)
On	Off	Off	ATP Therapy Detail B (page 112)
Off	Off	On	ATP Therapy Detail C (page 112)
On	Off	On	ATP Therapy Detail D (page 112)
Off	On	Off	ATP Therapy Detail E (page 112)
On	On	Off	ATP Therapy Detail F (page 113)
Off	On	On	ATP Therapy Detail G (page 113)
On	On	On	ATP Therapy Detail H (page 113)

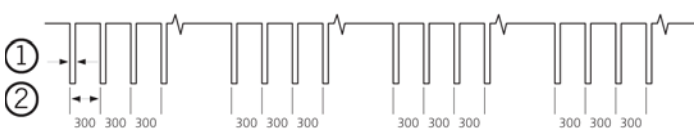
Note

Minimum Burst Cycle Length (page 110). Regardless of the programmed burst configuration, the device never delivers antitachycardia pacing therapy at an interval shorter than the programmed Minimum Burst Cycle Length interval.

ATP Therapy Detail A

Ramp (page 111) Off, Readaptive (page 110) Off, Scanning (page 110) Off. The Burst Cycle Length (page 109) interval between stimuli within all bursts is constant. The Burst Cycle Length parameter is programmed as either a Fixed interval (in milliseconds) or Adaptive interval (a percentage of the average tachycardia rate).

The figure below diagrams ATP with a fixed Burst Cycle Length interval of 300 ms.

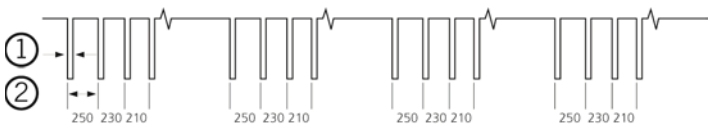


1. Pulse width
2. Burst cycle length

ATP Therapy Detail B

Ramp **(page 111) On,** Readaptive **(page 110) Off,** Scanning **(page 110) Off**. The Burst Cycle Length (page 109) interval between stimuli within each burst is successively decreased. The Ramp Step (page 111) interval determines how much each interval within a burst is decreased.

The figure below diagrams ATP with a fixed Burst Cycle Length interval of 250 ms and a Ramp Step interval of 20 ms.

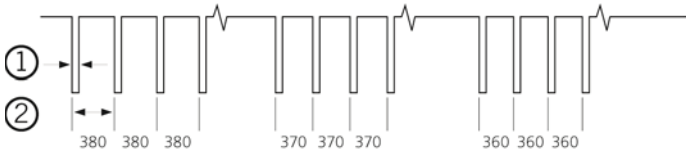


1. Pulse width
2. Burst cycle length

ATP Therapy Detail C

Ramp **(page 111) Off,** Readaptive **(page 110) Off,** Scanning **(page 110) On**. The Burst Cycle Length (page 109) interval between stimuli within each burst is constant. The Burst Cycle Length from one burst to the next is decreased by the Scan Step (page 110) interval.

The figure below diagrams ATP with a fixed Burst Cycle Length interval of 380 ms and a Scan Step interval of 10 ms.

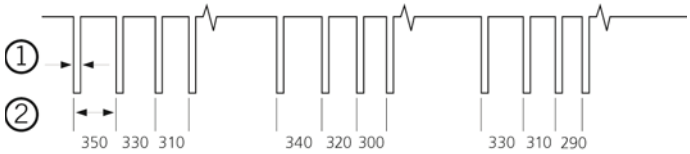


1. Pulse width
2. Burst cycle length

ATP Therapy Detail D

Ramp **(page 111) On,** Readaptive **(page 110) Off,** Scanning **(page 110) On**. The Burst Cycle Length (page 109) interval between stimuli within each burst is successively decreased by the Ramp Step (page 111) interval. The initial Burst Cycle Length interval for each subsequent burst is decreased by the Scan Step (page 110) interval.

The figure below diagrams ATP with fixed Burst Cycle Length interval of 350 ms, a Ramp Step interval of 20 ms, and a Scan Step interval of 10 ms.

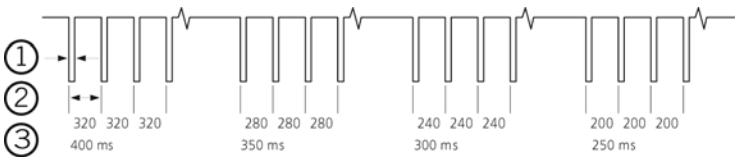


1. Pulse width
2. Burst cycle length

ATP Therapy Detail E

Ramp **(page 111) Off,** Readaptive **(page 110) On,** Scanning **(page 110) Off**. The Burst Cycle Length (page 109) interval between stimuli within all bursts is constant. The initial burst is delivered at the programmed Burst Cycle Length interval. The Burst Cycle Length interval for each subsequent burst is recalculated based on the most recent tachycardia rate.

The figure below diagrams ATP with an adaptive Burst Cycle Length of 80%.

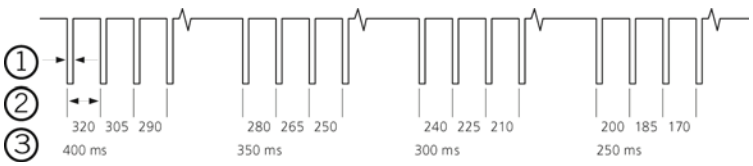


1. Pulse width
2. Burst cycle length
3. VT cycle length

ATP Therapy Detail F

Ramp **(page 111) On,** Readaptive **(page 110) On,** Scanning **(page 110) Off**. The Burst Cycle Length (page 109) interval between stimuli within each burst is successively decreased by the Ramp Step (page 111) interval. The initial burst is delivered at the programmed Burst Cycle Length interval. The Burst Cycle Length interval for each subsequent burst is recalculated based on the most recent tachycardia rate.

The figure below diagrams ATP with an adaptive Burst Cycle Length of 80% and a Ramp Step interval of 15 ms.

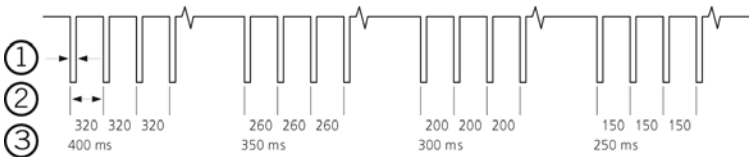


1. Pulse width
2. Burst cycle length
3. VT cycle length

ATP Therapy Detail G

Ramp **(page 111) Off,** Readaptive **(page 110) On,** Scanning **(page 110) On**. The Burst Cycle Length (page 109) interval between stimuli within each burst is constant. The initial burst is delivered at the programmed Burst Cycle Length interval. The Burst Cycle Length interval for each subsequent burst is recalculated based on the most recent tachycardia rate. The Burst Cycle Length interval is also decreased by the Scan Step (page 110) interval. The maximum difference between the first cycle length of the current burst and the first cycle length of the previous burst is limited by the Max Step (page 111) interval.

The figure below diagrams ATP with an adaptive Burst Cycle Length of 80%, a Scan Step interval of 20 ms, and a Max Step interval of 80 ms. The minimum Burst Cycle Length is 150 ms.

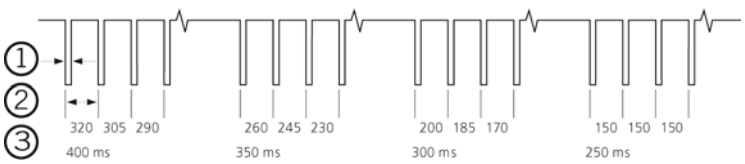


1. Pulse width
2. Burst cycle length
3. VT cycle length

ATP Therapy Detail H

Ramp **(page 111) On,** Readaptive **(page 110) On,** Scanning **(page 110) On**. The Burst Cycle Length (page 109) interval between stimuli within each burst is successively decreased by the Ramp Step (page 111) interval. The initial burst is delivered at the programmed Burst Cycle Length interval. The initial Burst Cycle Length interval for each subsequent burst is also recalculated based on the most recent tachycardia rate. The Burst Cycle Length interval is also decreased by the Scan Step (page 110) interval. The maximum difference between the first cycle length of the current burst and the first cycle length of the previous burst is limited by the Max Step (page 111) interval.

The figure below diagrams ATP with an adaptive Burst Cycle Length of 80%, a Scan Step interval of 20 ms, a Ramp Step interval of 15 ms, and a Max Step interval of 80 ms. The minimum Burst Cycle Length is 150 ms.



1. Pulse width
2. Burst cycle length
3. VT cycle length

DeFT Response™ Technology Settings (Shock Waveform)

The DeFT Response™ Settings window allows you to program the high-voltage shock waveform parameters. The central panel in the window displays the Waveform Settings (page 115), including the Pulse Width or Tilt settings for each programmed phase and therapy. The availability of parameters and data in the Waveform Settings panel depends on the setting of the Zone Configuration (page 89), Waveform Mode (page 114), and Waveform (page 114).

- Waveform (page 114)
- Waveform Mode (page 114)
- Shock Configuration. The direction that the high-voltage current travels based on the SVC Electrode and RV Polarity settings.
- RV Polarity (page 114)
- VF Shocks (Defib) and VT Shocks (CVRT) (page 115) buttons. See Waveform Settings (page 115).
- Tuned Waveform Help (page 116)
- DynamicTx Over-Current Detection (page 115)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Waveform

The Waveform parameter determines if a biphasic or a monophasic waveform is delivered during high-voltage therapy. The Waveform setting is used for all high-voltage therapies.

- A **Biphasic** waveform is generated by the concatenation of both positive-polarity and negative-polarity truncated exponential waveforms. The leading-edge voltage of the second phase of the waveform is 100% of the residual voltage of the first phase of the waveform.
- A **Monophasic** waveform is only the first half of a biphasic waveform.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Waveform Mode

The Waveform Mode parameter determines if the delivered high-voltage therapy waveform is based on Tilt or Pulse Width. This parameter determines the settings for the VF Shocks (Defib) and VT Shocks (CVRT) (page 115) parameters.

- **Tilt**. The percentage of the delivered energy either in a monophasic waveform or in the first phase of a biphasic waveform.
- **Pulse Width**. The amount of time it will take for 65% of the initial delivered voltage to dissipate in either a monophasic waveform or in the first phase of a biphasic waveform.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Shock Configuration

The Shock Configuration parameter determines how the high-voltage current travels between the SVC electrode, can, and RV electrode.

See also:

- Parameter Availability and Settings (page 197)

  Note

  - In devices with DynamicTx™ Over-Current Detection algorithm capability (page 185), you can program Shock Configuration to the RV to SVC setting (see DynamicTx Over-Current Detection algorithm (page 115)). However, you must confirm that the HV lead contains a working SVC coil.
  - Programming the Shock Configuration parameter to the RV to Can setting automatically programs the DynamicTx algorithm parameter to Off.

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

RV Polarity

The RV Polarity parameter determines the polarity of the RV electrode and the direction of current flow for the shock waveform.

- When the Waveform (page 114) parameter is set to Biphasic, the setting for the RV Polarity parameter determines the direction of current flow across the Shock Configuration setting. When the parameter is set to Anode (+), the current flows from the RV electrode to the destination of the Shock Configuration parameter. The Cathode (-) setting reverses this flow. The second phase of the biphasic high-voltage waveform is reversed.

- When the Waveform parameter is set to Monophasic, the RV electrode polarity is the same as the first phase of a Biphasic waveform.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

DynamicTx™ Over-Current Detection Algorithm

In devices with DynamicTx™ Over-Current Detection algorithm capability (page 185) connected to a dual-coil lead, the DynamicTx™ algorithm enables the device to automatically change the Shock Configuration and Shock Energy settings if the pulse generator detects an abnormally low lead impedance when high voltage therapy begins.

If an excessive amount of current is detected during high voltage therapy due to low lead impedance, the device stops the shock delivery and generates a high voltage lead issue marker on the Rhythm Display (see Markers (page 9)). An alert warning ("possible high voltage lead issue") is presented on the FastPath™ Summary and a patient notification is delivered. The next attempts at therapy during the same VT/VF episode are delivered using an alternative shock configuration.

If normal impedance is measured at the alternative setting, therapy is delivered. However, therapy is withheld if low impedance continues to be detected, and the DynamicTx algorithm switches the Shock Configuration to the next possible setting.

RV to SVC & Can. If the lead issue occurs when the programmed Shock Configuration setting is RV to SVC & Can, the algorithm changes the setting first to RV to Can. If low impedance is detected at the RV to Can setting, the algorithm changes the setting to RV to SVC. If low impedance is detected at the RV to SVC setting, then the algorithm changes the setting back to RV to SVC & Can and restarts the procedure.

RV to SVC. If the lead issue occurs when the programmed Shock Configuration setting is RV to SVC, the algorithm changes the setting first to RV to Can. If low impedance is detected at the RV to Can setting, then the algorithm switches to the RV to SVC setting and restarts the procedure.

The algorithm continues to search for a viable setting until the episode ends or a shock can be delivered.

Note

Programming the Shock Configuration parameter to the RV to Can setting automatically programs the DynamicTx algorithm parameter to Off.

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Waveform Settings

The Waveform Settings panel in the center of the DeFT Response™ Technology Settings (Shock Waveform) (page 114) window shows:

- Buttons to program the VF Shocks (Defib) and VT Shocks (CVRT) (page 115) (depending on the setting of the Waveform Mode (page 114) parameter) for one or two waveform phases (depending on the setting of the Waveform (page 114) parameter).
- The Estimated Defib and CVRT Tilt are based on a calculation using the last measured shock impedance measurement. This is available if the Waveform Mode (page 114) parameter is set to Pulse Width.
- The Estimated Defib and CVRT Pulse Width are based on a calculation of the capacitor strength and the last HV Lead Impedance measurement. This is available if the Waveform Mode (page 114) parameter is set to Pulse Width.
- The last measured Shock Impedance value
- If the Waveform Mode (page 114) parameter is set to Pulse Width, the panel shows a table of Tuned Waveform values to help you choose an appropriate VF Shocks and VT Shocks Pulse Width setting. To see all possible values in the table select the Tuned Waveform Help (page 116) button.

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

VF Shocks (Defib) and VT Shocks (CVRT)

The VF Shocks (Defib) and VT Shocks (CVRT) parameters determine the length of the defibrillation therapy (Defib) or cardioversion therapy (CVRT) shock waveform. Use these parameters to set the waveform's Tilt or Pulse Width, depending on the type of shock set by the Waveform Mode (page 114) parameter. When the Waveform parameter is set to Biphasic, you can manually program both phases.

To assist in setting this parameter, the Waveform Settings panel shows the estimated shock waveform Pulse Width or Tilt (depending on the setting for the Waveform Mode parameter), based on the device settings and measurements.

The available settings are shown in the table below.

Table 23. Settings for the high-voltage output Tilt and Pulse Width

Waveform	Therapy	HV Output Mode	
		Tilt	Pulse Width
Monophasic	VF Shocks	42; 50; 60; 65% (Nominal: 65%)	3.0; 3.5; … 12.0 ms (Nominal: 5.5 ms)

Table 23. Settings for the high-voltage output Tilt and Pulse Width

Waveform	Therapy	HV Output Mode	
		Tilt	Pulse Width
	VT Shocks	Same as Defib; 42; 50; 60; 65% (Nominal: 65%)	Same as Defib; 3.0; 3.5; … 12.0 ms (Nominal: Same as Defib)
Biphasic - 1st Phase	VF Shocks	42; 50; 60; 65% (Nominal: 65%)	3.0; 3.5; … 12.0 ms (Nominal: 5.5 ms)
	VT Shocks	Same as Defib; 42; 50; 60; 65% (Nominal: 65%)	Same as Defib; 3.0; 3.5; … 12.0 ms (Nominal: Same as Defib)
Biphasic - 2nd Phase[123]	VF Shocks	Equal to first phase	1.2; 1.5; 2.0; … 12.0 ms (Nominal: 5.5 ms)
	VT Shocks	Equal to first phase	Same as Defib; 1.2; 1.5; 2.0; … 12 ms (Nominal: Same as Defib)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Tuned Waveform Help

Note

In order to ensure a 10 J safety margin, verify that the maximum delivered energy at the new Pulse Width setting is at least 10 J greater than the defibrillation threshold (DFT).

The values presented in these tables are based on a theory of biphasic defibrillation waveforms ("Burping Theory[124]"). They should only be used as a supplement to the values listed in the section on Waveform Settings (page 115)

Use the tables below and these instructions to guide you in the selection of an appropriate Pulse Width setting for the VF Shocks (Defib) and VT Shocks (CVRT) (page 115) parameters.

Instructions for Tuned Waveform Help

1. Note the Shock Impedance measurement on the Waveform Settings (page 115) panel.
2. Look in the first column in the appropriate table for your device (based on battery model) for the corresponding Shock Impedance value (R value, in Ω).

   The first table below is for devices with Battery Model 2356 (page 182) (30 J/830 V) and Battery Model 2950 (page 183) (36 J/875 V).
   The second table below is for devices with Battery Model 2555 (page 182) (36 J/830 V), Battery Model 2753 (page 183) (40 J/875 V), and Battery Model 2850 (page 183) (40 J/890 V)
3. Scan across the row to the first two columns. The values in the "Typical" column for P1 (Phase 1 of the biphasic shock) and P2 (Phase 2) show a typical response. You can program these settings for the VF Shocks (Defib) and VT Shocks (CVRT) (page 115) parameters and attempt to defibrillate the patient again.
4. If the shock delivered using the "Typical" settings was not effective, attempt to defibrillate again using the Pulse Width settings first in the "Faster" column. If that is not acceptable, attempt to defibrillate again using settings in the "Slower" column.

Note

Tips for using these tables:

- When removing the SVC coil, make sure to double-check Shock Impedance due to the likely change in measured impedance.
- If P1 or P2 are not altered by more than half a millisecond, little has changed.
- Optimization may not help a poor vector.
- Common sense preempts the tables

Table 24. ICD alternative defibrillation biphasic waveform Pulse Width setting recommendations for devices with Battery Model 2356 (page 182) (30 J/830 V) and Battery Model 2950 (page 183) (36 J/875 V)

R (Ω)	Block #1	Block #2	Block #3
	Typical	Faster	Slower

[123] The second phase must be less than or equal to the first phase.
[124] Kroll MW. A minimal model of the single capacitor biphasic defibrillation waveform. PACE 1994; 17:1782 – 1792.

Table 24. ICD alternative defibrillation biphasic waveform Pulse Width setting recommendations for devices with Battery Model 2356 (page 182) (30 J/830 V) and Battery Model 2950 (page 183) (36 J/875 V)

R (Ω)	Block #1		Block #2		Block #3	
	Typical		Faster		Slower	
	P1 (ms)	P2 (ms)	P1 (ms)	P2 (ms)	P1 (ms)	P2 (ms)
30	3.0	3.0	N/A	N/A	3.5	3.5
32	3.0	3.0	3.0	2.5	3.5	3.5
34	3.5	3.5	3.0	2.5	N/A	N/A
36	3.5	3.5	3.0	2.5	4.0	4.0
38	3.5	3.5	3.0	2.5	4.0	4.0
40	3.5	3.5	3.0	2.0	4.0	4.0
42	3.5	3.5	3.0	2.0	4.0	4.0
44	3.5	3.0	3.0	2.0	4.0	4.0
46	4.0	3.5	3.0	2.0	4.5	4.5
48	4.0	3.5	3.0	2.0	4.5	4.5
50	4.0	3.0	3.5	2.0	4.5	4.5
52	4.0	3.0	3.5	2.0	4.5	4.5
54	4.0	3.0	3.5	2.0	4.5	4.0
56	4.0	3.0	3.5	2.0	5.0	4.5
58	4.0	3.0	3.5	2.0	5.0	4.5
60	4.0	3.0	3.5	2.0	5.0	4.0
62	4.0	3.0	3.5	2.0	5.0	4.0
64	4.0	3.0	3.5	2.0	5.0	4.0
66	4.0	3.0	3.5	2.0	5.0	4.0
68	4.0	3.0	4.0	2.0	5.0	4.0
70	4.0	3.0	4.0	2.0	5.5	4.0
72	4.0	3.0	4.0	2.0	5.5	4.0
74	4.0	3.0	4.0	2.0	5.5	4.0
76	5.0	3.0	4.0	2.0	5.5	4.0
78	5.0	3.0	4.0	2.0	5.5	4.0
80	5.0	3.0	4.0	2.0	5.5	4.0
82	5.0	3.0	4.0	2.0	5.5	3.5
84	5.0	3.0	4.0	2.0	6.0	4.0
86	5.0	3.0	4.0	2.0	6.0	4.0
88	5.0	2.5	4.0	2.0	6.0	4.0
90	5.0	2.5	4.5	2.0	6.0	3.5
92	5.0	2.5	4.5	2.0	6.0	3.5
94	5.5	3.0	4.5	2.0	6.0	3.5
96	5.5	3.0	4.5	2.0	6.0	3.5
98	5.5	3.0	4.5	2.0	6.0	3.5
100	5.5	3.0	4.5	2.0	6.0	3.5
102	5.5	2.5	4.5	2.0	6.5	3.5
104	5.5	2.5	4.5	2.0	6.5	3.5
106	5.5	2.5	4.5	2.0	6.5	3.5
108	5.5	2.5	4.5	2.0	6.5	3.5

Table 25. ICD alternative defibrillation biphasic waveform Pulse Width setting recommendations for devices with Battery Model 2555 (page 182) (36 J/830 V), Battery Model 2753 (page 183) (40 J/875 V), and Battery Model 2850 (page 183) (40 J/890 V)

R (Ω)	Block #1		Block #2		Block #3	
	Typical		Faster		Slower	
	P1 (ms)	P2 (ms)	P1 (ms)	P2 (ms)	P1 (ms)	P2 (ms)

Table 25. ICD alternative defibrillation biphasic waveform Pulse Width setting recommendations for devices with Battery Model 2555 (page **182**) (36 J/830 V), Battery Model 2753 (page **183**) (40 J/875 V), and Battery Model 2850 (page **183**) (40 J/890 V)

R (Ω)	Block #1		Block #2		Block #3	
	Typical		Faster		Slower	
30	3.5	3.5	3.0	2.5	N/A	N/A
32	3.5	3.5	3.0	2.5	4.0	4.0
34	3.5	3.5	3.0	2.0	4.0	4.0
36	3.5	3.5	3.0	2.0	4.0	4.0
38	3.5	3.0	3.0	2.0	4.0	4.0
40	4.0	3.5	3.0	2.0	4.5	4.5
42	4.0	3.5	3.0	2.0	4.5	4.5
44	4.0	3.0	3.5	2.0	4.5	4.5
46	4.0	3.0	3.5	2.0	4.5	4.5
48	4.0	3.0	3.5	2.0	4.5	4.0
50	4.0	3.0	3.5	2.0	5.0	4.5
52	4.5	3.0	3.5	2.0	5.0	4.0
54	4.5	3.0	3.5	2.0	5.0	4.0
56	4.5	3.0	3.5	2.0	5.0	4.0
58	4.5	3.0	3.5	2.0	5.0	4.0
60	4.5	3.0	4.0	2.0	5.5	4.0
62	4.5	3.0	4.0	2.0	5.5	4.0
64	4.5	3.0	4.0	2.0	5.5	4.0
66	5.0	3.0	4.0	2.0	5.5	4.0
68	5.0	3.0	4.0	2.0	5.5	4.0
70	5.0	3.0	4.0	2.0	5.5	4.0
72	5.0	3.0	4.0	2.0	5.5	3.5
74	5.0	3.0	4.0	2.0	6.0	4.0
76	5.0	3.0	4.0	2.0	6.0	4.0
78	5.0	2.5	4.0	2.0	6.0	4.0
80	5.0	2.5	4.5	2.0	6.0	3.5
82	5.5	3.0	4.5	2.0	6.0	3.5
84	5.5	3.0	4.5	2.0	6.0	3.5
86	5.5	3.0	4.5	2.0	6.0	3.5
88	5.5	2.5	4.5	2.0	6.5	3.5
90	5.5	2.5	4.5	2.0	6.5	3.5
92	5.5	2.5	4.5	2.0	6.5	3.5
94	5.5	2.5	4.5	2.0	6.5	3.5
96	5.5	2.5	4.5	2.0	6.5	3.5
98	5.5	2.5	4.5	2.0	6.5	3.5
100	5.5	2.5	4.5	2.0	6.5	3.5
102	6.0	2.5	4.5	2.0	6.5	3.5
104	6.0	2.5	4.5	2.0	6.5	3.5
106	6.0	2.5	5.0	2.0	7.0	3.5
108	6.0	2.5	5.0	2.0	7.0	3.5

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > DeFT Response Settings (Shock Waveform) button

Redetection & Post Detection Criteria

The programmer allows you to change other detection criteria not used for routine programming but that may be necessary to fine-tune a device in some patients. These criteria include:

- VT Redetection (page 119)
- Sinus Redetection (page 119)
- Post Detection Interval/Rate (page 119)

See also:

- Rate Zone Legend (page 124)
- Post Detection Description (page 120)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Redetection & Post-Detection button

VT Redetection

The VT Redetection parameter determines the number of binned tachycardia intervals necessary for the redetection of tachycardia after VT, VT-1, or VT-2 therapy.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Redetection & Post-Detection button

Note

No. Intervals (page 90). The number of VT Redetection intervals must be less than or equal to the programmed number of VT, VT-1, or VT-2 detection intervals.

Zone Configuration (page 89). In the 3 Zone configuration, VT Redetection defines the number of binned intervals required for tachycardia redetection in the VT-1 and VT-2 zones.

SVT Discriminators (page 93). When a tachycardia is detected but diagnosis is inhibited due to the SVT discriminators, the device requires six intervals for tachycardia redetection, regardless of the programmed VT Redetection setting.

Sinus Redetection

The Sinus Redetection parameter determines the number of binned sinus intervals required after the detection of a tachyarrhythmia to consider the arrhythmia terminated. A Fast (3 intervals) setting decreases the number of intervals necessary for the redetection of a sinus rhythm. A Slow (7 intervals) setting increases the number of intervals for redetection of sinus rhythm.

Changing the Zone Configuration (page 89) does not nominalize this parameter.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Redetection & Post-Detection button

Post Detection Interval/Rate

The Post Detection Interval/Rate parameter determines the interval/rate used for the redetection of an arrhythmia slowed by device therapy. Once device therapy is delivered and the arrhythmia cycle length remains shorter than the post detection interval/rate for the programmed number of VT Redetection (page 119) intervals, the device delivers the next therapy.

The names and number of Post Detection Interval/Rate buttons available vary based on the Zone Configuration (page 89). The parameter settings for each Post Detection Interval/Rate are listed in the following table.

Table 26. Post Detection Interval/Rate settings[125]

Post Detection Interval/Rate	Zone Configuration		
	1 Zone	2 Zones	3 Zones

[125] This is the full range of settings displayed by the programmer. Depending on other parameter settings, the programmer may not allow all settings to be programmed.

Table 26. Post Detection Interval/Rate settings[125]

Post Detection Interval/Rate	Zone Configuration		
	1 Zone	2 Zones	3 Zones
Post VT or Post VT-1	N/A	Same as VT to VT +30 ms in 5 ms increments (Nominal: Same as VT) Absolute Range: 300, 310, … 590 ms	Same as VT-1 to VT-1 +30 ms in 5 ms increments (Nominal: Same as VT-1) Absolute Range: 300, 305, … 590 ms
Post VF or Post VF/VT-2	Same as VF or VF +50 ms in 10 ms increments (Nominal: Same as VF) Absolute Range: 200, 210, … 590 ms	Same as VT to Same as VF in 10 ms increments (Nominal: Same as VT) Absolute Range: 200, 210, … 590 ms	Same as VT-1 to Same as VT-2 in 10 ms increments (Nominal: Same as VT-1) Absolute Range: 200, 210, … 590 ms

Accessed From: Parameters button > Redetection & Post-Detection button

Post Detection Description

- 1 Zone Configuration (page 120)
- 2 Zones Configuration (page 120)
- 3 Zones Configuration (page 120)

1 Zone Configuration

Changing the Post VF Detection Interval/Rate (page 90) setting can be useful in the 1 Zone (page 123) configuration for a patient whose initial tachyarrhythmia is routinely slowed by therapy but remains hemodynamically compromised. In this case, the Post VF Detection Interval/Rate Interval parameter can be reprogrammed to allow detection of this slower rhythm.

If the Post VF Detection Interval/Rate parameter is left at the nominal setting, intervals from 0 to 50 ms longer than the VF Detection Interval/Rate parameter are not counted toward either redetection of sinus or redetection of fibrillation.

Appropriately setting the Post VF Detection Interval/Rate parameter assures that the next VF therapy is delivered if the arrhythmia cycle length is temporarily lengthened by therapy. This prevents the device from identifying a new episode and delivering the same, previously ineffective therapy.

If the Post VF Detection Interval/Rate parameter is changed from the nominal setting, redetection of sinus requires the average interval to be longer than the programmed Post VF Detection Interval/Rate setting.

See also:

- ShockGuard™ Technology Settings (Zone Configuration Window) (page 89)
- Detection Criteria (page 89)
- Redetection & Post Detection Criteria (page 119)

2 Zones Configuration

Changing the Post VF Detection Interval/Rate parameter can be useful in the 2 Zones (page 123) configuration for a patient whose arrhythmia is routinely converted by VF therapy to a fast sinus tachycardia within the VT Detection Interval/Range. It may not be appropriate to attempt to treat that rhythm. The Post VF Detection Interval/Rate setting could, therefore, be made shorter than the interval of the sinus tachycardia. Intervals longer than the Tach Detection Interval/Rate setting are counted toward sinus redetection.

After VT therapy has been delivered, the Post VT Detection Interval/Rate setting defines the criteria for tachycardia redetection.

If VT therapy slows the arrhythmia but the interval is still short enough to satisfy the Post VT Detection Interval/Rate criteria, the device delivers additional VT therapy. Intervals that are longer than the Post VT Detection Interval/Rate setting are counted toward sinus redetection.

After VF therapy has been delivered, the Post VF Detection Interval/Rate setting is used as the criteria for VF redetection.

If VF therapy was delivered as the result of expiration of the VT Therapy Timeout (page 105) period, redetection occurs if the arrhythmia cycle length meets either the VT Therapy Timeout or the Post VF Detection Interval/Rate criteria for a minimum of six intervals. The programmed VT Therapy Timeout detection time does not have to expire again before delivery of the next therapy.

See also:

- ShockGuard™ Technology Settings (Zone Configuration Window) (page 89)
- Detection Criteria (page 89)
- Redetection & Post Detection Criteria (page 119)

3 Zones Configuration

After VT-1 therapy has been delivered in the 3 Zones (page 123) configuration, the Post VT-1 Detection Interval/Rate setting defines the criteria for VT-1 redetection. If VT-1 therapy slows the arrhythmia but the interval is still short enough to satisfy the Post VT-1 Detection

Interval/Rate criteria, the device delivers additional VT-1 therapy. Intervals longer than the Post VT-1 Detection Interval/Rate setting are counted toward sinus redetection.

After delivering the VT-1 therapy in the 3 Zone configuration, the average of the intrinsic intervals must be longer than the programmed Post VT-1 Detection Interval/Rate setting for the device to redetect sinus rhythm.

After delivering the VT-2 or VF therapy, the average of the intrinsic intervals must be longer than the programmed VT-1 Detection Interval/Rate setting for the device to redetect sinus rhythm.

After VF therapy has been delivered, the Post VF/VT-2 Detection Interval/Rate setting is used as the criteria for VF Redetection. Thus, if the VF therapy slows the arrhythmia, but the interval is still short enough to satisfy the Post VF/VT-2 Detection Interval/Rate criteria, the device delivers additional VF therapy.

When the Post VF/VT-2 Detection Interval/Rate setting is changed from the nominal setting, if a VF therapy slows the rate to less than the Post VF/VT-2 Interval/Rate setting but faster than VT-1, the device monitors the arrhythmia but does not give additional therapy until the rhythm accelerates or the VT Therapy Timeout (page 105) period expires.

See also:

- ShockGuard™ Technology Settings (Zone Configuration Window) (page 89)
- Detection Criteria (page 89)
- Redetection & Post Detection Criteria (page 119)

Post-Shock Pacing

From the Post-Shock Pacing window, you can change the settings for the following parameters:

- Post-Shock Mode (page 121)
- Post-Shock Base Rate (page 121)
- Post-Shock Pause (page 121)
- Post-Shock Duration (page 122)
- Pulse Amplitude (page 122)
- Pulse Width (page 122)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Post-Shock Mode

The Post-Shock Mode parameter determines the pacing mode used after a high-voltage shock is delivered. The Post-Shock Mode begins when sinus rhythm is redetected. The settings available depend on the programmed pacing Mode (page 61) setting and are shown in the table below.

Table 27. Post-Shock Mode settings

Pacing Mode	Available Post-Shock Mode for CRT-Ds and Dual-Chamber ICDs	Available Post-Shock Mode for Single-Chamber ICDs
AAI(R)	Off, AAI, VVI, DDI	N/A
VVI(R)	Off, VVI, DDI	Off, VVI
DDI(R)	Off, AAI, VVI, DDI	N/A
DDD(R)	Off, AAI, VVI, DDI, DDD	N/A
Pacer Off, AOO(R),VOO(R) or DOO(R)	N/A	N/A

See also:

- Redetection & Post Detection Criteria (page 119)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Post-Shock Base Rate

The Post-Shock Base Rate parameter sets the minimum pacing rate after a high-voltage shock is delivered. The Post-Shock Base Rate is effective immediately after the Post-Shock Pause (page 121) interval.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Post-Shock Pause

The Post-Shock Pause parameter is the length of time that must pass after a high-voltage shock is delivered and post-shock pacing can begin. In some patients, pacing immediately after a high-voltage shock is delivered may be arrhythmogenic.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Post-Shock Duration

The Post-Shock Duration parameter is the length of time that pacing, using the post-shock pacing parameters, continues after a high-voltage shock is delivered. The Post-Shock Duration interval begins immediately after the high-voltage shock is delivered.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

> **Note**
>
> **Interactions**. During the Post-Shock Duration interval, the Sensor (rate-responsive pacing) and Rate Responsive AV Delay (page 70) parameters are disabled.

Pulse Amplitude

The post-shock Pulse Amplitude parameter determines how much electrical potential is applied to the myocardium during pacing that follows the delivery of a high-voltage shock. The post-shock Pulse Amplitude setting must be equal to or greater than the permanent pacing Pulse Amplitude (page 108) setting. The post-shock Pulse Amplitude setting is effective immediately after the Post-Shock Pause (page 121) interval.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Pulse Width

The post-shock Pulse Width parameter determines how long the pulse amplitude is applied to the myocardium during pacing that follows the delivery of a high-voltage shock. The post-shock Pulse Width setting must be equal to or greater than the permanent pacing Pulse Width (page 108) setting. The post-shock Pulse Width setting is effective immediately after the Post-Shock Pause (page 121) interval.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Post-Shock Pacing button

Capacitor Maintenance

The Capacitor Maintenance window shows the voltage that the high-voltage capacitors will charge to for capacitor maintenance charging. You can change the setting of the Charge Interval (page 122).

See also:

- Capacitor test (page 39)
- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Parameters button > Tachy tab > Capacitor Maintenance button

Charge Interval

The Charge Interval parameter determines the time between automatic capacitor maintenance charges.

> **Note**
>
> For devices with Battery Model 2356 (page 182) and Battery Model 2555 (page 182), when the battery voltage falls to between 2.56 and 2.86 V, the Charge Interval parameter only allows the 1 month setting[126]. See Factors That Affect Device Longevity (page 322)

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Tachy tab > Capacitor Maintenance button

[126] For devices with Battery Model 2753, Battery Model 2850, and Battery Model 2950, the 4, 5, and 6 month settings are available.

Tachy Therapy Detailed Descriptions

- Zone Descriptions (page 123)
- Rate Zone Legend (page 124)
- Tachyarrhythmia Detection Description (page 123)
- SVT Discrimination Description (page 124)
- Tachyarrhythmia Therapy Description (page 131)

Zone Descriptions

The following tachyarrhythmia therapy zone configurations are available:

- Off (page 123)
- 1 Zone (page 123)
- 2 Zones (page 123)
- 3 Zones (page 123)

Note

In devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193), this feature is applicable in all therapy zones.

Off

The Off configuration does not allow tachyarrhythmia diagnosis or therapy. The device does not store diagnostic information or episodes associated with ventricular tachyarrhythmias. Episodes induced by device-based testing are stored. Morphology Scoring Window (page 104) is available.

This configuration is useful during:

- An immediate postoperative period when there may be an increased incidence of supraventricular arrhythmias
- A period when the patient is under continuous surveillance in the hospital
- Surgery using electrosurgical equipment that might trigger high-voltage outputs from the device
- Device implant or explant

Use the Tachy Therapy Enable/Disable (page 168) button to temporarily disable tachy therapies.

1 Zone

The 1 Zone configuration allows detection of a single tachyarrhythmia rate (referred to as "fibrillation").

SVT discriminators are not available in this device configuration.

2 Zones

The 2 Zones configuration recognizes two tachyarrhythmia detection rates:

- Tachycardia (VT), the slower rate
- Fibrillation (VF), the faster rate

SVT discriminators are available in the VT rate zone. See SVT Discrimination Details (page 92).

3 Zones

The 3 Zone configuration recognizes three tachyarrhythmia detection rates:

- Tachycardia (VT-1), the slowest rate
- Tachycardia (VT-2), a faster rate
- Fibrillation (VF), the fastest rate

SVT discriminators are available in the VT-1 and VT-2 rate zones. See SVT Discrimination Details (page 92).

Tachyarrhythmia Detection Description

Detection of a tachyarrhythmia is based on two criteria: (1) the Detection Interval/Rate (page 90); and (2) the No. Intervals (page 90). The device classifies detected events based on both the current interval and a running interval average (an average of the current interval and the previous three intervals). To satisfy the detection criteria and be counted toward detection, both the current interval and the running interval average must be shorter than or equal to the longest tachyarrhythmia Detection Interval/Rate. The interval is classified as the shorter of either (1) the interval or (2) the interval average. Detection occurs when a detection zone classifies its required No. Intervals.

After therapy is delivered or a rhythm is classified as SVT, the device must classify a minimum number of intervals before it redetects a tachyarrhythmia or classifies the rhythm as SVT. See SVT Discrimination Details (page 92), VT Redetection (page 119), Post Detection Interval/Rate (page 119), and Tachyarrhythmia Therapy Description (page 131).

After several intervals are classified during an episode, the device forces a **mode switch** to a non-tracking pacing mode and disables rate-responsive pacing (Sensor) to prevent high-rate pacing during an episode from potentially masking an arrhythmia.

A **bigeminal rhythm** may have intervals as well as running interval averages faster than the programmed Detection Interval/Rate. To protect against delivering therapy into a bigeminal rhythm, the device must detect more tachyarrhythmia intervals than sinus intervals before it delivers therapy.

If discriminators are enabled, they must classify a rhythm as VT before the device will deliver tachycardia therapy. See SVT Discrimination Details (page 92).

Rate Zone Legend

The Rate Zone Legend is a graphical display of the Detection Interval/Rate (page 90) settings for each rate zone as well as the SVT Discrimination (page 91) cutoff. The SVT Upper Limit (page 93) interval/rate is shown if a specific interval is selected for the SVT Discrimination Zone cutoff.

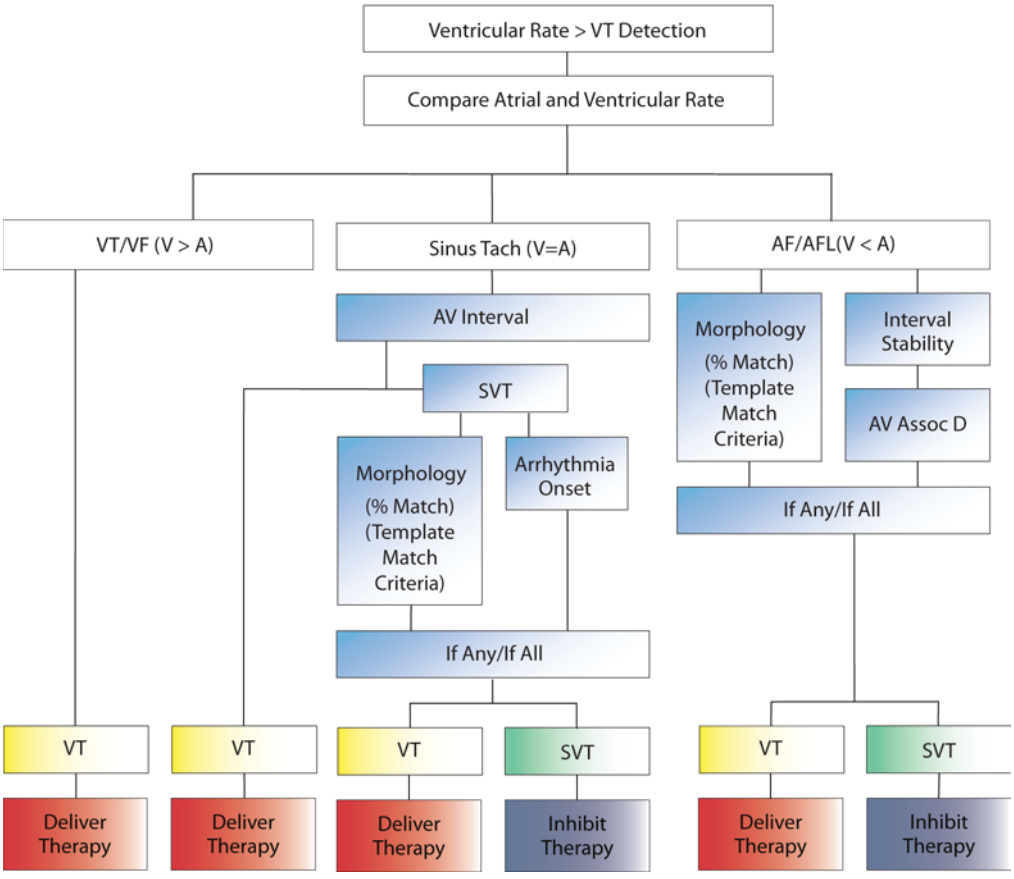
SVT Discrimination Description

- Rate Branch Detailed Description (page 124)
- Morphology Detailed Description (page 125)
- Interval Stability Detailed Description (page 125)
- Arrhythmia Onset Description (page 125)
- Sudden Onset Description (page 126)
- SVT Discrimination Criteria Programming Guidelines (page 126)
- SVT Discrimination Timeout Description (page 131)

Rate Branch Detailed Description

The following figure diagrams how the Rate Branch discriminator works with the other SVT discriminators to classify a rhythm as VT or SVT in the Dual Chamber discrimination setting.

Figure 9. Rate Branch flow diagram



- **AF/AFL Rate Branch**. When the ventricular rate is less than the atrial rate (V<A), Morphology (page 95) and Interval Stability (page 101) are available to further qualify the rhythm. These discriminators can help distinguish VT from atrial fibrillation or atrial flutter.
- Rate Branch **(page 94).** When the right-ventricular rate is the same as the atrial rate (V=A), Morphology, and Sudden Onset (page 103) or Chamber Onset (page 102) is available to further qualify the sinus tachycardia rhythm. These discriminators can help distinguish 1:1 retrograde VT from sinus tachycardia or atrial tachycardia with 1:1 conduction.

In the Sinus Tach rate branch, the AV Interval Delta (page 95) may be used as a pre-qualifier. If the AV Interval Delta determines that there is dissociation between the atrial and ventricular rhythms, Morphology and Sudden Onset or Chamber Onset (page 102) are not evaluated and diagnosis occurs immediately.

- **VT/VF Rate Branch**. When the ventricular rate is greater than the atrial rate (V>A), no discrimination criteria are used to qualify the diagnosis. Diagnosis occurs and the device initiates therapy.

Morphology Detailed Description

The Morphology discriminator compares the shape (morphology) of sinus complexes to an arrhythmia's complexes to help distinguish SVT from VT. In devices with Far Field MD™ Morphology Discrimination Capability (page 187), you can select which configuration to use to select the complexes: Far Field or Original MD. These settings are explained here: see Morphology Type.

The Morphology discriminator compares each QRS complex in a group of recent complexes (Morphology Window Size (page 97)) to a stored template complex. A morphology score is assigned, indicating the percentage similarity of the complex to the stored template. See Morphology Template (page 103).

When Morphology (page 95) is set to On, scoring begins when the first arrhythmia interval of an episode is detected or when scoring is requested by the programmer (for example, during real-time EGM display). During an episode, scoring stops once the initial diagnosis of VT has been made. Therefore, no scores appear on the EGM after charging begins or during redetection. Scoring starts again for a few complexes after sinus rhythm has been redetected. See Tachyarrhythmia Detection Description (page 123).

When Morphology is set to Passive, the device stores diagnostic information, but the Morphology discriminator does not affect diagnosis. For CRT-Ds and Dual-Chamber ICDs, Morphology is programmed independently for the AF/AFL and Sinus Tach rate branches. In devices with Far Field MD Morphology Discrimination Capability, the Far Field MD/SecureSense™ Configuration parameter can also be independently programmed.

Interval Stability Detailed Description

The Interval Stability discriminator can help distinguish between atrial fibrillation (AF) and VT. Interval Stability (page 101) can be set to Off and to the following settings:

- **On**. When the Interval Stability discriminator is set to On, the device stores diagnostic information on AV association (AVA) or sinus interval history (SIH) as well as the stability of the arrhythmia; however, only the Interval Stability discriminator affects the diagnosis of a rhythm.
- **Passive**. When the Interval Stability discriminator is set to Passive, the device stores diagnostic information on AVA or SIH as well as the stability of the arrhythmia, but the Interval Stability discriminator does not affect the diagnosis of a rhythm.
- **On w/AVA**. When the Interval Stability discriminator is set to On w/AVA and the rhythm is classified as VT, the measured AV Association Delta (the difference between the second longest and the second shortest AV interval in a recent group of intervals defined by the Interval Stability Window Size (page 102)) is examined. If the measured AV Association Delta shows stable AV intervals, the rhythm is classified as SVT. If the AV intervals are unstable, the rhythm is classified as VT. This setting may be useful in recognizing atrial flutter. See Interval Stability Window Size (page 102).
- **On w/SIH**. When the Interval Stability discriminator is set to On w/SIH (Sinus Interval History) and the rhythm is classified as VT, the number of sinus intervals or average intervals during detection of the arrhythmia (the measured SIH Count) is examined. If the measured SIH Count is less than the programmed SIH Count (page 101), the rhythm is classified as VT. If the measured SIH Count is equal to or greater than the programmed Interval Stability: SIH Count, the rhythm is classified as SVT. When Interval Stability is On w/SIH and the rhythm is classified as SVT, the SIH Count is not checked. This setting may be useful in recognizing AF that has regularized.

Arrhythmia Onset/Sudden Onset Detailed Description

In devices with Chamber Onset Discrimination Capability (page 184) and dual-chamber capability, the clinician has two options for using the onset of the tachyarrhythmia as a discriminator for diagnosing SVT: Chamber Onset and Sudden Onset. All other devices provide only the Sudden Onset discriminator.

Chamber Onset Description

The Chamber Onset discriminator compares the timing of the rate increase in the atrium to that of the ventricle. If the onset of the rate increase occurs in the atrium before the ventricle, than the arrhythmia is considered an SVT. Alternatively, a rate increase occurring in the ventricle before the atrium is considered to be a VT. The algorithm also factors in how quickly the ventricular rate changed (see Sudden Onset (page 103)), and will also diagnose an SVT based on that criterion. The chamber that drove the rate change is provided in either the VT/VF or SVT Episode Detail. See also Chamber Onset (page 102).

Since the Chamber Onset algorithm looks for a defined and sustained change in rate in either the atrium or the ventricle just prior to detection of the arrhythmia, frequent PACs very close to the arrhythmia initiation, or a highly variable ventricular rate may cause the feature to misdiagnose a VT with 1:1 retrograde conduction as an AT with 1:1 antegrade conduction. Additionally, if the arrhythmia initiation occurs at a rate slower than the programmed VT detection rate and then gradually accelerates into the VT zone, it is possible that Chamber Onset will misdiagnose the arrhythmia as having a gradual onset and may misdiagnose the VT as SVT.

When the Chamber Onset parameter is set to Passive, the device stores diagnostic information about the onset of an arrhythmia, but the Chamber Onset discriminator does not affect diagnosis. If the Chamber Onset discriminator is programmed On, the device stores diagnostic information and considers the arrhythmia initiation pattern before diagnosing VT.

Sudden Onset Description

The Sudden Onset discriminator compares the average interval to previous interval averages to determine whether the difference (either absolute or percentage change) is large enough to satisfy the Sudden Onset criterion. Since average intervals are used for the comparison, a single long interval during a gradual increase in rate may (appropriately) result in failure to satisfy the Sudden Onset criterion. Alternatively, after an abrupt change in cycle length greater than the selected Onset Delta (page 103) setting, a single long interval amid several short intervals will probably still allow the Sudden Onset criterion to be satisfied. Additionally, if the arrhythmia initiation occurs at a rate slower than the programmed VT detection rate and then gradually accelerates into the VT zone, it is possible that the Sudden Onset discriminator will misdiagnose the arrhythmia as having a gradual onset and may misdiagnose the VT as SVT.

When Sudden Onset is Passive, the device stores diagnostic information about the onset of an arrhythmia, but the Sudden Onset discriminator does not affect diagnosis. If Sudden Onset is programmed On, the device stores diagnostic information and considers the Onset Delta before diagnosing VT.

Chamber Onset vs. Sudden Onset

The Chamber Onset discriminator is a good choice for avoiding inappropriate therapies in patients who are at risk for rapidly conducted atrial tachycardias with 1:1 antegrade conduction that overlaps with their expected symptomatic VT rate. For patients that are susceptible to VT with 1:1 retrograde conduction that overlaps with their expected sinus rate, Sudden Onset may be a preferred choice.

SVT Discrimination Criteria Programming Guidelines

- Programming Considerations (page 127)
- Ventricular Only SVT Discrimination (page 128)
- Dual Chamber SVT Discrimination (page 129)
- Nominal Settings (page 129)

The utility of the SVT Discriminators (page 93) is summarized in the following table.

Table 28. Summary of SVT discrimination criteria and their uses

SVT Discriminator	Possible Application	Considerations in Selecting
Rate Branch (page 94)	Distinguish SVT with rapid atrial rates from VT	Use only if an atrial lead is in place and reliable atrial sensing is present.
Morphology (page 95)	Distinguish normally conducted rhythms, such as sinus tachycardia or atrial fibrillation, from VT	Use only if the baseline rhythm % Match (page 96) scores are near 100% during baseline rhythm. May be inappropriate for use in patients with rate-related bundle-branch blocks or in patients with VT morphology similar to their baseline rhythm. Morphology collects its automatic template during sinus rhythm and is unlikely to recognize the rate-related bundle branch block as matching sinus. In these cases, a manual template can be collected during rapid atrial pacing in-clinic. In some cases, AF can conduct to the ventricle with some degree of aberrancy. For these patients, it is valuable to have Morphology turned On with Interval Stability in an "If Any" Diagnosis Criteria configuration.
Sudden Onset (page 103)	Distinguish sinus tachycardia from VT	May be inappropriate for use in patients with exercise induced VT or very slow VT. If the exercise-induced VT rate is not faster than the sinus tachycardia rate, consider setting the Sudden Onset parameter to passive or use it with Morphology and an "If Any" Diagnosis criteria. If the patient's sinus rate is unlikely to be in the VT detection zone, the Sudden Onset discriminator may not be useful. May be inappropriate for patients with atrial tachycardias that conduct to the ventricles on a 1:1 basis.
Chamber Onset (page 102)	Distinguish atrial tachycardia and 1:1 SVTs from VT	Use in patients with Atrial Flutter and other SVTs likely to fall into the V=A rate branch. Use in combination with Morphology in "If All" Diagnosis criteria. May be inappropriate for use in patients with exercise induced VT or very slow VT. If the exercise-induced VT rate is not faster than the sinus tachycardia rate, consider setting the Chamber Onset parameter to passive or use it with Morphology and an "If Any" Diagnosis criteria.
Interval Stability (page 101)	Distinguish atrial fibrillation from VT	Use with caution if the patient's VT has exhibited rate variability
Interval Stability with SIH	Distinguish atrial fibrillation with rate regularization from VT	Use with caution if the patient's VT has exhibited rate variability

Table 28. Summary of SVT discrimination criteria and their uses

SVT Discriminator	Possible Application	Considerations in Selecting
Interval Stability with AVA	Distinguish atrial flutter from VT	Use with caution if the patient's VT has exhibited rate variability

Programming Considerations

When making changes to the SVT Discrimination parameter settings, consider that each individual parameter setting influences whether the device defines a rhythm as VT or SVT. The figures below represent the range of settings for each discriminator; the center values represent the nominal settings of each discriminator in devices with DecisionTx™ Programming Capability and with Far Field MD Morphology Discrimination Capability (page 187).

Figure 10. SVT discrimination parameters for devices with DecisionTx Programming Capability (for the Number of Intervals parameter, the nominal setting varies according to the Zone Configuration setting and the device). See tables below for nominal settings

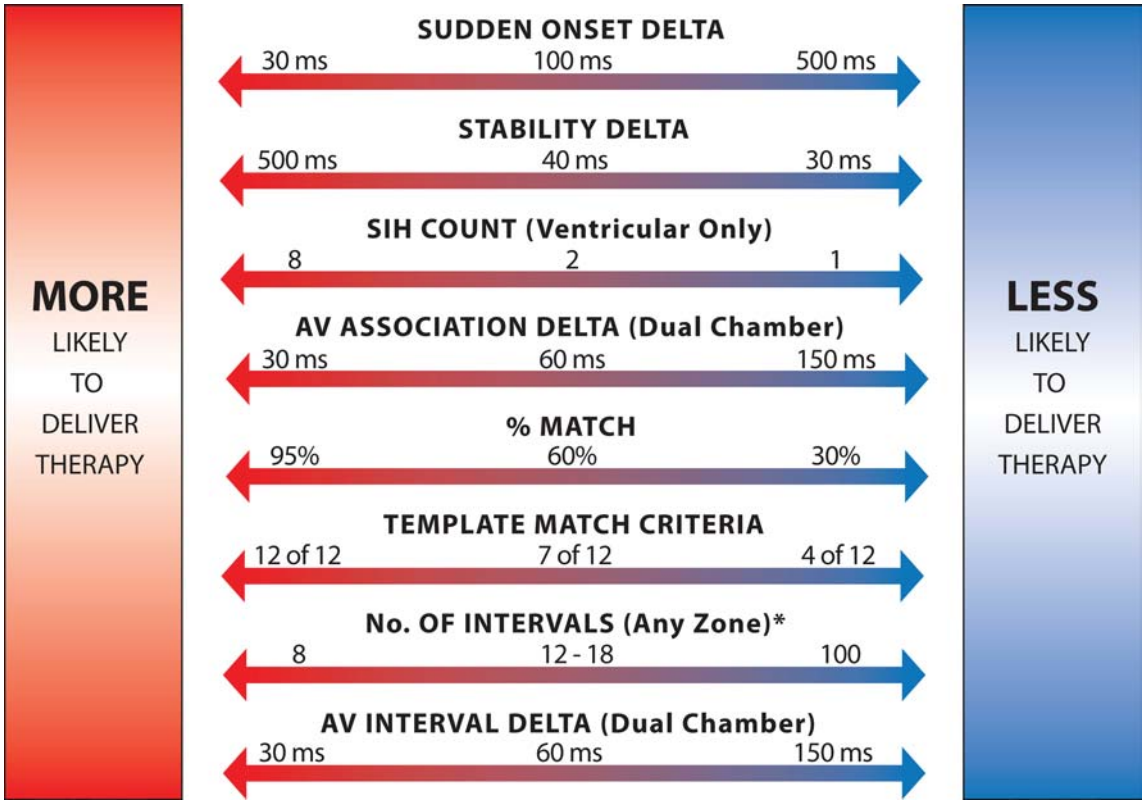
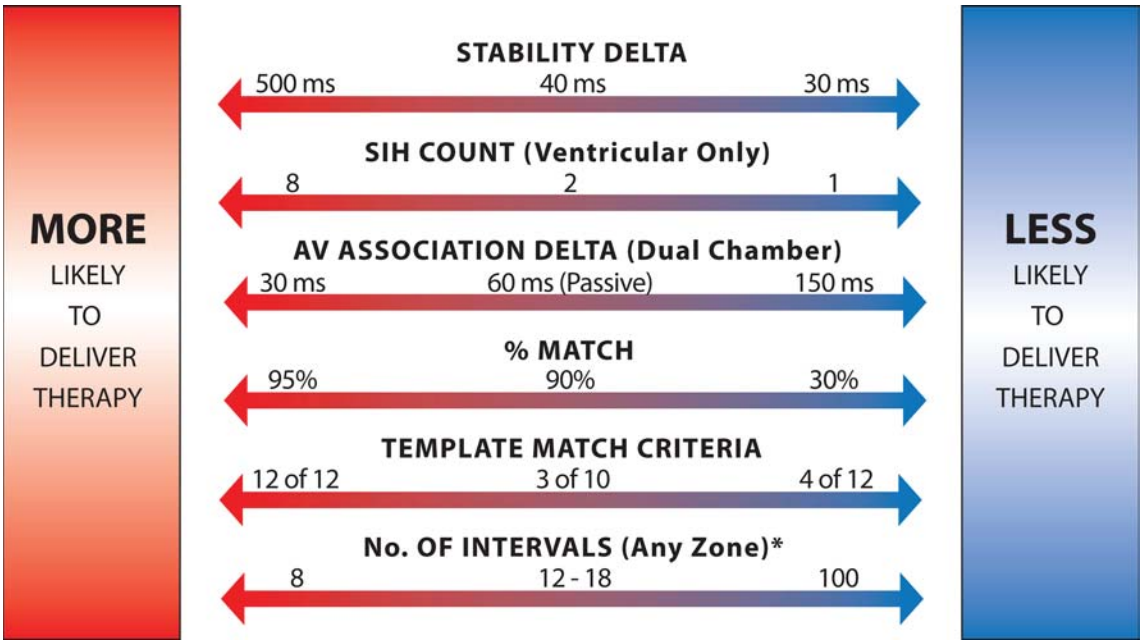


Figure 11. SVT discrimination parameters for devices with Far Field MD Morphology Discrimination Capability (for the Number of Intervals parameter, the nominal setting varies according to the Zone Configuration setting and the device). See the tables below for nominal settings.



Ventricular Only SVT Discrimination

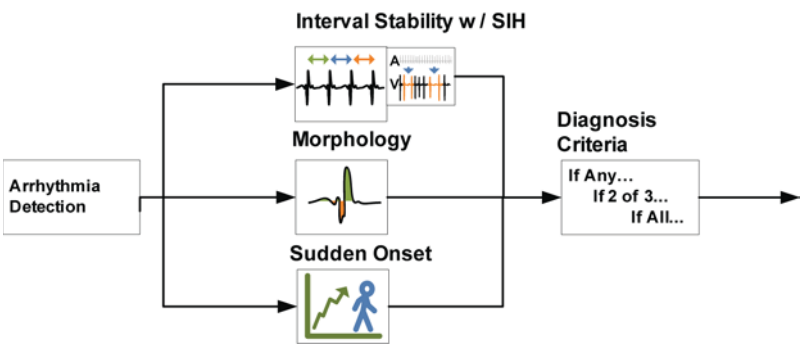
Once a potential episode is detected, the VR discrimination mode looks at four factors prior to designating the rhythm as an SVT or a VT. These are:

1. How suddenly did the rhythm start? (Sudden Onset (page 103))
2. What is the shape of the QRS complex compared to normal sinus rhythm? (Morphology (page 95))
3. Is the ventricular rhythm stable? (Interval Stability (page 101))
4. How often does the ventricular rhythm alternate with sinus beats? (SIH Count (page 101))

Until you have determined more appropriate settings by considering the patient's history or diagnostic data, use the recommended (nominal) settings found in the tables below.

When the discriminators are set to On or Passive, the device stores diagnostic data for events that fall within the SVT Discrimination. This includes the measured deltas for the Sudden Onset and Interval Stability parameters, information about the morphology template performance, and the classification of the rhythm by each discriminator. Refer to this data when choosing the appropriate discriminators and settings to use in the future.

Figure 12. Ventricular Only SVT discriminators

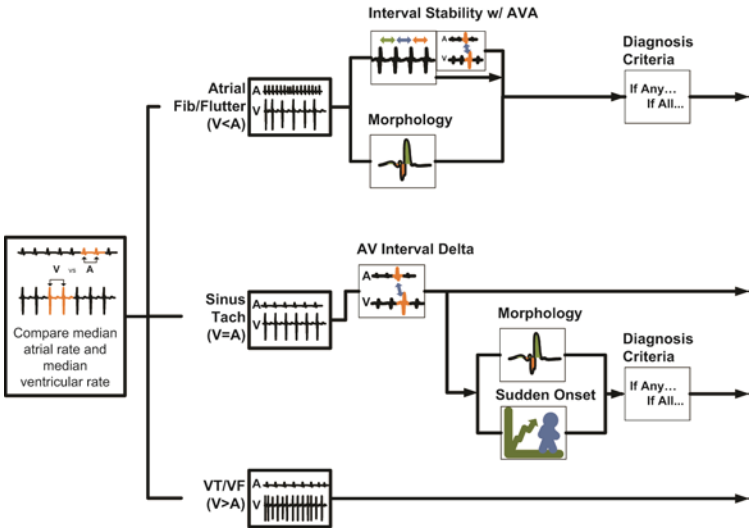


Dual Chamber SVT Discrimination

Once a potential episode is detected, Dual Chamber Discrimination mode looks at five factors prior to making a determination of whether the rhythm is SVT or VT. These are:

1. Which chamber is going faster? (Rate Branch (page 94))
2. How suddenly did the rhythm start? (Sudden Onset (page 103)) In which chamber did the rhythm start? (Chamber Onset (page 102))
3. What is the shape of the QRS complex compared to the normal sinus rhythm? (Morphology (page 95))
4. Is the ventricular rhythm stable? (Interval Stability (page 101))
5. What is the atrio-ventricular (AV) relationship? (AV Association Delta (page 101)/AV Interval Delta (page 95))

Figure 13. Dual-Chamber SVT discriminators



Until you have determined more appropriate settings by considering the patient's history or diagnostic data, use the recommended (nominal) settings found in the tables below.

Nominal Settings

The following tables summarize the nominal values for the SVT Discrimination parameters. These values are automatically selected when VT/VF detection is enabled via the Zone Configuration parameter. The final table displays the nominal settings for the Detection Rate/Interval and Number of Intervals parameters for each Zone Configuration.

Older generation devices with the previous nominal settings can also take advantage of the new recommended nominal settings via manual programming of these settings.

Table 29. Nominal SVT discriminator settings for the Dual Chamber SVT Discrimination setting

Parameter	Current, Current+, Current RF, Current Accel, Promote, Promote RF, Promote Accel, Promote+, Promote Q devices		Devices with DecisionTx™ Programming Capability		Devices with Far Field MD™ Morphology Discrimination Capability (page 187)	
	AF/AFl (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch	AF/AFl (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch	AF/AFl (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch
Interval Stability (page 101)	On		On w/AVA		On w/AVA	
Stability Delta (page 101)	80 ms		40 ms		40 ms	

Table 29. Nominal SVT discriminator settings for the Dual Chamber SVT Discrimination setting

Parameter	Current, Current+, Current RF, Current Accel, Promote, Promote RF, Promote Accel, Promote+, Promote Q devices		Devices with DecisionTx™ Programming Capability		Devices with Far Field MD™ Morphology Discrimination Capability (page 187)	
	AF/AFI (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch	AF/AFI (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch	AF/AFI (V<A) Rate Branch	Sinus Tach (V=A) Rate Branch
Interval Stability Window Size (page 102)	12		12		12	
AV Association Delta (page 101)	60 ms (Passive)		On, 60 ms		On, 60 ms	
Morphology (page 95)	On	On	On	On	On	On
% Match (page 96)	60%		60%		90%	
Template Match Criteria (page 96) (Morphology No. of Matches (page 96) of Morphology Window Size (page 97))	5 of 8		7 of 12		3 of 10	
Morphology Type (page 98)	n/a (Original MD)		n/a (Original MD)		Far Field	
AV Interval Delta (page 95)		Off		On,60 ms		Off
Arrhythmia Onset (Sudden Onset (page 103)/Chamber Onset (page 102))		Sudden Onset: On (Fixed)		Sudden Onset: On (Fixed)		Chamber Onset: On
Onset Delta (page 103)		100 ms		100 ms		n/a
Diagnosis (page 94)	If Any	If Any	If All	If All	If All	If All

Table 30. Nominal SVT discriminator settings for the Ventricular Only SVT Discrimination setting

Parameter	Current, Current+, Current RF, Current Accel, Promote, Promote RF, Promote Accel, Promote+, Promote Q devices	Devices with DecisionTx™ Programming Capability	Devices with Far Field MD™ Morphology Discrimination Capability (page 187)
Interval Stability (page 101)	Passive	On w/SIH	Passive
Stability Delta (page 101)	80 ms	40 ms	40 ms
Interval Stability Window Size (page 102)	12	12	12
SIH Count (page 101)	2 (Passive)	2	2 (Passive)
Morphology (page 95)	On	On	On
% Match (page 96)	60%	60%	90%
Template Match Criteria (page 96) (Morphology No. of Matches (page 96) of Morphology Window Size (page 97))	5 of 8	7 of 12	3 of 10
Morphology Type (page 98)	n/a	n/a	Far Field
Sudden Onset (page 103)	Passive (Fixed)	On (Fixed)	Passive (Fixed)
Onset Delta (page 103)	100 ms	100 ms	100 ms
Diagnosis (page 94)	If Any	If 2 of 3	n/a

Table 31. Nominal settings for Detection/Interval Rate, Number of Intervals, and SVT Upper Limit parameters for each Zone Configuration

Parameter	Current, Current+, Current RF, Current Accel, Promote, Promote RF, Promote Accel, Promote+, Promote Q devices	Devices with DecisionTx™ Programming Capability and Far Field MD™ Morphology Discrimination Capability (page 187)
1 Zone		
VF Detection Rate	167 bpm / 360 ms	187 bpm / 320 ms
VF Number of Intervals	12 intervals	12 intervals
2 Zones		
VF Detection Rate	181 bpm / 330 ms	214 bpm / 280 ms
VF Number of Intervals	12 intervals	12 intervals
VT Detection Rate	139 bpm / 430 ms	171 bpm / 350 ms
VT Number of Intervals	12 intervals	16 intervals
3 Zones		
VF Detection Rate	181 bpm / 330 ms	214 bpm / 280 ms
VF Number of Intervals	12 intervals	12 intervals
VT2 Detection Rate	160 bpm / 375 ms	181 bpm / 330 ms
VT2 Number of Intervals	12 intervals	16 intervals
VT1 Detection Rate	139 bpm / 430 ms	150 bpm / 400 ms
VT1 Number of Intervals	12 intervals	18 intervals
SVT Upper Limit	Same as VT-2 (160 bpm / 375 ms)	Same as VF (214 bpm / 280ms)

SVT Discrimination Timeout Description

The programming flexibility of the device allows it to inhibit therapy when supraventricular tachycardias (SVT) are detected. To prevent the potentially inappropriate inhibition of therapy for a long period of time, however, the device has an SVT discrimination timeout feature. This feature is a "timer" that allows the device to inhibit therapy delivery for SVTs for a programmable length of time. If an arrhythmia satisfying the slowest tachyarrhythmia Detection Interval/Rate (page 90) exists longer than a programmed duration (SVT Discrimination Timeout (page 92)), the device abandons use of the SVT Discriminators (page 93) (including Rate Branch (page 94)) and initiates the programmed Therapy After Timeout (page 93).

When SVT discriminators are set to On or the SVT Discrimination mode is set to Dual Chamber, the SVT Discrimination Timeout timer starts when a Diagnosis is inhibited by the SVT Diagnosis algorithm.

The SVT Discrimination Timeout timer stops and resets when it expires and therapy is initiated, when a tachyarrhythmia diagnosis occurs, or when sinus rhythm is detected.

See also:

- SVT Discrimination Timeout in a Monitor Only Zone (page 131)

SVT Discrimination Timeout in a Monitor Only Zone

The SVT Discrimination Timeout (page 92) timer is not available in the 2 Zones (page 123) configuration when VT therapies are disabled to create a monitor only zone. In this case, all VT therapies are disabled and SVT discriminators do not operate in the only zone that does have therapies enabled (fibrillation).

The SVT Discrimination Timeout timer is available in the 3 Zones (page 123) configuration when VT-1 therapies are disabled to create a Monitor Only Zone and the SVT discriminators apply to rhythms within the VT-2 rate zone. In that case, the SVT Discrimination Timeout timer starts when the device detects an average interval shorter than or equal to the VT-2 detection interval. Therapy After Timeout (page 93) is programmable to VF Therapy or VT Therapy. If the SVT Discriminators (page 93) do not apply to rhythms within the VT-2 rate zone, the SVT Discrimination Timeout timer is not available and therapy is delivered as programmed.

Tachyarrhythmia Therapy Description

While charging its capacitors for a high-voltage shock, the device checks continuously for the presence of a tachyarrhythmia and confirms that one is still present before it delivers therapy. Therapy is delivered even if the arrhythmia rate slows but is still within any programmed tachyarrhythmia detection rate range (or faster than the sinus redetection interval). This is the process of reconfirmation.

If the device detects sinus rhythm before delivering therapy, it terminates charging and aborts the shock. The voltage on the capacitors is not "dumped" when charging terminates, but decreases gradually with time. Within 1 hour, very little voltage is left on the capacitors. The residual voltage on the high-voltage capacitors can be measured using the Capacitor (page 39) test.

If ATP (ATP Parameters (page 108)) is the first tachycardia therapy, ATP is delivered followed by a maximum of four cardioversion shocks in a single episode. When the Diagnosis (page 94) has been satisfied, and the first therapy is set to ATP, the device delivers ATP synchronously into the sensed event that caused diagnosis.

If cardioversion is the first tachycardia therapy, a maximum of five cardioversion shocks can be delivered for that rhythm in a single episode. If the 3 Zones (page 123) configuration is selected, five therapies are available in each of the VT-1 and VT-2 therapy zones.

A maximum of 6 fibrillation shocks can be delivered in a single episode. The first and second shocks are delivered once each; the third fibrillation therapy consists of up to 4 shocks, as necessary. All high-voltage shocks are delivered synchronously with sensed events.

When the Waveform Mode (page 114) is configured to Tilt, therapies are programmed in energy (J) and displayed with the associated initial voltage. When the HV Output Mode is configured to Pulse Width, therapies are programmed in voltage and displayed with the associated estimated delivered energy.

If all therapies in a zone are delivered without terminating the tachyarrhythmia, the device will continue to count intervals (consecutive or isolated) that fall into other zones until either the patient's rate falls below the programmed detection rate (i.e., sinus detection) or another zone's detection criteria are met

VT Therapy Timeout Description

The VT Therapy Timeout (page 105) feature is a "timer" that limits the amount of time a device can deliver VT therapy before switching to defibrillation therapy. When the VT Therapy Timeout parameter is enabled, the timer begins counting once VT or VT-1 and VT-2 therapy is initiated. (The choice of using VT or VT-1 and VT-2 therapy is made by using the Timeout Trigger (page 105) parameter.) If the therapy is not effective in stopping the tachyarrhythmias within the time specified by the Timeout setting, then the device abandons tachycardia therapies and delivers fibrillation therapies.

If the tachycardia accelerates to fibrillation, the device delivers fibrillation therapy in the normal manner without requiring the VT Therapy Timeout timer to expire. If all tachycardia therapies have been delivered and the arrhythmia is still present and has not been accelerated, no further therapy is delivered until the VT Therapy Timeout timer expires.

The VT Therapy Timeout timer also terminates when sinus rhythm is detected.

Once the VT Therapy Timeout timer is triggered, expires, or terminates, it cannot restart within that episode.

See also:

- VT Therapy Timeout in a Monitor Only Zone (page 132)

VT Therapy Timeout in a Monitor Only Zone

The VT Therapy Timeout (page 105) timer is not available in the 2 Zones (page 123) configuration when VT therapies are disabled to create a monitor only zone.

The VT Therapy Timeout timer is available in the 3 Zones (page 123) configuration when VT-1 therapies are disabled to create a monitor only zone. The VT Therapy Timeout timer starts after VT-2 therapy is delivered.

Alert Notification Parameters

Contains:

- Alert Notification (page 133)
- Alert Triggers (page 133)
- AT/AF Alert Triggers (page 134)
- Patient Notifier Delivery (page 136)
- Patient Notifier Description (page 136)
- Percent Pacing Alert Triggers (page 137)

Alert Notification

The Alert Notification window contains two buttons that you can use to program the Alert Triggers. The Alert Triggers can be used for two functions: (1) the monitoring function generates Alerts (page 15) that are labeled "Shown on FastPath™" if the device detects certain critical conditions; (2) the Patient Notifier function emits a vibratory[127] or auditory[128] sensation so that the patient is aware of the condition (see Patient Notifier Description (page 136)). The window also contains the Test Notifier button from which you can initiate a test of the stimulation experienced during a Patient Notification.

To program an Alert Notification, select the Alert Triggers (page 133) button to choose the conditions you want tracked and whether the alert should be monitored and/or sent to the patient. Select the Patient Notifier Delivery (page 136) button to program the type and duration of the patient notification signal.

See also:

- Patient Notifier Sequence (page 137)
- Patient Notifier Daily Measurements (page 137)

Available In: Devices with Patient Notifier Capability (page 190)

Accessed From: Parameters button > Alert Notification tab

Alert Triggers

The Alert Triggers window allows you to select which conditions you want to monitor (record in the programmer Alerts (page 15) and show on the FastPath™ Summary (page 15) screen) and/or to send to the patient through the Patient Notifier Delivery (page 136) function.

You can select to view alerts on the FastPath Summary Alerts box for a condition by selecting the Show on FastPath check-box next to the Trigger conditions listed in the window. You can also notify the patient of any triggering condition by selecting the Patient Notifier check-box.

For some Alert Triggers listed below, you cannot de-select the Show on FastPath option for these conditions. That is, these conditions will always generate a programmer Alert:

- Device at ERI
- Device Parameter Reset
- Backup VVI
- Charge Time Limit Reached
- Possible HV Circuit Damage.

Available triggers are listed below:

- **Device at ERI**[129].The unloaded battery voltage has reached the elective replacement indicator (ERI) voltage (See Factors That Affect Device Longevity (page 322)).
- **Charge Time Limit Reached**[130]. The high-voltage capacitors have not reached the programmed voltage within 32 s.
- **Possible HV Circuit Damage**[131]. The device circuitry or a high voltage lead may be damaged.
- **Device Parameter Reset**. A reset has occurred that altered some or all of the permanently programmed parameters.
- **Lead Impedance Out of Range**. The lead impedance was measured above or below the limits specified by the Lead Monitoring Parameters for a specific chamber (A, V, RV, LV). To adjust the upper and lower limits of optimal impedance range for all leads, select any button to open the Lead Monitoring Parameters (page 80) window. Note that for CRT-Ds (page 163) and CRT-Ps (page 164), the lead impedances for the right- and left-ventricular leads are programmed and monitored independently. When the Monitoring button is selected, the trigger is noted in the Lead Impedance (page 38) window.
- **HVLI Out of Range**[132]. The high-voltage lead impedance was measured above or below the limits specified by the Lead Monitoring Parameters. To adjust the upper and lower limits of the optimal impedance range, select this button to open the Lead Monitoring Parameters (page 80) window. When the Monitoring button is selected, the trigger is noted in the Lead Impedance (page 38) window.

[127] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[128] Available in devices with Auditory Patient Notifier capability.
[129] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[130] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[131] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[132] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

- **Backup VVI**. The device has experienced a hardware reset. For parameter settings during a hardware reset, see Reset Function (page 175).
- **AT/AF Episode**[133]. A single AT/AF episode has exceeded the programmed Episode Duration setting Continuous Time in AT/AF (page 135)). Select this button to open the AT/AF Alert Triggers (page 134) window to program this parameter.
- **AT/AF Burden**[134]. The time spent in AT/AF exceeded the setting of the Total Time in AT/AF (page 135) parameter during the AT/AF Burden Evaluation Period (page 135) setting. Select this button to open the AT/AF Alert Triggers (page 134) window to program these parameters.
- **V Rate During AT/AF**[135]. The ventricular rate has exceeded the High V. Rate Threshold (page 135) setting for the period set by the Total Time in High V. Rate (page 135) setting for the V Rate During AT/AF Evaluation Period (page 135). Select this button to open the AT/AF Alert Triggers (page 134) window to program these parameters.
- **Therapy is Inhibited Due to Lead Noise.**[136] (Available when the SecureSense™ paramter is On.) The SecureSense™ algorithm has detected lead noise and inhibited therapy. Select this button to open the SecureSense™ Settings (page 90) window.
- **Episodes of Non-sustained RV/V Oversensing (NSO) detected.** (Available when the SecureSense™ parameter is set to On or Passive).[137] The SecureSense™ algorithm has detected non-sustained RV or V oversensing. Therapy is not inhibited. Select this button to open the SecureSense™ Settings (page 90) window.
- **Percent BiV/RV/V Pacing Alert (Less/Greater Than __%)**[138]. The percentage of paced events to total events has exceeded the current setting for the Percentage BiV Pacing Limit (page 137) or the Percentage RV/V Pacing Limit (page 137) parameter, displayed on the button. Select this button to open the Percent Pacing Alert Triggers (page 137) window to set these parameters and the Percent Pacing Alert Duration (page 137) parameter.
- **High Ventricular Rate Alert**. In devices with High V Rate Diagnostic capability (page 188), the device automatically monitors changes in the ventricular rate and creates an Alert if the rate exceeds the Ventricular Rate Threshold setting for a duration specified by the Number of Cycles parameter. To program these parameters, select this button to open the High Ventricular Rate (page 134) window. You can also program the device to create a Patient Notification when triggered.

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button

Note

Battery Voltage Below ERI. The Patient Notifiers may not work if the battery voltage falls below ERI.

Note

Patient Notifier in MR Conditional Devices. For MR Conditional pacemakers with Patient Notifier Capability (page 190), the patient notifier within the pulse generator is permanently disabled when in or near an MRI scanner.

High Ventricular Rate: Episode Trigger & Alert Trigger

The High Ventricular Rate: Episode Trigger and Alert Trigger window allows you to set two parameters that generate either a High V Rate episode or a High V Rate alert. The triggers must be programmed from the Episode Trigger (page 142) or Alert Trigger (page 133) windows. Episode and Alert triggers are independently programmed, so programming one does not affect the other.

- **Ventricular Rate Threshold**. The sensed ventricular rate above which the device will record a High V Rate trigger if the rate occurs for longer than the Number of Cycles parameter.
- **Number of Cycles**. The number of cycles above the Ventricular Rate Threshold that the device counts before it generates an episode or alert.

Available in: Devices with High Ventricular Rate Diagnostic capability (page 188)

Accessed From: Parameters button > Episode Settings tab > Episode EGMs button > High Ventricular Rate button

AT/AF Alert Triggers

The AT/AF Alert Triggers window allows you to set the conditions for monitoring and notifying the patient of AT/AF conditions. The three alerts include:

- **AT/AF Episode**. The time in AT/AF, programmed through the Continuous Time in AT/AF (page 135) parameter.
- **AT/AF Burden**. The time in AT/AF for a given evaluation period, programmed through the Total Time in AT/AF (page 135) and Evaluation Period (page 135) parameters.
- **V Rates During AT/AF**. The ventricular rate above which monitoring and notification occurs and the duration of the high ventricular rates, programmed through the High V. Rate Threshold (page 135), Total Time in High V. Rate (page 135), and Evaluation Period (page 135) parameters.

Available In: Devices with AT/AF Alert Triggers Capability (page 180)

[133] Available in devices with AT/AF Alert Triggers Capability.
[134] Available in devices with AT/AF Alert Triggers Capability.
[135] Available in devices with AT/AF Alert Triggers Capability.
[136] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[137] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.
[138] Available in devices with Percent Pacing Alert Capability.

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Continuous Time in AT/AF

The Continuous Time in AT/AF parameter sets the length of time a patient must be in AT/AF before triggering the AT/AF Episode alert trigger.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Total Time in AT/AF

The Total Time in AT/AF parameter sets the minimum duration that the patient must be in AT/AF for the programmed Evaluation Period (page 135) by the before generating an AT/AF Burden Alert Trigger.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Evaluation Period (AT/AF Burden)

The Evaluation Period parameter sets the period (daily or weekly) in which AT/AF Burden alerts are generated. The daily setting limits the number of AT/AF Burden alerts to a single day. The Weekly setting limits the number of alerts to a single week.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

High V. Rate Threshold

The High V. Rate Threshold is the sensed or sensor-driven ventricular rate during AT/AF above which the device defines as a High V. Rate. The device records a High V. Rate During AT/AF Alert Trigger if the rate continues for a time longer that the Total Time in High V. Rate (page 135) setting and during the Evaluation Period (page 135). This parameter is always set above either the Base Rate (page 66) setting or the AMS Base Rate (page 87) setting.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Total Time in High V. Rate

The Total Time in High V. Rate parameter is the amount of time the device must record high ventricular rates during AT/AF (defined by the High V. Rate Threshold (page 135) parameter) and during the Evaluation Period (page 135) before generating a High V. Rate During AT/AF Alert Trigger.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Evaluation Period (V. Rate During AT/AF)

The Evaluation Period parameter sets the time period during which the V. Rate During AT/AF is measured. When the Evaluation Period ends, the device restarts the measurement.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > AT/AF Episode button, AT/AF Burden button, or V Rates During AT/AF button

Patient Notifier Delivery

From the Patient Notifier Delivery window you can change the settings for the following parameters:

- Vibration Duration (page 136)
- Auditory Duration (page 136)
- Number of Notifications (page 136)
- Time Between Notifications (page 136)

See also:

- Patient Notifier Description (page 136)
- Patient Notifier Sequence (page 137)
- Patient Notifier Daily Measurements (page 137)

Available In: Devices with Patient Notifier Capability (page 190)

Accessed From: Parameters button > Patient Notifiers tab > Patient Notifier Delivery button

Vibration Duration

The Vibration Duration parameter determines the length of time that the individual vibratory stimulus lasts.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Patient Notifiers tab > Patient Notifier Delivery button

Auditory Duration

The Auditory Duration parameter determines the length of time that the individual auditory stimulus lasts.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Patient Notifiers tab > Patient Notifier Delivery button

Number of Notifications

The Number of Notifications parameter determines the number of times a notification (2 vibrations/auditory stimuli, 16 seconds apart) is delivered.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Patient Notifiers tab > Patient Notifier Delivery button

Time Between Notifications

The Time Between Notifications parameter is the amount of elapsed time between notifications.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Patient Notifiers tab > Patient Notifier Delivery button

Patient Notifier Description

- Patient Notifier Sequence (page 137)
- Patient Notifier Daily Measurements (page 137)

The Patient Notifier is a vibratory[139] stimulus that comes from a small motor in the device or an auditory[140] stimulus that comes from a small beeper inside the device. The device can be programmed to vibrate (or beep) when specific triggers occur.

Since the device may identify the stimulus as the patient's physical activity, rate-responsive pacing (Sensor (page 63)) is disabled during the delivery of a Patient Notifier and for 10 seconds afterwards.

Only one Patient Notifier Sequence (page 137) occurs at a time. If a second Patient Notifier Trigger is met during a Patient Notifier Sequence, the current notification sequence continues and there is no second sequence. However, all Patient Notifier triggers that have been met are listed in the Alerts portion of the FastPath™ Summary Screen (page 15).

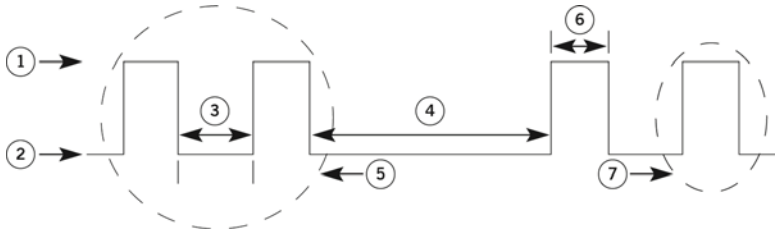
Once a Patient Notifier is delivered, that specific Patient Notifier trigger is auto-selected Off until you have (1) re-enabled the trigger (select the Alert for that Patient Notifier condition on the FastPath Summary (page 15), then select the Re-enable Notifier button), or (2) set the trigger to On from the Alert Triggers (page 133) window. A bell icon appears next to a Patient Notifier trigger on the Patient Notifier Triggers window when the Patient Notifier condition has been met and all the notifications have been delivered.

[139] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[140] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.

Patient Notifier Sequence

The Patient Notifier sequence is a programmable Number of Notifications (page 136), separated by a programmable Time Between Notifications (page 136). Each notification includes 2 stimuli of a programmable Vibration Duration (page 136) or Auditory Duration (page 136) delivered 16 seconds apart.

Figure 14. The Patient Notifier sequence



1. Stimulus On
2. Stimulus Off
3. 16 seconds
4. Time Between Notifications
5. Notification
6. Stimulus Duration
7. Stimulus

The Patient Notifier sequence for the following triggers is not programmable:

- The **Device Parameter Reset** sequence is 2 stimuli, 6 seconds long, 16 seconds apart every 10 hours for a total of 4 sequences.
- The **Back Up VVI** sequence is 2 stimuli, 6 seconds long, 16 seconds apart every 10 hours until telemetry connection with the programmer is established.

Patient Notifier Daily Measurements

The unloaded battery voltage and pacing lead impedance measurements are made once every 23 hours to ensure that the measurements are made at various times throughout the day. These measurements are recorded in the Lead Impedance (page 38) trends and Battery Voltage trend (see Battery Details (page 37)).

Percent Pacing Alert Triggers

The Percent Pacing Alert Triggers window enables you to program an alert if the percent pacing falls below or above a certain percentage for a specified duration. Two parameters can be programmed.

Available In: Devices with Percent Pacing Alert Capability (page 191)

Percentage BiV Pacing Limit

The Percentage BiV Pacing Limit (Percent Pacing Less Than) parameter sets the minimum percentage of total paced pulses that will trigger an alert, if the criteria for the Percent Pacing Alert Duration (page 137) parameter is met. This parameter is available only for CRT-Ds and Allure devices.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > Percent V Pacing Alert

Percentage RV/V Pacing Limit

The Percentage RV/V Pacing Limit (Percent Pacing Greater Than) parameter sets the maximum percentage of total paced pulses that will trigger an alert, if the criteria for the Percent Pacing Alert Duration (page 137) parameter are met. This parameter is available only for dual-chamber and single-chamber ICDs, CRT-Ds, and Allure, Assurity, and Endurity devices[141].

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > Percent V Pacing Alert

Percent Pacing Alert Duration

The Percent Pacing Alert Duration (Duration) parameter sets the length of time that the Percentage BiV Pacing Limit (page 137) or Percentage RV/V Pacing Limit (page 137) parameter must be exceeded before an alert is triggered.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Alert Notification tab > Alert Triggers button > Percent V Pacing Alert

[141] CRT-Ps with this feature must have the Ventricular Pacing parameter programmed to RV Only.

Episode Settings

Contains:

- Stored EGM Configuration (page 139)
- Episode Triggers (page 142)
- Episode Trigger: High Ventricular Rate (page 143)

Episode Settings

The Episode Settings window contains two buttons that you can use to program the following:

- Stored EGM Configuration (page 139). This button displays the current settings for the stored EGM configuration parameters.
- Episode Triggers (page 142). This button displays the types of episodes that will trigger EGM storage and the priority of each.

See also:

- Episodes (page 19)

Note

To ensure that all important episodes are collected, it is recommended that you clear the episodes from the device memory at the end of each session. See Clear Diagnostics (page 151).

Stored EGM Configuration

From the Stored EGM Configuration window you can change the settings for the following parameters:

- VT/VF EGM Max Duration (page 139)
- High V Rate EGM Max Duration (page 139)
- VT/VF Pre-Trigger Max Duration (page 140)
- High V Rate Pre-Trigger Max Duration (page 140)
- Channels (page 140). The total amount of EGM storage time is displayed below the number of channels selected for storage.
- Configuration (page 141)

VT/VF EGM Max Duration

The VT/VF EGM Max Duration parameter determines the maximum length of a VT/VF stored EGM. The VT/VF EGM Max Duration parameter is timed from the beginning of the pre-trigger and stops either four seconds after the redetection of sinus rhythm or when the VT/VF EGM Max Duration setting is reached, whichever occurs first.

A longer duration of stored EGMs allows fewer episodes to be stored. For information on the number of EGMs that can be stored in the device, see "Priority" in Episode Triggers (page 142).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

High V Rate EGM Max Duration

The High V Rate EGM Max Duration parameter determines the maximum length of a high ventricular rate stored EGM. The High V Rate EGM Max Duration parameter is timed from the beginning of the pre-trigger and stops when the High V Rate EGM Max Duration setting is reached.

A longer duration of stored EGMs allows fewer episodes to be stored. For information on the number of EGMs that can be stored in the device, see "Priority" in Episode Triggers (page 142).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

The VT/VF EGM Max Duration parameter determines the maximum length of a VT/VF stored EGM. The VT/VF EGM Max Duration parameter is timed from the beginning of the pre-trigger and stops either four seconds after the redetection of sinus rhythm or when the VT/VF EGM Max Duration setting is reached, whichever occurs first.

A longer duration of stored EGMs allows fewer episodes to be stored. For information on the number of EGMs that can be stored in the device, see "Priority" in Episode Triggers (page 142).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

The VT/VF Pre-Trigger Max Duration parameter determines the amount of time recorded before the EGM storage trigger.

The VT/VF Pre-Trigger Max Duration setting should be based on the programmed Event Trigger and the type of information you wish to store. For example, to store events leading up to detection, program the Event Trigger to VT/VF with a relatively long pre-trigger duration. The available settings for the VT/VF Pre-Trigger Max Duration depend upon the number of EGM channels (page 141) stored.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

The High V Rate EGM Max Duration parameter determines the maximum length of a high ventricular rate stored EGM. The High V Rate EGM Max Duration parameter is timed from the beginning of the pre-trigger and stops when the High V Rate EGM Max Duration setting is reached.

A longer duration of stored EGMs allows fewer episodes to be stored. For information on the number of EGMs that can be stored in the device, see "Priority" in Episode Triggers (page 142).

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

VT/VF Pre-Trigger Max Duration

The VT/VF Pre-Trigger Max Duration parameter determines the amount of time recorded before the EGM storage trigger.

The VT/VF Pre-Trigger Max Duration setting should be based on the programmed Event Trigger and the type of information you wish to store. For example, to store events leading up to detection, program the Event Trigger to VT/VF with a relatively long pre-trigger duration. The available settings for the VT/VF Pre-Trigger Max Duration depend upon the number of EGM channels (page 141) stored.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

High V Rate Pre-Trigger Max Duration

The High V Rate Pre-Trigger Max Duration parameter determines the amount of time recorded before the EGM storage trigger.

The High V Rate Pre-Trigger Max Duration setting should be based on the programmed Event Trigger and the type of information you wish to store. For example, to store events leading up to detection, program the Event Trigger to high ventricular rate with a relatively long pre-trigger duration. The available settings for the High V Rate Pre-Trigger Max Duration depend upon the number of EGM channels (page 141) stored.

See also:

- Parameter Availability and Settings

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

Channels

The Channels parameter determines the number of EGM channels stored with each stored EGM. More stored channels allow fewer episodes to be stored.

When the SecureSense™ (page 90) parameter is enabled or the Morphology Type (page 98) parameter is set to Far-Field, the device uses Channel 3 as the Discrimination Channel to store SEGMs for VT/VF episodes.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

Note

Stored EGM Capacity.

- CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164) can store approximately 45 minutes of stored EGM records at a setting of 1 Channel. A setting of 2 Channels stores approximately 22 minutes. A setting of 3 Channels stores approximately 15 minutes.
- CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164) can store approximately 14 minutes of stored EGM records at a setting of 1 Channel. A setting of 2 Channels stores approximately 8 minutes. A setting of 3 Channels stores approximately 5 minutes.
- In devices with Far Field MD™ Morphology Discrimination Capability (page 187) and SecureSense™ RV Lead Noise Discrimination Capability (page 193), the addition of the discrimination channel has no effect on the Stored EGM capacity.

Configuration

The Configuration parameters determine the electrode source for each of the EGM channels. The Leadless ECG setting is a representation of what a surface ECG may have recorded during the episode.

For CRT-Ds (page 163) and Dual-Chamber ICDs (page 163), the Leadless ECG setting is equal to the A tip-to RV coil configuration.

For Single-Chamber ICDs (page 164), the Leadless ECG setting is equal to the SVC-to-Can configuration. For single-chamber ICDs without an SVC coil, select a cathode.

For CRT-Ps (page 164) and Dual-Chamber Pacemakers (page 164), the Leadless ECG setting is equal to the A tip-to-RV ring configuration.

In Single-Chamber Pacemakers (page 164), the Leadless ECG setting is not available.

When Custom (page 142) is selected as the Configuration, you can select the anode and cathode source for the stored EGMs.

Table 32. Stored EGM Configuration settings for CRT-Ds without quadripolar lead support

Configuration			
A Bipolar	RV Bipolar	LV Bipolar	Leadless ECG
A Unipolar Tip	RV Unipolar Tip	LV Unipolar Tip	A tip-RV tip
A Unipolar Ring	RV Unipolar Ring	LV Unipolar Ring	Custom
A Sense Amp	V Sense Amp		

Table 33. Stored EGM Configuration settings for CRT-Ds with quadripolar lead support

Configuration			
A Bipolar	RV Bipolar	Distal tip 1 - Mid 2	Leadless ECG
A Unipolar Tip	RV Unipolar Tip	Distal tip 1 - Can	A tip-RV tip
A Unipolar Ring	RV Unipolar Ring	Mid 2 - Can	Custom
A Sense Amp	V Sense Amp		

Table 34. Stored EGM Configuration settings for dual-chamber ICDs

Configuration		
A Bipolar	V Bipolar	Leadless ECG
A Unipolar Tip	V Unipolar Tip	A tip-V tip
A Unipolar Ring	V Unipolar Ring	Custom
A Sense Amp	V Sense Amp	

Table 35. Stored EGM Configuration settings for single-chamber ICDs

Configuration
V Bipolar
V Unipolar Tip
V Unipolar Ring
V Sense Amp
Leadless ECG
Custom

Table 36. Stored EGM Configuration settings for CRT-Ps without quadripolar lead support

Configuration				
A Bipolar	RV Bipolar	LV Bipolar	BV Bipolar	A ring-RV ring
A Unipolar Tip	RV Unipolar Tip	LV Unipolar Tip	BV Unipolar Tip	A tip-BV tip
A Unipolar Ring	RV Unipolar Ring	LV Unipolar Ring	BV Unipolar Ring	Custom
A Sense Amp	V Sense Amp			Leadless ECG

Table 37. Stored EGM Configuration settings for CRT-Ps with quadripolar lead support

Configuration			
A Bipolar	RV Bipolar	Distal tip 1 - Mid 2	Leadless ECG
A Unipolar Tip	RV Unipolar Tip	Distal tip 1 - Can	Custom
A Unipolar Ring	RV Unipolar Ring	Mid 2 - Can	
A Sense Amp	V Sense Amp		

Table 38. Stored EGM Configuration settings for dual-chamber pacemakers

Configuration			
A Bipolar	V Bipolar	A tip-V tip	Leadless ECG
A Unipolar Tip	V Unipolar Tip	A ring-V ring	
A Unipolar Ring	V Unipolar Ring	A ring-V tip	
A Sense Amp	V Sense Amp		

Table 39. Stored EGM Configuration settings for single-chamber pacemakers

Configuration
V Bipolar
V Unipolar Tip
V Unipolar Ring
V Sense Amp

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button

Note

EGM Storage. If an episode that triggers electrogram storage occurs while the programmer is communicating with the device, the real-time ECG/EGM configuration rather than the EGM source Configuration settings are used to store the EGM.

Custom

Stored EGMs can be recorded using custom anode and cathode Configuration (page 141) settings. Custom settings allow you to store far-field EGMs.

See also:

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Stored EGM Configuration button > Configuration button

Episode Triggers

From the Episode Triggers window, you can prioritize episode triggers for EGM storage.

- **Triggers**. The device stores EGMs for various types of episodes.
  - **Atrial Episode**[142]. An EGM is stored when the Atrial Tachycardia Detection Rate (page 87) is exceeded (AT/AF Detection setting) or when a mode switch event occurs (AMS setting). In CRT-Ps (page 164) and Dual-Chamber Pacemakers (page 164), select this button to open the Episode Trigger: Atrial Episode (page 144) window to select which type of episode to record. The device stores the first, last and fastest rate episodes.
  - **VF**[143]. An EGM is stored when a VF episode is detected (Detection setting) or when a diagnosis is made (Diagnosis setting). The VF Trigger can only be set to high Priority.
  - **VT**[144]. An EGM is stored when a VT episode is detected (Detection setting) or when a diagnosis is made (Diagnosis setting). The VT Trigger can be set to low or high Priority.
  - **PMT**[145]. An EGM is stored when a pacemaker-mediated tachycardia (PMT) detection occurs since diagnostics were last cleared.

[142] Not available in single-chamber devices.
[143] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[144] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

- **PVC**[146]. An EGM is stored when the device counts a number of consecutive PVCs equal to or greater than the Consecutive PVCs parameter.
- **Consecutive PVCs**[147]. Sets the number of consecutive PVCs that must be counted before the PVC Trigger parameter stores an episode.
- **Advanced Hysteresis**[148]. An EGM is stored when the device detects a drop in the intrinsic rate that triggers the Intervention Rate (page 69) algorithm (see Advanced Hysteresis Functions (page 68)).
- **High Ventricular Rate**[149]. An EGM is stored when the ventricular rate exceeds the Ventricular Rate Threshold setting for a duration specified by the Number of Cycles parameter. To program these parameter, select this button to open the High Ventricular Rate: Episode Trigger and Alert Trigger window where you can select the settings for the Ventricular Rate Threshold (page 143) and Number of Cycles (page 143) parameters.
- **Noise Reversion**. An EGM is stored when atrial and/or ventricular noise reversion is exited.
- **Magnet Response**. An EGM is stored when the magnet is applied.
- **Morphology Template Update**[150]. An EGM is stored when the morphology template is updated automatically. See Template Auto Update (page 97).
- **Non-sustained VT/VF**[151]**.** An EGM is stored when a non-sustained VT/VF episode is recorded (See Note (page 19) for definition).
- **Non-sustained RV Lead Noise**[152]**.** An EGM is stored when a SecureSense™ non-sustained RV lead noise episode is recorded. See SecureSense™ Settings (page 90).

- **Priority**. The Priority determines the number of EGMs stored for each episode trigger.
  - **Off**. No EGMs are stored for an episode trigger.
  - **Low**. At least one EGM is stored and protected in the memory. Subsequent triggers of the same type are stored on a first-in, first-out basis. When the memory is full, high-priority episodes overwrite any unprotected low-priority or high-priority episodes.
  - **High**. At least one EGM is stored and protected in the memory. Subsequent triggers of the same type are stored on a first-in, first-out basis. When the memory is full, high-priority episodes overwrite any unprotected low-priority or high-priority episodes.

Accessed From: Parameters button > Episode Settings tab > Episode EGMs button

Note

Auto Mode Switch (page 86) and Mode (page 61). The Atrial Episode setting of AMS is only available when the Auto Mode Switch parameter is enabled and the Mode parameter is set to DDD(R).

PMT Termination is only available if PMT Response (page 85) is enabled.

Non-sustained VT/VF. In devices with Non-sustained VT/VF Episode Capability (page 189), non-sustained VT/VF episodes are defined as VT/VF episodes that are longer than six intervals but shorter than the programmed No. Intervals required for classification as tachyarrhythmia.

Episode Trigger: High Ventricular Rate

A High Ventricular Rate EGM is recorded if the sensed ventricular rate exceeds the setting for the Ventricular Rate Threshold parameter for a duration set by the Number of Cycles parameter.

Accessed From: Parameters button > Episode Settings tab > Episode EGMs button > High Ventricular Rate button

Ventricular Rate Threshold

The Ventricular Rate Threshold (High Ventricular Rate) parameter specifies the minimal rate that the device must sense before it begins to count cycles to record a High Ventricular Rate EGM. If the device counts a series of consecutive cycles greater than the Number of Cycles (page 143) parameter, then it triggers the collection of an EGM.

See also:

- Parameter Availability and Settings (page 197)

Number of Cycles (High Ventricular Rate)

The Number of Cycles (Consecutive High Ventricular Rate Cycles) parameter specifies the number of consecutive cycles that the device must count for rates above the Ventricular Rate Threshold (page 143) to trigger a High Ventricular Rate EGM.

See also:

---

[145] Not available in single-chamber devices.
[146] Not available in single-chamber devices.
[147] Not available in single-chamber devices.
[148] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[149] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[150] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[151] Available in devices with Non-sustained VT/VF Episode Capability.
[152] Available in devices with SecureSense™ RV Lead Noise Discrimination Capability.

- Parameter Availability and Settings (page 197)

Accessed From: Parameters button > Episode Settings tab > Episode Triggers button > High Ventricular Rate button

Episode Trigger: Atrial Episode

Use the window to select the type of episode you want to record as well as the criteria for each episode type to be recorded.

Accessed From: Parameters button > Episode Settings tab > Episode EGMs button > Atrial Episode button

Atrial Episode Type

The Atrial Episode Type selects the type of atrial episode you want to record. When you select a type, one of the three panels below becomes active to set the trigger criteria.

See also:

- Parameter Availability and Settings (page 197)

AMS Trigger Type

The AMS Trigger Type determines if an atrial episode is recorded on AMS Entry, AMS Exit, or both exit and Entry.

See also:

- Parameter Availability and Settings (page 197)

Atrial Tachycardia Detection Rate

The Atrial Tachycardia Detection Rate sets the threshold above which all rates are defined as tachycardias and are recorded as High Atrial Rate EGMs.

See also:

- Atrial Tachycardia Detection Rate parameter (page 87)
- Parameter Availability and Settings (page 197)

High Atrial Rate

The High Atrial Rate parameter specifies the minimal atrial rate that the device must sense before it begins to count cycles for a High Atrial Rate EGM. If the device counts a series of consecutive cycles greater than the Number of Cycles (page 144) parameter, then it triggers the collection of an EGM.

See also:

- Parameter Availability and Settings (page 197)

Number of Cycles (High Atrial Rate)

The Number of Cycles parameter specifies the number of consecutive cycles that the device must count for rates above the High Atrial Rate (page 144) setting to trigger a High Atrial Rate EGM.

See also:

- Parameter Availability and Settings (page 197)

Diagnostic Settings

The Diagnostic Settings tab of the Parameters window allows you to enable or disable:

- CorVue™ Thoracic Impedance Monitoring Diagnostic Feature (page 145)

CorVue™ Thoracic Impedance Monitoring Feature

The CorVue™ Thoracic Impedance Monitoring Diagnostic feature can be turned On or Off from the Diagnostic Settings tab available from the Parameters button. You can view detailed impedance monitoring information in the Impedance Monitoring (page 29) tab of the Diagnostics window.

See also:

- Parameter Availability and Settings (page 197)

Available In: Devices with CorVue™ Thoracic Impedance Monitoring Capability (page 184)

Accessed From: Parameters button > Diagnostic Settings tab

Custom Sets

Custom Sets are predefined "snapshots" of parameter settings that can be saved in the programmer memory and loaded into the device from the Custom Sets window. From this window, you can also review all saved custom sets, rename a set, and delete a set.

A maximum of 20 custom parameter sets can be stored for each device model. You can load customized parameters at any time during a programming session.

- Create and Save a Custom Set (page 147)
- Load a Custom Set (page 147)
- Delete a Custom Set (page 147)
- Rename a Custom Set (page 148)
- Export a Custom Set (page 148)
- Import a Custom Set (page 148)

Available In: All Devices

Accessed From: Parameters button > Custom Sets tab

Create and Save a Custom Set

To create and save the currently programmed settings as a custom set:

1. Select the Custom Sets tab.
2. Select the Save Parameter Set button.

   If the selected setting for a parameter is different from the programmed setting (for example, a temporarily programmed setting), the selected setting is saved.
   The on-screen keyboard appears.
3. Type a name for the custom settings and select the Done button.

   The Custom Sets window appears with the newly saved custom set listed by its name and Lead Type settings.

   Note

   You cannot change settings of a saved custom set. If you wish to change a parameter in a saved custom set, you must load the custom set you want to change, select the Rename Set button and give the older custom set a new name or delete it, and then save the changed set with the desired name.

Load a Custom Set

To load a saved custom set:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select one of the existing parameter sets from the list in the Custom Sets window.
4. Select the Load Set button.
5. To review the newly loaded parameter settings, select the Preview button.
6. To program the settings, select the Program button.
7. To revert to the previously programmed parameters, select the Undo button.

   Note

   Review the parameter settings after you load a custom parameter set to ensure that the loaded custom parameter set is appropriate for the patient.

   You cannot load a set if the current Lead Type parameter is set to Unipolar and the custom set is set to Bipolar

Delete a Custom Set

To delete a saved custom set:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select one of the existing parameter sets from the list in the Custom Sets window.
4. Select the Delete Set button.

Rename a Custom Set

To rename a saved custom set:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select one of the existing parameter sets from the list in the Custom Sets window.
4. Select the Rename Set button.
5. Type in the new name for the custom set and select the Done button.
6. To review the newly loaded parameter settings, select the Preview button.
7. To program the settings, select the Program button.
8. To revert to the previously programmed parameters, select the Undo button.

Export a Custom Set

To export a saved custom set:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select one of the existing parameter sets from the list in the Custom Sets window.
4. Select the Export Set button.
5. Select where you want to export the custom set.
6. Select the Export button.
7. Select the Done button.

To export a batch of saved custom sets, grouped by device family:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select the Export by Family button.
4. Select the device family.
5. Select where you want to export the custom set.
6. Select the Export button.
7. Select the Done button.

Import a Custom Set

This procedure will import all customs sets saved to a media device. To import one or several custom sets:

1. Select the Parameters button.
2. Select the Custom Sets tab.
3. Select the Import All button.
4. Select where you want to import the custom set from.
5. Select the Import button.
6. Select the Done button.

MRI Settings

Contains:

- MRI Settings (page 149)
- MRI Checklist (page 150)
- MRI Settings: Active (page 150)

MRI Settings

The MRI Settings window allows you to program basic operating parameters for an MR Conditional pulse generator that are in effect during an MRI scan.

See also:

- MRI Parameters (page 149)

From the MRI Settings window, you can:

- Enable the MRI Settings in an MR Conditional pulse generator
- Change and save the MRI Settings in the pulse generator
- Temporarily program the pulse generator to test the effect of the MRI Settings on the patient
- Access the MRI Checklist (page 150) to prepare the patient for an MRI scan
- Determine if communication between the pulse generator and the handheld activator device is enabled (only in devices with SJM MRI Activator™ handheld device capability (page 189))
- Enable the pulse generator to communicate with the handheld activator device (only in devices with SJM MRI Activator™ handheld device capability (page 189)).

> WARNING
>
> **Before you attempt to scan a patient with an implanted MR Conditional pacing system, read all the instructions in the MRI Procedure Information document. If you have any questions, please contact Technical Support (page 163) before proceeding with the MRI scan.**

In addition to the parameter settings, the MRI Settings window contains the following buttons:

- **Undo All**. Restores all nominal or previously programmed MRI Settings.
- **Test MRI Settings**. Temporarily programs the MRI Settings to help you determine their effect on the patient. When the test is complete, select the **Cancel Test** button.
- **Save MRI Settings**. Saves the currently selected MRI Settings.
- **Setup MRI Activator**. Opens the MRI Checklist (page 150) to enable the handheld activator to communicate with the pulse generator (only in devices with SJM MRI Activator™ handheld device capability (page 189)).
- **Setup for MRI Now**. Opens the MRI Checklist (page 150) to use the Merlin PCS to set up the pulse generator for an MRI scan.

> Note
>
> **Patient Notifier in MR Conditional Devices**. For MRI-conditional devices with Patient Notifier Capability (page 190), the patient notifier within the pulse generator is permanently disabled when in or near an MRI scanner.

Available In: Devices with MR Conditional Programming Capability (page 189)

Accessed From: Parameters button > MRI Settings tab

MRI Parameters

The MRI parameter settings are stored and tested from the MRI settings screen. These settings are only in effect when you select the Test MRI Settings button or when you enable the MRI Settings from the MRI Checklist (page 150) window or from the handheld activator (only in devices with SJM MRI Activator™ handheld device capability (page 189)).

In MR Conditional devices, diagnostic data collection is suspended while MRI Settings are enabled.

The MRI Settings provide only basic pacing functions and limit the pulse generator's interactions with the electromagnetic radiation during the MRI scan.

- MRI Mode (page 61). During an MRI scan, all sensing should be turned off so the pulse generator does not respond to the MR-induced voltages.
- MRI Base Rate (page 66)
- MRI Paced AV Delay (page 70)
- MRI Pulse Amplitude (page 75)
- MRI Pulse Width (page 75)

- MRI Pulse Configuration (page 58)

See also:

- Parameter Availability and Settings (page 197)

MRI Checklist

Use the MRI Checklist window to verify the current MRI Settings and to ensure that all the conditions for an MRI scan are in place before programming the MRI Settings. From this window, you can also enable the SJM MRI Activator™ handheld device (only in devices with SJM MRI Activator™ handheld device capability (page 189)). Verify each condition in the checklist and check each box after each condition is verified. If a box is left unchecked, you will not be able to program the MRI settings or enable the handheld activator.

After you have checked all the boxes, you will see one of the following green buttons:

Program MRI Settings. Select this button to program the MRI settings in the pulse generator in preparation for an imminent MRI scan. When you select this button, the programmer displays the MRI Settings: Active (page 150) window.

Enable MRI Activator (only in devices with SJM MRI Activator™ handheld device capability (page 189)). Select this button to enable the pulse generator to communicate with the handheld activator and save the MRI Settings. This button does not enable the MRI Settings. When you select this button, the programmer displays the MRI Settings (page 149) window with a note that communication with the handheld activator is enabled.

Conditions Required for MRI

Specific conditions must be met before a patient with an MR Conditional pulse generator can have an MRI scan. Refer to the MRI Procedure Information document for a complete list of all conditions.

In addition, the following conditions must all be met before the patient can have an MRI scan:

- **Bipolar Capture Thresholds are stable**. Select the test button for the corresponding chamber to perform a Capture Test (page 32) to verify that capture thresholds are stable.
- **Bipolar Pacing Lead Impedances are within range**. Select the buttons to view and update the Lead Impedance (page 38) data for each lead and verify the lead impedances are within range.

  Note

  The Bipolar Pacing Lead Impedance check-mark is not available (and the patient cannot be scanned) if any of the following conditions are present:

  - The most recent bipolar atrial or ventricular lead impedance measurement is not available
  - A clinical alert exists for a bipolar atrial or ventricular lead impedance measurement
  - The lead impedance is outside of the programmed range.

- **SJM leads are labeled for MRI**. Select the buttons to obtain the Patient Data: Lead Information (page 16) for each lead and ensure the implanted leads are St. Jude Medical MR Conditional leads. Refer to the MRI Procedure Information Document for more information on MR Conditional leads.
- **No Additional Cardiac Hardware (adapters, extenders, abandoned leads)**. The Additional Cardiac Hardware...[Present/Not Present/Unknown] button opens the Patient Data: Lead Information (page 16) window where information on additional hardware is stored. If you do not know whether additional hardware is present, you can confirm its absence with an x-ray or other diagnostic image.

Accessed From: Parameters button > MRI Settings tab > Setup MRI Activator or Setup for MRI Now button

MRI Settings: Active

The MRI Settings: Active window displays the currently programmed MRI Settings, the pulse generator's permanent programmed settings, and the following buttons:

- **Disable MRI Settings**. Select this button to return to the permanent programmed settings.
- **Print MRI Report**. Select this button to print a report containing the patient data, parameter settings, lead information, and a log of the times and durations the MRI Settings were enabled and disabled, and the MRI checklist results. Also accessible from the Print button > Reports tab.
- **End Session**. After enabling the MRI Settings, end the programming session before proceeding to the MRI scan. Once the scan is complete, interrogate the pulse generator to disable MRI Settings and restore the permanently programmed settings.

Accessed From: Parameters button > MRI Settings tab > Setup for MRI Now button > MRI Checklist window

Wrap-up™ Overview

Contents:

- Wrap-up™ Overview (page 151)
- Export Data (page 151)
- Clear Trends (page 151)
- Clear Diagnostics (page 151)
- Restore Initial Values (page 152)

Wrap-up™ Overview

The Wrap-up™ Overview window provides a place for your final review of session activities and includes the following:

- **Battery Information**. Shows the last measured battery voltage, a gauge illustrating the time left to ERI (based on battery voltage[153]), and the date and duration of the last max charge[154]. The text is displayed in red (alert status) if the device is at ERI.
- **Test Status** panel**.** Reports completed and uncompleted tests.
- **Session Notes** panel. Reports the status of routine follow-up tasks.
- **Programming Changes**. Lists all changes in programmed parameter settings.
- **Selected Reports** button. Lists the reports that have been selected to print and opens the Print Menu (page 169) window to add or delete Reports (page 169) for printing.
- Restore Initial Values **(page 152)** button. Programs the device to all valid settings read at the beginning of the session.
- Clear Trends **(page 151)** button. Opens the Clear Trends window to clear the Impedance Monitoring (page 29) Trend, AT/AF Burden (page 27) Trend and Exercise & Activity (page 29) Trend.
- Export Data **(page 151)** button. Opens a window to export Session Records (page 1) data to a USB device or PC.
- **Clear Diagnostics (page 151)** button. Opens a window from which you can selectively clear the Diagnostics (page 25) (except for the AT/AF Burden and Exercise & Activity Trend data), Episodes (page 19), and stored EGMs from the device memory.
- **Clear after Printing** button. Select this check-box to automatically clear diagnostics from the device memory after printing the reports from the Wrap-Up window.
- **Print Reports** button. Prints all reports listed in the Selected Report button.

Accessed From: Wrap-up Overview button

Export Data

The Export Data window lists the data formats available for export of Session Records (page 1) to a USB media device or a PC.

To export data:

1. Insert the USB connector from a media device into one of the three USB ports on the programmer.

   The media device can be a USB floppy drive, a USB flash drive, or a PC connected to the Merlin™ PCS through a 9-pin serial to USB connector cable. The floppy drive must be powered through the USB drive, not by an external power source.
2. Select the format for the exported data.

   The PC database-compatible record is smaller and contains only data for PC-based database programs. Select the Export Data button. The Merlin.net™ PCN-compatible record is larger and contains more detailed information.
   The programmer lists all connected media devices.
3. Select the desired media device. If a media device has not been detected, select the Redetect Media button.
4. Select the Export button.

Accessed From: Wrap-Up Overview button > Export Data button

Clear Trends

The Clear Trends window clears the CorVue™ Impedance Monitoring (page 29) Trend, AT/AF Burden (page 27) Trend and Exercise & Activity (page 29) Trends data from the device memory. Device data collected by the programmer during the session remains available until you select the End Session button.

Accessed From: Wrap-up Overview button > Clear Trends button

Clear Diagnostics

From the Clear Diagnostics window you can clear the Diagnostics (page 25) (except for the AT/AF Burden (page 27) and Exercise & Activity (page 29) Trend data), Episodes (page 19), and stored EGMs from the device memory. Device data collected by the programmer during the session remains available until you select the End Session button.

[153] Battery voltage is not shown for devices with a Greatbatch Medical Models 2753, 2850, and 2950 batteries.
[154] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Note

Clearing Diagnostics will clear all AT/AF Alerts.

Accessed From: Wrap-up Overview button > Clear Diagnostics button

Restore Initial Values

The Restore Initial Values button reprograms the settings that were read at the initial interrogation. When you press the Program button, all parameter changes made during the session are lost.

Accessed From: Wrap-up Overview button > Restore Initial Values button

Mode Descriptions

St. Jude Medical™ devices may be programmed to the following pacing and therapy modes. All permanent pacing modes can also be programmed to operate with rate-modulation (R). See Rate-Responsive Modes (page 160).

Table 40. Available Modes[155][156]

Dual-Chamber	Atrial	Ventricular	Off Modes
DDD (page 153)	AAI (page 159)	VVI (page 157)	Pacing Off (page 160)
DDI (page 154)	AOO (page 160)	VOO (page 157)	
DOO (page 155)	AAT (page 159)	VVT (page 159)	
DDT (page 155)	VVI(R)-AAI(R) (page 161)		
DVI (page 156)	VOO(R)-AOO(R) (page 161)		
VDD (page 158)	VVT(R)-AAT(R) (page 161)		

DDD

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

See DDD Mode timing diagram (page 154).

The DDD Mode is a dual-chamber, atrial-based timing mode in which increases or decreases in the sensed atrial rate are duplicated by similar changes in the ventricular rate. Sensed P-waves or R-waves inhibit output pulses, while no intrinsic activity during the alert periods result in delivered pulses. There are four pacing states:

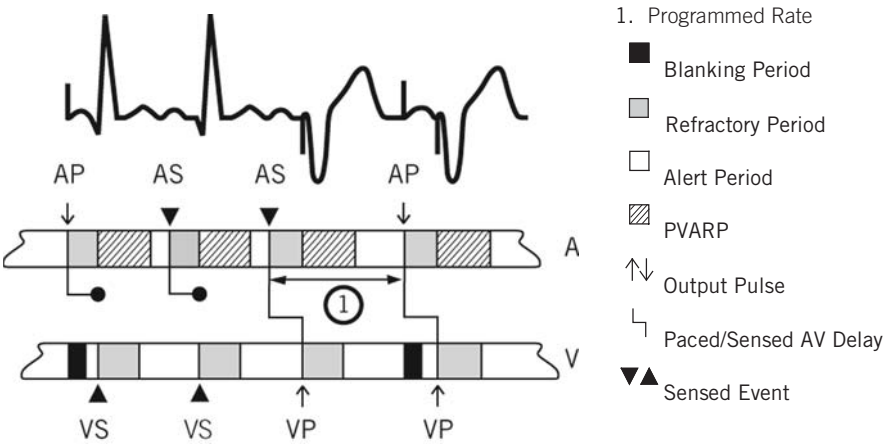
1. **AS.** A sensed atrial event (AS) inhibits an A. pulse and begins the Sensed AV Delay (page 70), and resets the device timing. The A. sense channel becomes refractory until the end of the PVARP (page 81) while the V. channel becomes alert to R-waves.
2. **AP.** During the atrial alert period, no atrial sensed event is detected, and the device delivers an atrial pulse (AP) at the end of the alert period. This starts the Paced AV Delay (page 70), where the A. channel is refractory to atrial sensed events, while the V. channel becomes alert to R-waves.
3. **VS.** During the Paced/Sensed AV Delay, the V. channel senses a ventricular sensed event (VS) and inhibits the pulse but does not reset the timing. The Ventricular Sense Refractory (page 83) period and PVARP begin and continue until the periods time out. Then, both channels become alert to sensed events.
4. **VP.** The V. channel does not sense any signals during the Paced/Sensed AV Delay and delivers a ventricular pulse (VP) at the end of the delay. The Ventricular Pace Refractory (page 83) period and PVARP begin and continue until the periods time out. Then, both channels become alert to sensed events.

Indications. DDD operation is indicated in the presence of AV conduction disorders with normal or abnormal sinus node function and if the patient may benefit from a high degree of ventricular pacing.

Contraindications. DDD operation with Auto Mode Switch (page 86) set to Off is contraindicated in the presence of chronic atrial tachyarrhythmias or silent atria. However, the device's Auto Mode Switch feature can automatically switch the device to DDI operation in the presence of atrial tachyarrhythmias. Retrograde conduction, though not a contraindication, requires the careful setting of the PVARP parameter.

[155] In CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs, DOO, AOO, and VOO modes are available as permanent pacing modes only when the Zone configuration is set to Off or Tachy Therapy is set to Disabled. Otherwise, DOO, AOO, and VOO modes are available only for Temporary Pacing.
[156] In CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs, AAT mode is available only for Temporary Pacing.

Figure 15. DDD Mode timing diagram



DDI

(Dual-Chamber Pacing, Sensing, and Inhibition; No Atrial Tracking)

See DDI Mode timing diagram (page 155).

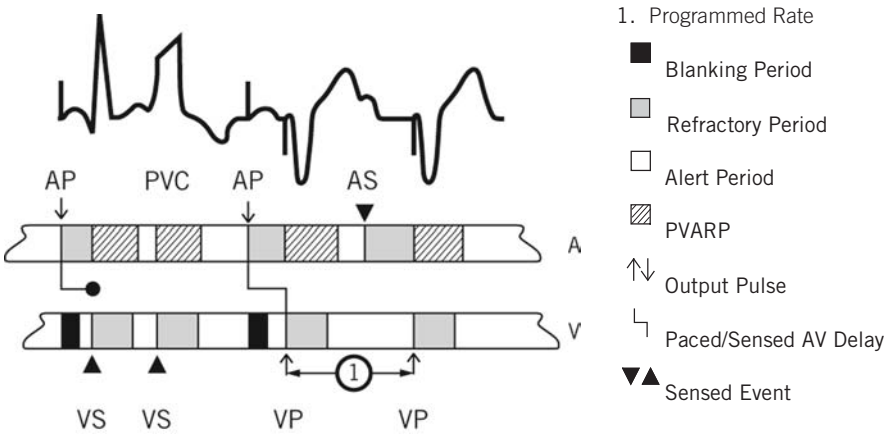
The DDI mode is a non-tracking, dual-chamber mode in which sensed atrial activity does not cause a change in timing. Atrial tachycardias do not result in increased pacing rates. There are four pacing states:

1. **AS.** A sensed atrial event (AS) inhibits the A. pulse and begins an atrial refractory period which ends at the V. pulse. The V. channel remains alert to R-waves except during the Ventricular Sense Refractory (page 83) period and after an A. pulse.
2. **AP.** During the atrial alert period, no atrial sensed event is detected, and the device delivers an atrial pulse (AP) at the end of the alert period. This starts the Paced AV Delay (page 70), where the A. channel is refractory to atrial sensed events. The V. channel remains alert to R-waves except during the Ventricular Pace Refractory (page 83) period and after an A. pulse.
3. **VS.** During the V. alert period of the Paced AV Delay, the channel detects a ventricular sensed event (VS), inhibits the pulse, and resets the timing. The V. Sense Refractory and PVARP (page 81) begin and remain in effect until the periods time out. Then, both channels become alert to sensed events.
4. **VP.** The V. channel does not detect a sensed event during the alert period or the Paced AV Delay and delivers a pulse (VP) at the end of the delay. The Ventricular Pace Refractory and PVARP begin and remain in effect until the periods time out. Then, both channels become alert to sensed events.

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

Contraindications. DDI operation is contraindicated in AV block with normal sinus node function and silent atria and in AV block with chronic atrial fibrillation or flutter.

Figure 16. DDI Mode timing diagram



DDT

(Dual-Chamber Pacing, Sensing, and Triggering)

See DDT Mode timing diagram (page 155).

The DDT mode is a non-tracking, dual-chamber mode in which sensed atrial activity does not cause a change in timing. Atrial tachycardias do not result in increased pacing rates.

In this atrial inhibited, ventricular triggered pacing mode, the device senses (in the atrium and right ventricle) and paces (in the atrium and both ventricles) at the programmed Base Rate, AV Delay, and Interventricular Delay. The device paces either in the absence of intrinsic activity or synchronously with the sensing of an R-wave. The device allows biventricular and RV-only pacing.

During the AV Delay, if the device senses a ventricular event, it delivers an output pulse synchronous with the sensed event and restarts the timing cycle. If it does not sense a ventricular event by the end of the AV Delay, it delivers an output pulse and restarts the timing cycle.

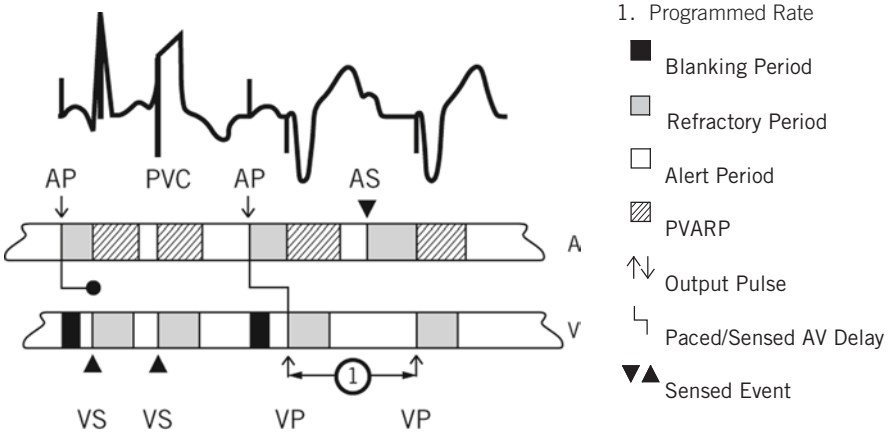
The figure below depicts the operation of DDT mode.

Indications. DDT operation is intended for patients who may benefit from simultaneous pacing of left and right ventricles when the ventricular intrinsic activity exceeds the Base Rate setting.

Contraindications. DDT mode is contraindicated in high-grade AV block with normal sinus nodal function and silent atria.

Available In: CRT-Ds and CRT-Ps with Ventricular Triggering Capability (page 194)

Figure 17. DDT Mode timing diagram



DOO

(Dual-Chamber Asynchronous Pacing)

See DOO Mode timing diagram (page 156).

In DOO mode, the device paces in the atrium and ventricle(s)[157] at the programmed Base Rate and Paced AV Delay (page 70) regardless of intrinsic activity.

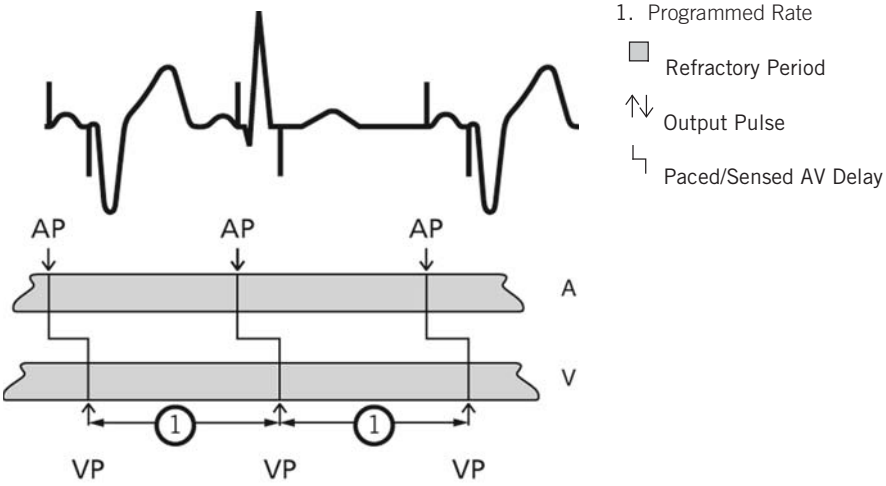
CAUTION

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

Indications. DOO operation is indicated when there is a need for pacing in the atrium and ventricle with the likelihood that significant electromagnetic or electromyogenic noise could inappropriately inhibit or trigger the device.

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

Figure 18. DOO Mode timing diagram



DVI

(Dual-Chamber Pacing; Ventricular Sensing, Inhibition)

See DVI Mode timing diagram (page 157).

The DVI mode is a dual-chamber mode in which sensed atrial activity is ignored, although the device can pace the atrium. The DVI mode has three states:

1. **AP.** At the end of the atrial escape interval, the device delivers an atrial pulse. This starts the Paced AV Delay (page 70), during which the V. channel remains alert to sensed events.
2. **VS.** During the Paced AV Delay, the V. channel detects a ventricular sensed event (VS), inhibits the pulse, and resets the timing. The V. Refractory Period begins and remains in effect until the periods time out. Then, the V. channel becomes alert to R-waves.
3. **VP.** The V. channel does not detect a sensed event during the Paced AV Delay and delivers a pulse (VP) at the end of the delay. The V. Refractory Period begins and continues until the period times out. Then, the V. channel becomes alert to R-waves.

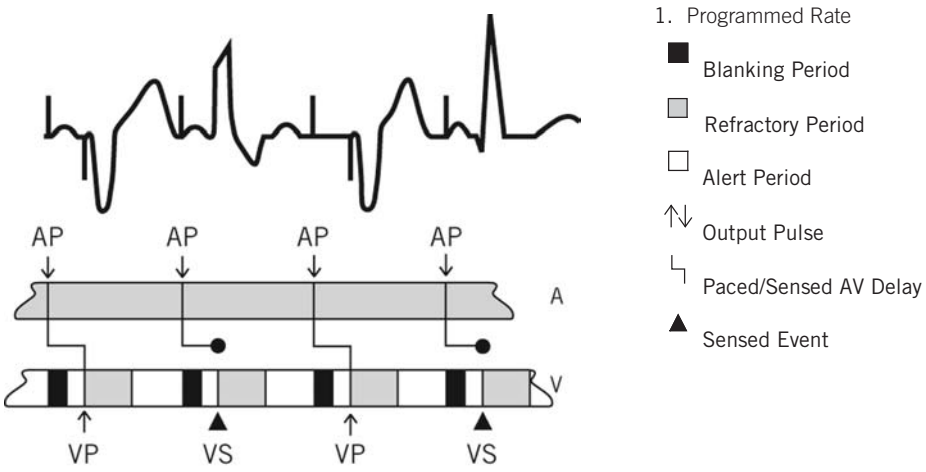
Indications. DVI operation is indicated in situations where atrial and ventricular pacing are required and there is a specific reason that atrial sensing is not desired.

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

Available In: CRT-Ps (page 164) and Dual-Chamber Pacemakers (page 164)

[157] All CRT-Ds and CRT-Ps allow biventricular and RV-only pacing.

Figure 19. DVI Mode timing diagram



VVI

(Ventricular Pacing, Sensing, and Inhibition)

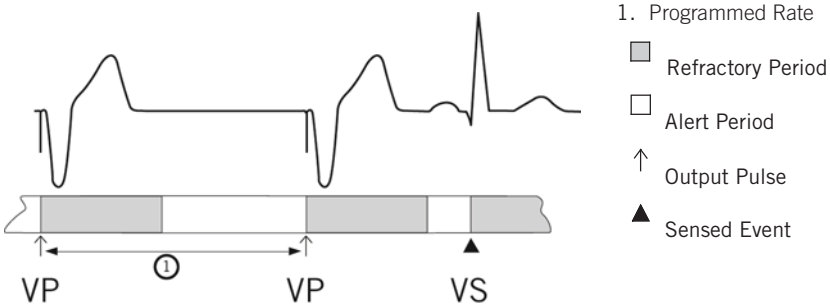
See VVI Mode timing diagram (page 157).

In VVI mode, the device paces the ventricle(s)[158] at the programmed rate if it does not detect a sensed event. If the device detects a sensed event during the alert period, it withholds the pulse and it resets the timing period to the start of the Ventricular Sense Refractory (page 83) period.

Indications. VVI operation is indicated for symptomatic bradycardia of any etiology. 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 operation is contraindicated in the presence of pacemaker syndrome.

Figure 20. VVI Mode timing diagram



VOO

(Ventricular Asynchronous Pacing)

See VOO Mode timing diagram (page 158).

In VOO mode, the device paces the ventricle(s)[159] at the programmed rate regardless of the intrinsic rhythm.

CAUTION

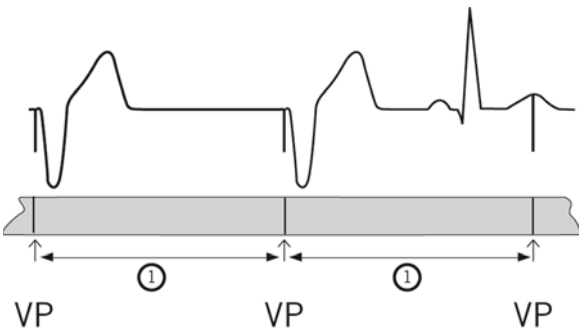
VOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous ventricular tachyarrhythmias.

Indications. VOO operation may be indicated for patients who are subject to electromagnetic interference or electromyogenic noise and who need continual ventricular pacing.

[158] All CRT-Ds and CRT-Ps allow biventricular and RV-only pacing.
[159] All CRT-Ds and CRT-Ps allow biventricular and RV-only pacing.

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

Figure 21. VOO Mode timing diagram



1. Programmed Rate
Refractory Period
Output Pulse

VDD

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

See VDD Mode timing diagram (page 158).

The VDD mode is a dual-chamber, atrial-tracking mode with no atrial output in which ventricular pacing is synchronized to intrinsic atrial activity. The device senses in both chambers but only paces in the ventricle. The mode maintains a minimum atrial alert window equal to the Sensed AV Delay (page 70) + 25 ms (preferential P-wave sensing). The PVARP (page 81) is shortened if other timing cycles infringe upon the atrial alert window. There are three pacing states:

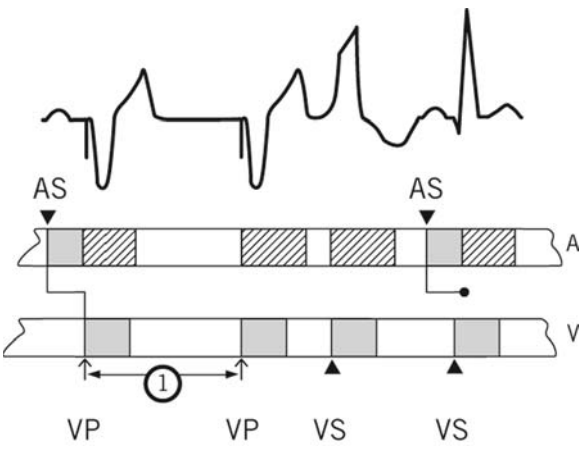
1. **AS.** A sensed atrial event during the V-V interval initiates the Sensed AV Delay and may extend the V-V interval while AV synchrony is maintained. It is possible to track a sinus rhythm resulting in a rate lower than the programmed Base Rate.
2. **VS.** If the atrial channel detects a sensed event and the V. channel detects a sensed event during the Sensed AV Delay, the device resets the V-V timing.
3. **VP.** If no atrial and no ventricular events are sensed, the device paces the ventricle (VVI pacing).

Indications. VDD operation is indicated for AV block with normal sinus function.

Contraindications. VDD operation is contraindicated for sinus node dysfunction, chronic atrial flutter or fibrillation, inadequate atrial sensing, or silent atria.

Available In: CRT-Ps (page 164) and Dual-Chamber Pacemakers (page 164)

Figure 22. VDD Mode timing diagram



1. Programmed Rate
Refractory Period
Alert Period
PVARP
Output Pulse
Paced/Sensed AV Delay
Sensed Event

VVT

(Ventricular Pacing, Sensing, and Triggering)

See VVT Mode timing diagram (page 159).

In VVT mode, the device stimulates the ventricles at the programmed rate in the absence of intrinsic ventricular activity. Intrinsic ventricular activity during the alert period causes the device to deliver an output pulse synchronously with the detected ventricular event.

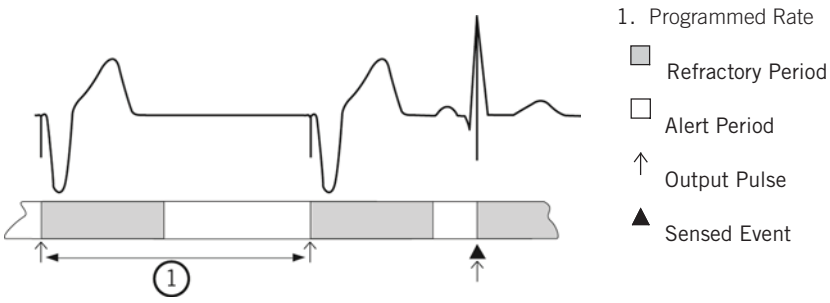
Indications. VVT operation may be useful in avoiding inappropriate inhibition of the pulse generator due to electromagnetic or electromyogenic interference. A triggered mode paces on detection of such signals, instead of being inhibited by them.

VVT operation may also be used to identify the sensing site within a complex and for temporary diagnostic use in the evaluation and management of arrhythmias performed by triggering the device output through chest wall pacing.

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

Available In: Devices with Ventricular Triggering Capability (page 194)

Figure 23. VVT Mode timing diagram



AAI

(Atrial Pacing, Sensing, and Inhibition)

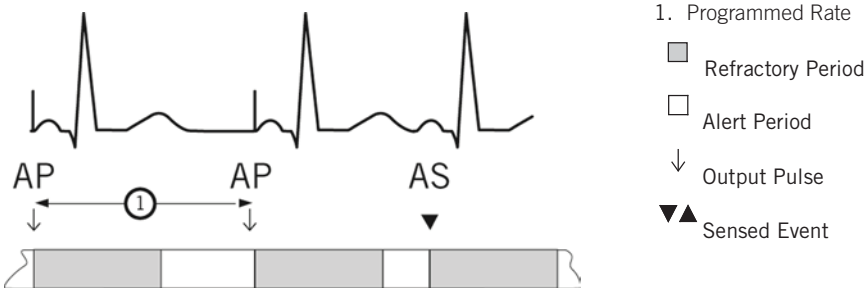
See AAI Mode timing diagram (page 159).

In AAI mode, the device paces the atrium at the programmed rate if the atrial events are not sensed. If the device detects a sensed event during the alert period, it withholds the pulse and resets the timing to the start of the Atrial Sense Refractory (page 83) period.

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

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

Figure 24. AAI Mode timing diagram



AAT

(Atrial Pacing, Sensing, and Triggering)

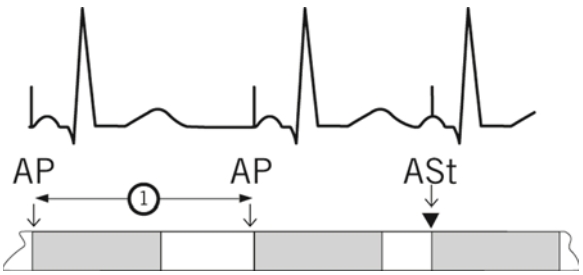
See AAT Mode timing diagram (page 160).

In AAT mode (available only for Temporary Pacing (page 58) in CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164)), the device paces the atrium at the programmed rate in the absence of atrial sensed events. If the device detects a sensed event during the alert period, it delivers a pulse synchronously with the sensed event.

Indications. AAT may be useful to avoid inappropriate pulse inhibition resulting from electromagnetic or electromyogenic interference. AAT operation can also be used to identify the sensing site within a complex and to evaluate and manage arrhythmias elicited by chest wall stimulation.

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

Figure 25. AAT Mode timing diagram



1. Programmed Rate
- Refractory Period
- Alert Period
- Output Pulse
- Sensed Event

AOO

(Atrial Asynchronous Pacing)

See AOO Mode timing diagram (page 160).

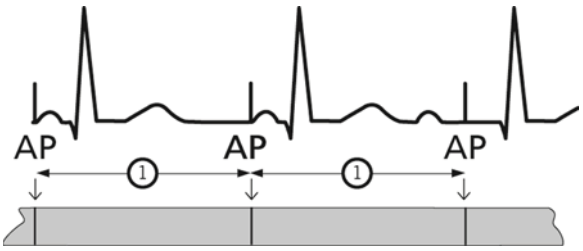
In AOO mode, the device paces the atrium at the programmed rate regardless of intrinsic rhythm.

> CAUTION
>
> **AOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous atrial tachyarrhythmias.**

Indications. AOO operation may be indicated for patients who are subject to electromagnetic interference or electromyogenic noise and who need continual atrial pacing.

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

Figure 26. AOO Mode timing diagram



1. Programmed Rate
- Refractory Period
- Output Pulse

Pacing Off

> CAUTION
>
> **Pacing Off mode is not recommended for pacemaker-dependent patients or patients who might be affected by even a short cessation of pacemaker function.**

In Pacing Off mode, atrial and ventricular pacing is disabled. This mode is useful primarily for temporary diagnostic evaluation and recording of intrinsic activity. When this mode is programmed, the programmer does not show the measured rate.

When Mode is set to Pacing Off, the Restore Parameters button is available. Since the previously programmed parameters are stored in the device, it is not necessary to use the same programmer to turn the device off and to restore parameters.

Rate-Responsive Modes

The function of rate-responsive modes (Sensor (page 63) On) is to alter the pacing rate to match activity changes in accordance with programmed parameters. Rate-responsiveness can be enabled with any permanent pacing mode.

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

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

Operating Modes for Single-Chamber Accent™ Devices

Additional atrial operating modes are available for Accent single-chamber devices[160] with the lead implanted in the atrium. To select one of these modes, you must first program the Lead Chamber parameter to the Atrium setting (accessible from the Brady Parameters > Leads window). Then select one of the available Mode settings from the Brady Parameters > Basic Operation window.

When you select the Atrium Lead Chamber setting, the programmer institutes the following values to ensure optimal operation in the atrium:

- Sensitivity is set to 0.5 mV
- Pace Refractory period is set to 250 ms[161]
- V. AutoCapture is set to Off.

Each mode can also be programmed with Sensor On (R).

> **Note**
>
> Although the atrial chamber is selected, some diagnostics, markers, and parameters will display a "V" label. For example, the atrial paced parameter is labeled "VP" in the Rhythm Display and the EGM is labeled Ventricular EGM.

VVI(R)-AAI(R)

The VVI-AAI(R) mode uses VVI (page 157) timing and markers but operates in the atrium.

In VVI-AAI(R) mode, the device paces the atrium at the programmed rate if it does not detect a sensed event. If the device detects a sensed event during the alert period, it withholds the pulse and it resets the timing period to the start of the Atrial Sense Refractory period.

VOO(R)-AOO(R)

The VOO(R)-AOO(R) mode uses VOO(R) (page 157) timing and markers but operates in the atrium.

In VOO(R)-AOO(R) mode, the device paces the atrium at the programmed rate regardless of the intrinsic rhythm.

> **Note**
>
> VOO(R)-AOO(R) mode is primarily intended for temporary use. Long-term use may result in competitive pacing, which may induce potentially dangerous tachyarrhythmias.

VVT(R)-AAT(R)

The VVT(R)-AAT(R) mode uses VVT(R) (page 159) timing and markers but operates in the atrium.

In VVT(R)-AAT(R) mode, the device stimulates the atrium at the programmed rate in the absence of intrinsic atrial activity. Intrinsic atrial activity during the alert period causes the device to deliver an output pulse synchronously with the detected atrial event.

[160] Applicable for the Merlin PCS equipped with Model 3330 software v. 10.2.2 or higher.
[161] If you program the Sensitivity setting to AutoSense, the Pace Refractory period is autoprogrammed to 190 ms.

Additional Programming Information

Contents:

- Technical Support (page 163)
- Supported Devices (page 163)
- Main Programming Window (page 165)
- Telemetry Communication (page 165)
- Tachy Therapy Enable/Disable (page 168)
- Device Parameters and Settings Selection (page 168)
- Preview Changes (page 169)
- Start Temporary (page 169)
- Print Menu (page 169)
- Emergency Operation (page 173)
- Reset Function (page 175)

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.

Supported Devices

Refer to the Merlin™ PCS Start-Up Help Manual for a list of all devices that can be interrogated by the Merlin PCS equipped with Model 3330 software.

The devices listed in the following tables are discussed in this help system.

- CRT-Ds (page 163)
- Dual-Chamber ICDs (page 163)
- Single-Chamber ICDs (page 164)
- CRT-Ps (page 164)
- Dual-Chamber Pacemakers (page 164)
- Single-Chamber Pacemakers (page 164)

CRT-Ds

Table 41. CRT-Ds

Name	Model Number
Promote	3107-30, 3107-36, 3107-36Q, CD3207-36Q
Promote RF	3207-30, 3207-36
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40Q, CD3369-40C, CD3369-40QC

Dual-Chamber ICDs

Table 42. Dual-chamber ICDs

Name	Model Number
Current DR	2107-30, 2107-36, CD2207-36Q
Current DR RF	2207-30, 2207-36
Current+ DR	CD2211-36, CD2211-36Q

Table 42. Dual-chamber ICDs

Name	Model Number
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC

Single-Chamber ICDs

Table 43. Single-Chamber ICDs

Name	Model Number
Current VR	1107-30, 1107-36, CD1207-36Q
Current VR RF	1207-30, 1207-36
Current+ VR	CD1211-36, CD1211-36Q
Current Accel VR	CD1215-30, CD1215-36, CD1215-36Q
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC

CRT-Ps

Table 44. CRT-Ps

Name	Model Number
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Dual-Chamber Pacemakers

Table 45. Dual-chamber pacemakers

Name	Model Number
Accent DR	PM2110
Endurity	PM2160
Endurity MRI	PM2172
Accent DR RF	PM2210
Assurity	PM2240
Assurity MRI	PM2272

Single-Chamber Pacemakers

Table 46. Single-chamber pacemakers

Name	Model Number
Accent SR	PM1110

Table 46. Single-chamber pacemakers

Name	Model Number
Endurity	PM1160
Endurity MRI	PM1172
Accent SR RF	PM1210
Assurity	PM1240
Assurity MRI	PM1272

Main Programming Window

The Main Programming window is the upper portion of the screen that contains the following buttons:

- **? button**. Opens the context-sensitive on-screen help menu.
- **Tools menu**. Opens a menu for the PSA application, preferences, and other functions.
- **Telemetry Communication** (page 165) icons. Displays the current condition of the RF Telemetry link.
- **Tachy Therapy Enable** (page 168)/**Disable**[162]. Opens a window to temporarily disable tachyarrhythmia therapies.
- **Patient Data** (page 16). Opens a window to write and edit patient information into the device memory.
- **Note** (page 17). Opens a window for additional patient data.
- **Measured Heart Rate**
- **Rhythm Display** (page 5). Shows the real-time waveforms.
- **Adjust Display** (page 12) button. Opens a window to adjust the Rhythm Display.
- **Freeze Capture button**. Freezes the Rhythm Display and opens a window to adjust and print the frozen waveform.
- **Print Settings** (page 172) button. Opens the Print Settings window. An icon without a cord indicates the programmer is using the internal printer. An icon with a cord indicates the programmer is connected to an external printer (see the figure below). The "PDF" icon indicates that a PDF report is available for export. See PDFs (page 3). To change printers, select Tools > Preferences > Printer (Printer Preferences (page 4)).

Figure 27. Printer icons

1. Internal printer in use
2. External printer connected
3. Paperless or PDF printing selected

Telemetry Communication

Contents:

- RF Telemetry Communication (page 165)
- Telemetry Interruption (page 167)
- Resuming Telemetry (page 167)
- Wand-Only Telemetry (page 168)

RF Telemetry Communication

Devices equipped with RF communication are programmed and operated identically to devices with inductive telemetry. To establish RF communication between the device and the programmer and to troubleshoot communications problems, you must first attach the RF Antenna to the programmer. Please refer to the Merlin™ Patient Care System User's Manual that accompanies the programmer and the Merlin Antenna. Use the telemetry strength indicators to evaluate the communication.

If the device is RF-compatible, an icon in the upper left-hand corner of the screen during the programming session indicates the status of the RF communication link. If an RF icon does not appear on the screen during the session, the device is not RF-compatible. See the table below.

Suboptimal RF Communication

The Merlin™ PCS indicates the quality of the RF communication by the telemetry strength indicator LEDs on both the programmer and the Merlin Antenna. Below is a list of potential causes of suboptimal radio communication:

Possible Causes

[162] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

- The Merlin Antenna orientation/location is suboptimal.
- People or objects interfere with the communication between the Merlin Antenna and the device.
- The Merlin Antenna is too far away from the device.
- Someone is holding the Merlin Antenna.
- Other products in the vicinity are causing electromagnetic interference (EMI).
- The Merlin Antenna cable is wound around the Merlin Antenna.

Solutions

- Try to optimize RF communication (increase the number of telemetry strength indicator LEDs):
- Move or reorient the Merlin Antenna slightly.
- Make sure that the space between the Merlin Antenna and the device is free from interfering objects/people.
- Move the Merlin Antenna closer to the device.
- Make sure that the front of the Merlin Antenna faces the implantable device.
- Power off or remove equipment that could cause EMI.
- Make sure the Merlin Antenna cable is not wound around the Merlin Antenna.
- Do not hold the Merlin Antenna.

If none of the above solutions solve the problem, avoid using RF communication and use the inductive telemetry wand instead.

CAUTION

Fibber & NIPS (page 50) Tests. While you are conducting the Fibber[163] and NIPS tests, ensure that at least four telemetry strength indicator LEDs appear on the programmer and the Merlin Antenna. If fewer LEDs are lit, the device may break its communication link when it charges or dumps the capacitors[164]. If this occurs, the test ends and the device returns to its permanently programmed parameters.

Loss of RF Communication. If RF communication is lost, a single LED on the antenna and the programmer flashes while the system attempts to recover telemetry contact. The system searches for the device for 60 seconds before prompting you to Continue Session (try to re-connect the RF communication) or Continue with Wand Only (try to establish inductive telemetry communication).

Note

Keep the inductive telemetry wand connected to the programmer during an RF communication session in case you lose RF communication.

When you interrogate an RF-capable device, the programmer uses RF communication as the primary telemetry method. If the system fails to establish RF communication, the programmer uses inductive telemetry.

To end RF communication, select the End Session button to close the device session. If you do not use the End Session button and simply move the device out of RF communication range, the system attempts to re-establish RF communication for up to three hours after the start of the session[165]. Use the End Session button to decrease battery drain and improve longevity.

Just as with the use of inductive telemetry, loss of RF communication during clinical testing ends the test and restores permanently programmed parameters. Ensure proper RF communication before any testing.

RF communication is suspended when you start the PSA application during a programming session and is restored when you close the PSA application

[163] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[164] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[165] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

Table 47. RF telemetry icons

Location	RF Telemetry Status	Icon
Start-Up Screen Icons	Disconnected RF Base Station/Not Working	
	Ready to connect to device	
Application Icons	Active RF telemetry connection	
	Inactive RF telemetry connection	
	Only wand telemetry is available	

Telemetry Interruption

Interruption in telemetry can occasionally occur, and when it does, you can resume communications with the programmer or you can end the device session:

- **Continue**. To attempt to resume the session using the current telemetry mode (RF or Inductive), select the Continue button.
- **Continue with Wand Only**[166]. In the event RF telemetry is interrupted, you can continue the session using inductive telemetry by selecting the Continue with Wand Only button. Once you have selected this button, position the wand over the device to continue the session.
- **End Session**. To close the device session, select the End Session button. To print summary reports for the session, select the Print Selected Reports check-box.

Loss of RF telemetry ends clinical testing and restores permanently programmed parameters. Restart the desired operation once inductive communication has been established.

In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164) devices, RF Telemetry can also be managed using the telemetry button on the main programming window. Select this button to enable or disable RF telemetry.

Resuming Telemetry

In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), RF telemetry is temporarily disabled after 3 minutes of programmer inactivity in order to preserve battery longevity. RF telemetry can also be disabled by pressing the telemetry button on the application screen. When this occurs, you can resume the current session using RF telemetry, inductive telemetry, or you can end the device session.

- **Continue.** To attempt to resume the session using RF Telemetry, select the Continue button.
- **Continue with Wand Only.**[167] To continue the session using inductive telemetry, select the Continue with Wand Only button. Once you have selected this button, position the wand over the device to continue the session.

[166] For devices with RF telemetry capability.
[167] Available in devices with RF Telemetry capability only.

- **End Session.** To close the device session, select the End Session button. To print summary reports for the session, select the Print Selected Reports check-box.

Loss of RF telemetry ends clinical testing and restores permanently programmed parameters. Restart the desired operation once inductive communication has been established.

In CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers, RF Telemetry can also be managed using the telemetry button on the main programming window. Select this button to enable or disable RF telemetry.

Wand-Only Telemetry

In CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164), in some instances RF telemetry may be temporarily disabled in order to preserve battery longevity. This is a normal maintenance function and is only in effect for the current session. When this temporary loss of RF telemetry occurs, you can continue the session using inductive telemetry.

When RF telemetry is temporarily disabled, you can choose to end the session or continue the session using wand-only inductive communication from the Wand-Only Telemetry window.

- **Continue with Wand Only.**[168] To continue the session using inductive telemetry, select the Continue with Wand Only button. Once you have selected this button, position the wand over the device to continue the session.
- **End Session.** To close the device session, select the End Session button. To print summary reports for the session, select the Print Selected Reports check-box.

Loss of RF telemetry ends clinical testing and restores permanently programmed parameters. Restart the desired operation once inductive communication has been established.

Tachy Therapy Enable/Disable

The Tachy Therapy Enable/Disable button on the main programming window is available when any tachyarrhythmia therapy has been programmed. Select this button to disable VT/VF detection and therapy delivery without affecting other programmed parameters[169]. This is useful prior to noise-generating medical procedures such as electrocautery, where the device could detect noise from the equipment, interpret it as an arrhythmic episode, and deliver therapy. When therapy is disabled, diagnostic data are not updated or cleared.

> **Note**
>
> When tachy therapy is disabled through this button, the device stores all previous tachy parameter settings and restores them when the therapy is enabled. When you use the Off Zone Configuration setting, the tachy parameters are not stored in the device and cannot be automatically restored when the Zone Configuration (page 89) setting is changed.

The button reports two states:

- **Tachy Therapy is Disabled**. The programmed parameters are stored in the device. Changes to the device parameters (including tachy parameters) may be programmed.
- **Tachy Therapy is Enabled**. All previously programmed parameters are restored, including any parameters programmed while therapies are disabled.

Since the previously programmed parameters are stored in the device, it is not necessary to use the same programmer to disable and enable therapies.

See also:

- Parameter Availability and Settings (page 197)

Available In: CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)

Accessed From: Main Programming window

Device Parameters and Settings Selection

To change the setting for any parameter, select the desired parameter button. A setting selection window appears. The range of settings is usually indicated at the top and bottom of the scroll bar. The current permanently programmed setting is marked with a small device icon. The nominal value for the setting is indicated by an "N" to the right of the setting.

Select the desired setting. Once a setting is selected, the Preview Changes (page 169) window appears.

Autoprogramming Designators

When you select a new setting, it may result in the automatic re-programming of related parameters. Settings that result in autoprogramming of other parameters are marked in the settings window with a right-angle arrow. The settings window also displays an explanatory note to clarify the setting's relationship with other parameters.

To see the entire set of pending programming changes before you program new settings, select the Preview button (Preview Changes (page 169)).

[168] Available in devices with RF Telemetry capability only.
[169] When tachy therapy is disabled, AT/AF Detection is also disabled.

Preview Changes

The Preview Changes window lists all parameters and settings selected for programming. It also contains the:

- **Discard Changes** button to reject all proposed parameter changes
- **Undo** button to return the last parameter you changed to its prior setting (and any associated auto-selection changes). This does not affect settings made before the last parameter change.
- **Program** button to permanently program the listed parameters
- Start Temporary (page 169) button to temporarily program the listed parameters

  Note

  The "down arrow" icon next to the programmed parameter indicates an autoprogramming change. The "triangle" icon indicates the parameter is actively selected by the user for change.

Start Temporary

When the Start Temporary button is selected from the Preview Changes window, the Discard Changes button disappears, the green highlights turn orange, and the device operates with those settings in effect until the:

- **Cancel Temporary** button is selected, which restores all permanently programmed settings or
- The **Program** button is selected, which permanently programs the temporary settings.

If telemetry is lost while temporary settings are programmed, the device reverts to its permanently programmed settings. The programmer prompts you to either continue or end the session. Select the Continue button to attempt to re-establish communication between the device and programmer.

Print Menu

The Print Menu window contains two tabs:

- Reports (page 169)
- Settings (page 172)

To send the image to an external printer, go to the Tools Menu > Preferences > Printer tab and select the External button.

Reports

- Episodes Settings (page 170)
- Select Diagnostics Reports for Printing (page 171)
- Test Results Settings (page 172)
- Select Episodes for Printing (page 172)
- Select Freezes for Printing (page 172)
- Select Referral Reports for Printing (page 172)
- Wrap-up™ Overview Settings (page 172)

The Reports tab of the Print Menu window allows you to select or deselect any report in the print queue, to select the data included in the report, and to print all selected reports.

The Reports tab contains all available reports, with the type of report currently selected and a check-box next to each selection. To change the type of data printed in any report, select the labeled button.

To place a report in the queue to print, select the check-box next to the report button.

To change the preferences for printing a report, select the button with the report name to open a pop-up dialogue. After you have selected your preferences, you have three choices:

- **Cancel button.** Select this button to cancel any changes to the preferences.
- **Done button.** Select this button to implement the changes for this programming session only.
- **Save Settings button.** Select this button to store your preferences for future programming sessions.

To export your saved PDFs, select the PDFs button. The PDFs button displays the number of pending files.

The types of reports that are available include:

- **FastPath™ Summary (page 15).** Select the FastPath Summary check-box to queue the following data for printing:
  - Patient data
  - Battery data
  - Capture and sense test results
  - Lead impedance measurements
  - Key parameter settings
  - Diagnostics and episodes summary
  - Notes
  - A listing of all alerts.

- **Episodes.** For CRT-Ds, Dual-chamber ICDs, and single-chamber ICDs, select the Episodes button to open the Episodes Settings (page 170) window. This allows you to choose to print the shorter summary ("Episodes Summary" report) or the extended summary ("Extended Episodes" report.)
  For CRT-Ps, Dual-chamber pacemakers, and single-chamber pacemakers, the Episodes Summary report contains the following data:
  - Time last read and last cleared
  - Selected Episodes Triggers, with the number of recorded episodes and EGMs
  - The number and type of device reversions
  - A listing of the Episodes Log.
- **Diagnostics.** Select the Diagnostics button to open the Select Diagnostics Reports for Printing (page 171) window. This allows you to choose to print the shorter summary ("Diagnostics Summary" report) or the extended summary ("Extended Diagnostics" report) and the DirectTrend™[170] report and the AT/AF[171] Alert reports.
- **Test Results.** Select the Test Results button to open the Test Results Settings (page 172) window to choose large or small freezes and the addition of leads and battery data.
- **Parameters.** Select the Parameters check-box to queue the following data for printing:
  - Patient and device data
  - All programmed parameter and trigger settings
- **VT/VF Stored EGMs[172], Other Stored EGMs[173], and Stored EGMs[174].** Select the Stored EGMs button to open the Select Episodes for Printing (page 172) window to choose which Stored EGMs to print.
- **Freezes.** Select the Freeze button to open the Select Freezes for Printing (page 172) window to choose which freezes to print.
- **Referral Reports.** Select the Referral Reports button to open the Select Referral Reports for Printing (page 172) window to select which Referral Reports to print.
- **Wrap-up Overview.** Select the Wrap-up Overview button to open the Wrap-up Overview Settings (page 172) window to print out a second Wrap-up Overview report for the patient.

Accessed From: Print button > Reports tab

Episodes Settings

For CRT-Ds, Dual-chamber ICDs, and single-chamber ICDs, the Episodes Summary Settings window allows you to select which data will be included in the Episodes Settings report. You can select either:

- **Summary,** which queues the following data for printing:
  - Time last read and last cleared
  - A summary of all antitachycardia therapy delivered
  - Last HV lead impedance measurement
  - ATP therapy results
  - Text of Alerts
  - The Episode Tree graphically displaying zone configurations and therapies
  - All recorded episodes (VT/VF and Other) with time, rate, type, duration, therapeutic response, and associated alert (Episodes Log)
- **Extended**, which queues all of the data in the Summary report for printing as well as:
  - Causes of aborted shock and number of emergency shocks
  - Selected Episode Triggers, with the number of recorded episodes
  - Graphs of the number of Episodes converted by ATP bursts for all therapies
  - Episodes converted by ATP
  - LIfetime ATP use in the VF Zone[175]
  - Morphology Template information
  - SVT diagnosis summary and Discrimination Criteria for SVT Diagnosis
  - A listing of Device Reversions
  - High-voltage charging data.

Accessed From: Print button > Reports tab > Episodes button

[170] The DirectTrend™ report is only available for devices with the Enhanced Diagnostic Trend Capability.
[171] The AT/AF Report is only available for devices with the AT/AF Alert Triggers Capability.
[172] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[173] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[174] Available in CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers.
[175] Available in devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability.

Select Diagnostics Reports for Printing

The Select Diagnostics Report for Printing window allows you to select the data that will be included in the Diagnostics report. You can select:

- **Summary**, which queues the following data for printing:
  - All Events recorded since the last reading
  - Atrial and Ventricular Heart Rate histograms
  - AT/AF Burden Trend
  - V Rates During AMS
  - AMS Summary.
  - AT/AF Episodes Mode Switch Duration
- **Extended**, which queues all of the data in the Summary report for printing as well as:
  - Key parameter settings
  - Events graphs
  - AV Intervals diagnostics
  - Tabular data for the V. Rates During AMS, Atrial and Ventricular Heart Rate histograms
  - Weekly readings of the AT/AF Burden
  - AMS Log
  - All Daily Exercise Training diagnostics.
  - CorVue™ Thoracic Impedance Monitoring Graph and CorVue Log (page 30).
- **DirectTrend™ Report.** The Direct Trend report, available for devices with the Enhanced Diagnostic Trend Capability (page 186), is a collection of three-month daily, one-year weekly[176] or one-year daily[177] ,diagnostic trends. Weekly reports compile the data once a week, while the daily reports compile trends every day. The DirectTrend report includes:
  - AT/AF Total Duration Trend. The total time in AT/AF (page 28).
  - V Rates During AT/AF (page 28) Trend. The average and maximum ventricular rate during AT/AF episodes.
  - AT/AF Frequency Trend. The number of AT/AF episodes per day.
  - AT/AF Episode Average/Max Duration Trend. The average and maximum AT/AF episode durations for each day.
  - Daily Percent Pacing Trend. The daily percentage of atrial and ventricular pacing.
  - Daily Heart Rate Trend. The night and day ventricular heart rates for each day.
  - Daily Activity Trend. The total daily activity duration.
  - CorVue Thoracic Impedance Monitoring Graph and Impedance Status Graph.
- **AT/AF Alert**. The AT/AF Alert report is available in devices with the AT/AF Alert Triggers Capability (page 180) when the AT/AF Alert Triggers (page 134) have been programmed and AT/AF Alerts have been recorded. If no AT/AF Alerts have occurred since the diagnostics were last cleared, the AT/AF Alert report is not available. However, you can still select the AT/AF Alert check-box to queue the report to be printed in future sessions should an AT/AF Alert be triggered.
  The report contains:
  - Recent AT/AF alerts
  - AT/AF Alert Trigger settings
  - Key parameter settings
  - AT/AF Detection and Response parameter settings
  - Key AT/AF Log Episodes
  - AT/AF Burden Trend
  - V. Rates During AMS
  - AMS Summary
  - AT/AF Episodes Mode Switch Duration

Accessed From: Print button > Reports tab > Diagnostics button

[176] One-year weekly trends are not available in devices with Enhanced Diagnostic Trend (1-Year Daily Reports) Capability.
[177] One-year daily trends are only available in devices with Enhanced Diagnostic Trend (1-Year Daily Reports) Capability.

Test Results Settings

The Test Results Settings window sets the size of the Capture and Sense test results printout and allows you to include or exclude information on Battery & Leads and the CRT Toolkit Report (in devices with VectSelect Quartet™ LV Pulse Configuration capability (page 194)). There are two radio buttons:

- **Small Freezes** radio button prints freezes and long-term trends in reduced size, with each chamber's results fitted to a single page.
- **Large Freezes** radio button prints larger sized freezes and long-term trends, resulting in longer reports.

Select the **Include Battery & Leads** (page 37) check-box to include data from the Battery & Leads window and the Lead Impedance (page 38) window in the report.

In devices with VectSelect Quartet™ LV Pulse Configuration capability (page 194), select the **CRT Toolkit** check-box to print programmed left ventricular programmed parameters, and data from MultiVector Testing (page 42), RV-LV Conduction Time Measurements (page 42), and QuickOpt™ Timing Cycle Optimization Measurements (page 48).

The **Save Settings** button records your preferences for future programming sessions.

Accessed From: Print button > Reports tab > Test Results button

Select Episodes for Printing

The Select Episodes for Printing window allows you to choose which episodes to include in the printed report. Select the check-box next to each episode to add to the print queue.

Accessed From: Print button > Reports tab > VT/VF Stored EGMs, Other Stored EGMs, Stored EGMs buttons

Select Freezes for Printing

The Select Freezes for Printing window allows you to choose which freezes to include in the printed report. Select the check-box next to each freeze to add to the print queue, or select the Select All button.

Accessed From: Print button > Reports tab > Freezes button

Select Referral Reports for Printing

The Select Referral Reports for Printing window allows you to choose which reports you would like to print. The availability of the reports depends on the capabilities of the devices. The choices can include:

- **Heart In Focus™ report.** The Heart in Focus report prints a one-page, abbreviated summary of selected diagnostics and episodes since date last cleared. These can include the current key parameter settings, patient information, Daily Exercise Training (page 29) and Total Daily Activity (page 29) trends, Ventricular Heart Rate Histogram (page 26), AT/AF Burden (page 27) trend, V Rates During AMS (page 27) histogram, and key AMS Log (page 27) Episodes.
- **CorVue™ Thoracic Impedance Monitoring.** The Thoracic Impedance Monitoring report shows the information in the CorVue™ Thoracic Impedance Monitoring tab, including the graphs, any impedance episodes recorded, and any clinical comments.
- **MRI Summary Report.** Select the MRI Summary Report button to print out a report containing the patient data, MRI Settings (page 149) values, lead information, a log of the times and durations the MRI Settings were enabled and disabled, and the MRI Checklist (page 150) results.

Accessed From: Print button > Reports tab > Referral Reports button

Wrap-up™ Overview Settings

Select the check-box on the Wrap-up™ Overview Settings window to print a second copy of the Wrap-up Overview for the patient.

Accessed From: Print button > Reports tab > Wrap-up Overview button

Settings

The Settings tab of the Print Menu window allows you to set print preferences for printing at the start of the programming session and let you change the settings for PDFs, Page Headers and Printer Preferences in the current session.

- **Reports Printed at Interrogation.** Select the check-box to enable the programmer to print reports when a device is initially interrogated. Un-check the box if you do not want reports printed at initial interrogation. Select the Reports Printed at Interrogation button to open the Reports Printed at Interrogation (page 173) window to select which reports are printed.
- **Reports Selected for Printing**. Select the check-box to select the reports for printing when you select the Print button on the FastPath™ Summary screen, the Print Menu, and the End Session screen. Select the Reports Printed at Interrogation button to open the Reports Selected for Printing (page 173) window to select which reports to print.
- **Printer Preferences**. Opens the Printer Preferences (page 4) window, which allows you to:
  - select the number of copies printed for each report
  - choose to print reports with paperless printing (to PDF) or paper printing from the internal printer or an external printer.

- **Page Headers**. Select this button to open the Page Header & Footer Settings (page 173) window to select information that appears on the page headers and footers of the reports.
- **PDFs**. Opens the PDFs (page 3) window to export or delete PDFs.

Accessed From: Print button > Settings tab

Reports Printed at Interrogation

The Reports Printed at Interrogation window allows you to choose which reports to include in the report printed at interrogation. When you have made your choices, select the Save Settings button to store your preferences for future programming sessions. The choices include:

- FastPath™ Summary
- Episodes
- Diagnostics
- Parameters
- Presenting Rhythm Freeze.

The type of report printed for the Episodes and Diagnostics reports is determined by the saved settings accessed on the Reports (page 169) tab.

Accessed From: Print button > Settings tab > Reports Printed at Interrogation button

Reports Selected for Printing

The Reports Selected for Printing window allows you to choose which reports to queue at the next programming session. When you have made your choices, select the Save Settings button to store your preferences for future programming sessions. The choices include:

- FastPath™ Summary
- Episodes
- Diagnostics
- Test Results
- Parameters
- Referral Reports
- Presenting Rhythm Freeze
- Wrap-up™ Overview.

The type of report printed is determined by the settings accessed on the Reports (page 169) window.

Accessed From: Print button > Settings tab > Reports Selected for Printing button

Page Header & Footer Settings

The Page header & footer settings window allows you to include the patient name and patient ID in the report header and the clinic name in the report footer. Select the appropriate check-box or the on-screen keyboard to input the clinic name. When you have made your choices, select the Save Settings button to store your preferences for future programming sessions.

Accessed From: Print button > Settings tab > Page Header Settings button

Emergency Operation

The console has two emergency option buttons:

- Emergency Shock. (page 173) Opens the Emergency Shock window.[178]
- **VVI**. Automatically resets the device to predefined high-output Emergency VVI Settings (page 174). All diagnostic data are cleared from the device. Selected but not yet programmed values are lost. The Emergency VVI settings are listed in the table below.

Another emergency operation built into the device is Reset Function (page 175)

Emergency Shock

See Emergency Shock Instructions (page 174).

The programmer can be used to manually deliver a shock synchronized to the R-wave[179].

The programmer transmits the Emergency Shock command to the device via the current device session's current telemetry channel. Thus, if the session uses RF communication, the programmer transmits the Emergency Shock command via the RF communication channel. If the session uses inductive telemetry, the programmer transmits the Emergency Shock command via the inductive telemetry channel. All Emergency Shocks delivered outside the current session use the inductive telemetry channel.

[178] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[179] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.

CAUTION

RF Communication. While you are performing an Emergency Shock procedure, ensure that at least four telemetry strength indicator LEDs appear on the programmer and the Merlin Antenna. If fewer LEDs are lit, the device may break its communication link when it charges or dumps the capacitors. If this occurs, the attempt to shock ends and the device returns to its permanently programmed parameters.

WARNING

A synchronous high-voltage shock delivered into a sinus rhythm may induce atrial or ventricular tachyarrhythmias.

See also:
- Parameter Availability and Settings (page 197)

Accessed From: Shock console button

Emergency Shock Instructions

To deliver an emergency shock[180]:

1. Select the Shock button on the console.
2. Select the Emergency Shock Energy/Voltage setting.
3. Select the Deliver Shock button.

   The currently programmed DeFT Response™ Technology Settings (Shock Waveform) (page 114) are used for the shock. If the Zone Configuration (page 89) setting is Off, the DeFT Response settings are set to a biphasic waveform with a 65% fixed tilt.
   The shock is delivered synchronously with the next sensed event. If sensed event does not occur, the shock is delivered after the next bradycardia pacing time-out. If bradycardia pacing is disabled, the shock is delivered as if the device were pacing at 30 bpm.
   The delivery of an emergency shock triggers the storage of an EGM.
   If the capacitors have started charging and the telemetry link is lost, the capacitors continue to charge and the emergency shock is delivered. After the shock is delivered, the detection counters are reinitialized and the device is ready to detect a new tachyarrhythmia episode.

Emergency VVI Settings

Table 48. Emergency VVI settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

Parameter	Setting
Pacing Mode	VVI
Pulse Amplitude	7.5 (V)
Pulse Width	0.6 (ms)
Sense Configuration	Bipolar
Pulse Configuration	Bipolar
Ventricular Pacing Chamber[181]	RV Only
Ventricular Pacing Rate	70 bpm
Ventricular Post- Pace Refractory	310 (ms)
Ventricular Sensitivity	Not affected
Rate Hysteresis	Off
Sensor	Off

Table 49. Emergency VVI settings for CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers

Parameter	Emergency VVI Settings
Mode	VVI
Ventricular Noise Reversion Mode	VOO
Sensor	Off
V. Triggering	Off
Base Rate	70 bpm

[180] Available in CRT-Ds, dual-chamber ICDs, and single-chamber ICDs.
[181] CRT-Ds only.

Table 49. Emergency VVI settings for CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers

Parameter	Emergency VVI Settings
Rest Rate	Off
Hysteresis Rate	Off
V. Pulse Amplitude	7.5 V
V. Pulse Width	0.6 ms
V. Sensitivity	2.0 mV
Ventricular Pacing Chamber[182]	No change
V. Pulse Configuration	Unipolar
V. Sense Configuration	Unipolar Tip
V. Sense Refractory	325 ms
V. Pace Refractory	325 ms

Reset Function

If the device encounters any transitory errors in the software or hardware, it operates a "reset" routine that attempts to overcome the error and restore normal operation. Whenever the reset function is invoked, the programmer displays a Device Parameter Reset alert at the next interrogation and directs you to contact your St. Jude Medical representative or Technical Support (page 163). In this case, the user typically downloads device history from the Session Records (page 1) window.

In the majority of cases, the reset function can successfully recover from an error. In some cases, the Stored EGMs are lost, even if the reset is successful.

If the reset function is unsuccessful, the device restores as many permanently programmed settings as possible, but it may resort to programming some or all of the non-programmable reset settings listed in the table below. In CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), fibrillation detection and defibrillation are available when the device is in reset state. In this mode, fibrillation is diagnosed after 12 fibrillation interval detections, if no prior backup defibrillation has occurred. If the device has counted a previous backup defibrillation therapy, then fibrillation is diagnosed after 6 detections. The system reconfirms the diagnosis when it bins 6 more fibrillation intervals.

Because the device stores permanently programmed parameters in RAM and ROM[183], full restoration of permanent settings and programmability is a likely outcome for an error condition.

Table 50. Device Reset settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

Parameter	Reset Setting
Backup Pacing	
Mode	VVI
Pulse Amplitude	5.0 V
Pulse Width	0.6 ms
Sensitivity	2.0 mV (fixed)
RV Pulse Configuration	RV Bipolar (Tip to Ring)
LV Pulse Configuration[184]	LV Distal Tip to RV Coil
V. Sense Configuration	RV-Tip to RV-Ring
Noise Refractory Extension	125 ms
Refractory Period	337.5 ms (62.5 ms absolute; 275 ms relative)
Base Rate	67 bpm
V. Pacing[185]	LV—>RV
Interventricular Pace Delay[186]	16 ms
Backup Defibrillation	
Sensitivity range	6.3 mV
Sensitivity	AutoSense mode
Post Pace Refractory	425 ms

[182] CRT-Ps only.
[183] CRT-Ds, dual-chamber ICDs, and single-chamber ICDs store permanently programmed parameters in RAM and ROM. CRT-Ps, dual-chamber pacemakers, and single-chamber pacemakers store permanently programmed parameters in RAM only.
[184] CRT-Ds only.
[185] CRT-Ds only.
[186] CRT-Ds only.

Table 50. Device Reset settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

Parameter	Reset Setting
Post Paced Sensitivity	25% of full scale
Post Sensed Decay Delay	0 ms
Post Paced Decay Delay	0 ms
HV Refractory Period	1 s
Post Sense Refractory	125 ms
Number of Tachy Therapy Levels	1 (VF)
Shock waveform	Biphasic, 65% tilt, maximum energy
Maximum Shocks per Episode	6
Shock Configuration	RV to SVC & Can

Table 51. Device Reset settings for CRT-Ps, dual-chamber pacemakers, and single chamber pacemakers

Parameter	Reset Setting
Backup Pacing	
Mode	VVI
Pulse Amplitude	5.0 V
Pulse Width	0.6 ms
Sensitivity	2.0 mV (fixed)
RV Pulse Configuration	RV Tip to Can
LV Pulse Configuration[187]	LV Tip to Can
V. Sense Configuration	RV-Tip to Can
Noise Refractory Extension	125 ms
Refractory Period	337 ms (62.5 ms absolute; 275 ms relative)
Base Rate	67 bpm
V. Pacing[188]	LV—>RV
Interventricular Pace Delay[189]	16 ms

MRI Settings Reset Values

If a problem is encountered in the device microprocessor while MRI settings are in effect, the device will institute these settings.

Table 52. MRI Settings reset values

Parameter	Reset Setting
Basic Operation	
MRI Mode	VOO
Magnet Response	Ignore
Rates	
MRI Base Rate	85 bpm
Delays	
MRI Paced AV Delay[190]	120 ms
Capture & Sense	
MRI A. Pulse Amplitude[191]	5.0 V
MRI V. Pulse Amplitude	5.0 V
MRI A. Pulse Width[192]	1.0 ms

[187] CRT-Ps only.
[188] CRT-Ps only.
[189] CRT-Ps only.
[190] Dual-chamber devices only.
[191] Dual-chamber devices only.
[192] Dual-chamber devices only.

Table 52. MRI Settings reset values

Parameter	Reset Setting
MRI V. Pulse Width	1.0 ms
Leads	
MRI A. Pulse Configuration[193]	Bipolar
MRI V. Pulse Configuration	Bipolar

Backup VVI and Backup Defibrillation Only Settings

In rare instances or during a firmware upgrade, the pulse generator may revert to Backup VVI (BVVI) and, if Tachy Therapy is Enabled, Backup Defibrillation Only (BDFO) operation at the programmed settings listed in the tables below. These values are not programmable.

When the device has reverted to Backup VVI operation, the programmer will display a pop-up message indicating that the device is operating at the Backup VVI values. Press [Continue] and the system will attempt to store device data, print a Backup VVI report, and export data to send to St. Jude Medical,

Under some conditions, the previously programmed settings can be restored. The programmer will execute a short routine (approximately five minutes) to restore the device to normal operation. Normal follow-up testing should be performed and the parameter settings should be reviewed.

In CRT-Ds and ICDs, if fibrillation detection and defibrillation are enabled when the device is in BDFO state, fibrillation is diagnosed after 12 fibrillation interval detections if no prior backup defibrillation has occurred. If the device has counted a previous backup defibrillation therapy, then fibrillation is diagnosed after six detections. The system reconfirms the diagnosis when it bins six more fibrillation intervals.

WARNING

In CRT-Ds and ICDs, Backup VVI (BVVI) operation changes the SenseAbility™ sensing algorithm, the SVT Discrimination settings, and other parameters. If oversensing occurs (such as T-wave oversensing) and Tachy Therapy is enabled, the device may deliver high voltage therapy(s) (based on the maximum sensitivity setting of 0.3 mV and the fixed VF Detection Rate of 146 bpm). When the device enters the BVVI mode, there may be a pause in pacing support of up to three seconds.

Table 53. Backup VVI/DFO operational settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

Parameter	Setting
Backup Pacing	
Mode	VVI
Pulse Amplitude	5.0 V
Pulse Width	0.6 ms
Pacemaker Max Sensitivity	2.0 mV (fixed)
RV Pulse Configuration	RV Bipolar (tip to ring)
LV Pulse Configuration[194]	LV Distal Tip to RV Ring
Sense Configuration	RV Bipolar (tip to ring)
V Pace Refractory Period[195]	321.5 ms
Base Rate	67 bpm
Ventricular Pacing[196]	LV -> RV
Interventricular Delay[197]	16 ms
Backup Defibrillation	
Low Frequency Attenuation Filter	Off
SVT Discrimination	Off
Sensitivity Range	6.3 mV
Sensitivity	AutoSense
Defib Max Sensitivity	0.3 mV
Post Paced Refractory	425 ms

[193] Dual-chamber devices only.
[194] CRT-Ds only.
[195] For dual-chamber and single-chamber devices only. For CRT-Ds , the V. Pace Refractory Period is 337.5 ms.
[196] CRT-Ds only.
[197] CRT-Ds only.

Table 53. Backup VVI/DFO operational settings for CRT-Ds, dual-chamber ICDs, and single-chamber ICDs

Parameter	Setting
Post Paced Sensitivity	25% of full scale
Post Paced Decay Delay	0 ms
Post Paced Threshold Start	1.0 mV
Post Sensed Decay Delay	0 ms
Post Sensed Threshold Start	50%
HV Refractory Period	1 s
Post Sensed Refractory	125 ms
Number of Tachy Therapy Levels	1 (VF)
Shock Waveform	Biphasic, 65% tilt, maximum energy
Maximum Shocks per Episode	6
Shock Configuration	RV to SVC & Can
VF Detection Rate	146 bpm

Table 54. Backup VVI operational settings for CRT-Ps, dual-chamber pacemakers, and single chamber pacemakers

Parameter	Setting
Mode	VVI
Base Rate	67 bpm
RV Pulse Configuration	Unipolar Tip
LV Pulse Configuration[198]	Unipolar Tip
Sense Configuration	Unipolar Tip
Pulse Amplitude	5.0 V
Pulse Width	0.6 ms
V Pace Refractory Period[199]	321.5 ms
Sensitivity	2.0 mV (fixed)
Ventricular Pacing[200]	LV -> RV
Interventricular Delay[201]	16 ms

[198] CRT-Ps only.
[199] For dual-chamber and single-chamber devices only. For CRT-Ps , the V. Pace Refractory Period is 337.5 ms.
[200] CRT-Ps only.
[201] CRT-Ps only.

Feature Capabilities Lists

- ACap™ Confirm Capability (page 179)
- AT/AF Alert Triggers Capability (page 180)
- ATP Therapy Prior to Charging and ATP Therapy While Charging Capability (page 181)
- Auditory Patient Notifier Capability (page 181)
- Auto VectSelect Quartet™ Test Capability (page 181)
- Battery Model 2356 (page 182)
- Battery Model 2555 (page 182)
- Battery Model 2662 (page 182)
- Battery Model 2753 (page 183)
- Battery Model 2850 (page 183)
- Battery Model 2950 (page 183)
- BiVCap™ Confirm Capability (page 183)
- Chamber Onset Discrimination Capability (page 184)
- CorVue™ Thoracic Impedance Monitoring Capability (page 184)
- DecisionTx™ Programming Capability (page 185)
- DynamicTX™ Over-Current Detection Capability (page 185)
- Enhanced AT/AF Diagnostics Capability (page 185)
- Enhanced Diagnostic Trend Capability (page 186)
- Enhanced Diagnostic Trend (1-Year Daily Reports) Capability (page 186)
- Enhanced Rate Responsive Pacing Capability (page 187)
- Far Field MD™ Morphology Discrimination Capability (page 187)
- Follow-up EGMs Capability (page 188)
- High Ventricular Rate Diagnostic Capability (page 188)
- Low Frequency Attenuation Capability (page 189)
- MultiPoint™ Pacing Capability (page 189)
- Non-sustained VT/VF Episode Capability (page 189)
- Patient Notifier Capability (page 190)
- Percent Pacing Alert Capability (page 191)
- Plugged Port Lead Type Capability (page 191)
- QuickOpt™ Timing Cycle Optimization Capability (page 192)
- RF Telemetry Capability (page 192)
- SecureSense™ RV Lead Noise Discrimination Capability (page 193)
- SyncAV™ CRT Capability (page 193)
- V AutoCapture™ Capability (page 194)
- VectSelect Quartet™ LV Pulse Configuration Capability (page 194)
- Ventricular Triggering Capability (page 194)

ACap™ Confirm Capability

Table 55. Devices with ACap Confirm capability

Name	Model Number
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Table 55. Devices with ACap Confirm capability

Name	Model Number
Endurity	PM1160[202], PM2160
Endurity MRI	PM1172[203], PM2172
Assurity	PM1240[204], PM2240
Assurity MRI	PM1272[205], PM2272
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

AT/AF Alert Triggers Capability

Table 56. Devices with AT/AF Alert Triggers capability

Name	Model Number
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent DR	PM2110
Endurity	PM1160[206], PM2160
Endurity MRI	PM1172[207], PM2172
Accent DR RF	PM2210
Assurity	PM1240[208], PM2240
Assurity MRI	PM1272[209], PM2272
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160

[202] Available only when chamber is set to Atrium.
[203] Available only when chamber is set to Atrium.
[204] Available only when chamber is set to Atrium.
[205] Available only when chamber is set to Atrium.
[206] Available only when chamber is set to Atrium.
[207] Available only when chamber is set to Atrium.
[208] Available only when chamber is set to Atrium.
[209] Available only when chamber is set to Atrium.

Table 56. Devices with AT/AF Alert Triggers capability

Name	Model Number
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

ATP Therapy Prior to Charging and ATP Therapy While Charging Capability

Table 57. Devices with ATP Therapy Prior to Charging and ATP Therapy While Charging capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Auditory Patient Notifier Capability

Table 58. Devices with Auditory Patient Notifier capability

Name	Model Number
Accent SR	PM1110
Accent SR RF	PM1210
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Auto VectSelect Quartet™ Test Capability

Table 59. Devices with Auto VectSelect Quartet Capability

Name	Model Number
Promote Q	CD3221-36
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q

Table 59. Devices with Auto VectSelect Quartet Capability

Name	Model Number
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Battery Model 2356

Table 60. Devices with a Greatbatch Medical Model 2356 battery

Name	Model Number
Current VR	1107-30
Current VR RF	1207-30
Current Accel VR	CD1215-30
Current DR	2107-30
Current DR RF	2207-30
Current Accel DR	CD2215-30
Promote	3107-30
Promote RF	3207-30
Promote Accel	3215-30

Battery Model 2555

Table 61. Devices with a Greatbatch Medical Model 2555 battery

Name	Model Number
Current VR	1107-36, CD1207-36Q
Current VR RF	1207-36
Current+ VR	CD1211-36, CD1211-36Q
Current Accel VR	CD1215-36, CD1215-36Q
Current DR	2107-36, CD2207-36Q
Current DR RF	2207-36
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-36, CD2215-36Q
Promote	3107-36, 3107-36Q, CD3207-36Q
Promote RF	3207-36
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-36, CD3215-36Q
Promote Q	CD3221-36

Battery Model 2662

Table 62. Devices with a Greatbatch Medical Model 2662 battery

Name	Model Number
Accent SR	PM1110
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Accent SR RF	PM1210

Table 62. Devices with a Greatbatch Medical Model 2662 battery

Name	Model Number
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Battery Model 2753

Table 63. Devices with a Greatbatch Medical Model 2753 battery

Name	Model Number
Promote Quadra	CD3245-40, CD3245-40Q

Battery Model 2850

Table 64. Devices with a Greatbatch Medical Model 2850 battery

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Unify	CD3231-40, CD3231-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Battery Model 2950

Table 65. Devices with a Greatbatch Medical Model 2950 battery

Name	Model Number
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC

BiVCap™ Confirm Capability

Table 66. Devices with BiVCap Confirm capability

Name	Model Number
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q

Table 66. Devices with BiVCap Confirm capability

Name	Model Number
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assure MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Chamber Onset Discrimination Capability

Table 67. Devices with Chamber Onset Discrimination capability

Name	Model Number
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

CorVue™ Thoracic Impedance Monitoring Capability

Table 68. Devices with CorVue Thoracic Impedance Monitoring capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222

Table 68. Devices with CorVue Thoracic Impedance Monitoring capability

Name	Model Number
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

DecisionTx™ Programming Capability

Table 69. Devices with DecisionTx Programming capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify DR	CD2231-40, CD2231-40Q
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q

DynamicTx™ Over-Current Detection Algorithm Capability

Table 70. Devices with DynamicTX Over-Current Detection algorithm capability

Name	Model Number
Fortify Assura VR	CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify Assura DR	CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Enhanced AT/AF Diagnostics Capability

Table 71. Devices with Enhanced AT/AF Diagnostics capability

Name	Model Number
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent DR	PM2110
Endurity	PM2160
Endurity MRI	PM2172
Accent DR RF	PM2210

Table 71. Devices with Enhanced AT/AF Diagnostics capability

Name	Model Number
Assurity	PM2240
Assurity MRI	PM2272
Anthem	PM3110
Anthem RF	PM3210
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Enhanced Diagnostic Trend Capability

Table 72. Devices with Enhanced Diagnostic Trend capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Enhanced Diagnostic Trend (1-Year Daily Reports) Capability

Table 73. Devices with Enhanced Diagnostic Trend (1-Year Daily Reports) capability

Name	Model Number
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC

Table 73. Devices with Enhanced Diagnostic Trend (1-Year Daily Reports) capability

Name	Model Number
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Enhanced Rate Responsive Pacing Capability

Table 74. Devices with Enhanced Rate Responsive Pacing Capability

Name	Model Number
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Far Field MD™ Morphology Discrimination Capability

Table 75. Devices with Far Field MD Morphology Discrimination capability

Name	Model Number
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Follow-up EGMs Capability

Table 76. Devices with Follow-up EGMs capability

Name	Model Number
Current+ VR	CD1211-36, CD1211-36Q
Current Accel VR	CD1215-30, CD1215-36, CD1215-36Q
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent SR	PM1110
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Accent SR RF	PM1210
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

High Ventricular Rate Diagnostic Capability

Table 77. Devices with High Ventricular Rate Diagnostic capability

Name	Model Number
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Low Frequency Attenuation Capability

Table 78. Devices with Low Frequency Attenuation capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1377-36C, CD1411-36Q, CD1411-36QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

MR Conditional Programming Capability

Table 79. Devices with MR Conditional Programming capability

Name	Model Number
Endurity MRI	PM1172, PM2172
Assurity MRI	PM1272, PM2272

SJM MRI Activator™ Handheld Device Capability

Table 80. Devices with MRI Activator™ Handheld Device capability

Name	Model Number
Endurity MRI	PM1172, PM2172
Assurity MRI	PM1272, PM2272

MultiPoint™ Pacing Capability

Table 81. Devices with MultiPoint Pacing capability

Name	Model Number
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Quadra Allure MP	PM3160
Quadra Allure MP RF	PM3262

Non-sustained VT/VF Episode Capability

Table 82. Devices with Non-sustained VT/VF Episode capability

Name	Model Number
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC

Table 82. Devices with Non-sustained VT/VF Episode capability

Name	Model Number
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

Patient Notifier Capability

Table 83. Devices with Patient Notifier capability

Name	Model Number
Current VR	1107-30, 1107-36, CD1207-36Q
Current VR RF	1207-30, 1207-36
Current+ VR	CD1211-36, CD1211-36Q
Current Accel VR	CD1215-30, CD1215-36, CD1215-36Q
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Current DR	2107-30, 2107-36, CD2207-36Q
Current DR RF	2207-30, 2207-36
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote	3107-30, 3107-36, 3107-36Q, CD3207-36Q
Promote RF	3207-30, 3207-36
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent DR	PM2110
Accent DR RF	PM2210
Accent SR	PM1110
Accent SR RF	PM1210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Percent Pacing Alert Capability

Table 84. Devices with Percent Pacing Alert capability

Name	Model Number
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40. CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Plugged Port Lead Type Capability

Table 85. Devices with Plugged Port Lead Type capability

Name	Model Number
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Endurity	PM2160
Endurity MRI	PM2172
Assurity	PM2240
Assurity MRI	PM2272
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160

Table 85. Devices with Plugged Port Lead Type capability

Name	Model Number
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

QuickOpt™ Timing Cycle Optimization Capability

Table 86. Devices with QuickOpt Timing Cycle Optimization capability

Name	Model Number
Current DR	2107-30, 2107-36, CD2207-36Q
Current DR RF	2207-30, 2207-36
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote	3107-30, 3107-36, 3107-36Q, CD3207-36Q
Promote RF	3207-30, 3207-36
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

RF Telemetry Capability

Table 87. Devices with RF Telemetry capability

Name	Model Number
Current VR	CD1207-36Q
Current VR RF	1207-30, 1207-36
Current+ VR	CD1211-36, CD1211-36Q
Current Accel VR	CD1215-30, CD1215-36, CD1215-36Q
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC

Table 87. Devices with RF Telemetry capability

Name	Model Number
Current DR	CD2207-36Q
Current DR RF	2207-30, 2207-36
Current+ DR	CD2211-36, CD2211-36Q
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Promote	CD3207-36Q
Promote RF	3207-30, 3207-36
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent SR RF	PM1210
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Accent DR RF	PM2210
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

SecureSense™ RV Lead Noise Discrimination Capability

Table 88. Devices with SecureSense™ RV Lead Noise Discrimination capability

Name	Model Number
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC

SyncAV™ CRT Capability

Table 89. Devices with the SyncAV™ CRT capability

Name	Model Number
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C , CD3369-40Q, CD3369-40QC
Allure Quadra	PM3140

Table 89. Devices with the SyncAV™ CRT capability

Name	Model Number
Allure Quadra RF	PM3242
Quadra Allure MP	PM3160, PM3262

V AutoCapture™ Capability

Table 90. Devices with V AutoCapture capability

Name	Model Number
Current Accel VR	CD1215-30, CD1215-36, CD1215-36Q
Fortify VR	CD1231-40, CD1231-40Q
Fortify Assura VR	CD1257-40, CD1257-40Q, CD1357-40, CD1357-40C, CD1357-40Q, CD1357-40QC
Ellipse VR	CD1275-36, CD1275-36Q, CD1311-36, CD1311-36Q, CD1411-36, CD1411-36C, CD1411-36Q, CD1411-36QC
Current Accel DR	CD2215-30, CD2215-36, CD2215-36Q
Fortify DR	CD2231-40, CD2231-40Q
Fortify Assura DR	CD2257-40, CD2257-40Q, CD2357-40, CD2357-40C, CD2357-40Q, CD2357-40QC
Ellipse DR	CD2275-36, CD2275-36Q, CD2311-36, CD2311-36Q, CD2411-36, CD2411-36C, CD2411-36Q, CD2411-36QC
Accent SR	PM1110
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Accent SR RF	PM1210
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Accent DR	PM2110
Accent DR RF	PM2210

VectSelect Quartet™ LV Pulse Configuration and IS4-LLLL Lead Capability

Table 91. Devices with IS4-LLLL Lead capability[210] and the VectSelect Quartet™ LV pulse configuration feature

Name	Model Number
Promote Q	CD3221-36
Promote Quadra	CD3245-40, CD3245-40Q
Unify Quadra	CD3249-40, CD3249-40Q
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q
Allure Quadra	PM3140
Allure Quadra RF	PM3242

Ventricular Triggering Capability

Table 92. Devices with Ventricular Triggering capability

Name	Model Number
Promote+	CD3211-36, CD3211-36Q
Promote Accel	CD3215-30, CD3215-36, CD3215-36Q
Promote Q	CD3221-36
Unify	CD3231-40, CD3231-40Q
Promote Quadra	CD3245-40, CD3245-40Q

[210] SJ4-LLLL is equivalent to IS4-LLLL. St. Jude Medical's SJ4 and IS4 connector cavities comply with ISO27186:2010(E).

Table 92. Devices with Ventricular Triggering capability

Name	Model Number
Unify Quadra	CD3249-40, CD3249-40Q
Unify Assura	CD3257-40, CD3257-40Q, CD3357-40, CD3357-40C, CD3357-40Q, CD3357-40QC
Quadra Assura	CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, CD3365-40QC
Quadra Assura MP	CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, CD3369-40QC
Accent SR	PM1110
Endurity	PM1160, PM2160
Endurity MRI	PM1172, PM2172
Accent SR RF	PM1210
Assurity	PM1240, PM2240
Assurity MRI	PM1272, PM2272
Accent DR	PM2110
Accent DR RF	PM2210
Anthem	PM3110
Allure	PM3120
Allure Quadra	PM3140
Quadra Allure MP	PM3160
Anthem RF	PM3210
Allure RF	PM3222
Allure Quadra RF	PM3242
Quadra Allure MP RF	PM3262

Parameter Availability and Settings

Parameter availability and settings described below are for all devices described in this help manual.

Parameter	Availability	Settings	Nominal
% Match (page 96)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	30; 35; … 95%	Devices with Far Field MD™ Morphology Discrimination Capability (page 187): 90% Other devices: 60%

Parameter	Availability	Settings	Nominal
1st Therapy, Ventricular Fibber Test (page 51)	30 J devices with Battery Model 2356 (page 182)	Timed or Manual 1st Therapy Method (page 54), Tilt Waveform Mode (page 114): 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 50; 100; … 800; 830 V	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 15 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 600 V
	36 J devices with Battery Model 2555 (page 182) and 40 J devices with Battery Model 2753 (page 183)	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 50; 100; … 800; 830 V	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 15 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 600 V
	40 J devices with Battery Model 2850 (page 183)	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 50; 100; … 800; 830; 845 V	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 15 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 600 V
	36 J Devices with Battery Model 2950 (page 183)	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 50; 100; … 800 V	Timed or Manual 1st Therapy Method, Tilt Waveform Mode: 15 J Timed or Manual 1st Therapy Method, Pulse Width Waveform Mode: 600 V

Parameter	Availability	Settings	Nominal
1st Therapy Method (page 54)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Automatic; Timed; Manual	Automatic

Parameter	Availability	Settings	Nominal
2:1 Block Rate (page 72)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Displayed value	n/a

Parameter	Availability	Settings	Nominal
Add Stimuli Per Burst (page 109)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Off	Off

Parameter	Availability	Settings	Nominal
AF Suppression (AF Suppression Algorithm) (page 87)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Family Single-Chamber Pacemakers when Chamber is set to Atrium	On; Off	Off

Parameter	Availability	Settings	Nominal
AMS Base Rate (page 87)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	40; 45; … 135 bpm	80 bpm
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	40; 45; … 170 bpm	80 bpm

Parameter	Availability	Settings	Nominal
AMS Max Trigger Rate (page 87)	CRT-Ds with Ventricular Triggering Capability (page 194)	90; 100; … 150 bpm	130 bpm
	CRT-Ps with Ventricular Triggering Capability	90; 100; … 180 bpm	130 bpm

Parameter	Availability	Settings	Nominal
AMS Trigger Type (page 144)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Entry; Exit; Entry & Exit	Entry

Parameter	Availability	Settings	Nominal
AMS V. Triggering (page 86)	Devices with Ventricular Triggering Capability (page 194)	On; Off	On

Parameter	Availability	Settings	Nominal
Arrhythmia Unhiding (page 84)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 2; 3; … 15 intervals	3 intervals

Parameter	Availability	Settings	Nominal
AT/AF Episode, see Continuous Time in AT/AF (page 135)			

Parameter	Availability	Settings	Nominal
ATP Pulse Amplitude (page 108)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	7.5 V	Non-programmable

Parameter	Availability	Settings	Nominal
ATP Pulse Width (page 108)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	1.0; 1.5 ms	1.0 ms

Parameter	Availability	Settings	Nominal
ATP Upper Rate Cutoff (page 107)	Devices with ATP Therapy Prior to Charging and ATP Therapy While Charging Capability (page 181)	200; 210; … 400 ms	240 ms

Parameter	Availability	Settings	Nominal
Atrial Episode Type (page 144)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Single-Chamber Pacemakers when Chamber is set to Atrium	AMS; AT/AF Detection; High Atrial Rate	High Atrial Rate

Parameter	Availability	Settings	Nominal
Atrial Pace Refractory (page 82)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	190; 220; … 400; 440; 470 ms	190 ms

Parameter	Availability	Settings	Nominal
Atrial Refractory (Pace)	Assurity and Endurity Family Single-Chamber Pacemakers when Chamber is set to Atrium	190; 220; … 400; 440; 470 ms	190 ms

Parameter	Availability	Settings	Nominal
Atrial Sense Refractory (page 83)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Dual-chamber pacing Mode: 93; 125; 157 ms AAI pacing mode: 93; 125; 157 ms	Dual-chamber pacing mode: 93 ms AAI pacing mode: 93 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Dual-chamber pacing Mode: 93; 125; 157; 190 ms AAI pacing mode: 93; 125; 157; 190; 220;... 400; 440; 470 ms	Dual-chamber pacing mode: 93 ms AAI pacing mode: 93 ms

Parameter	Availability	Settings	Nominal
Atrial Refractory (Sense)	Assurity and Endurity Family Single-Chamber Pacemakers when Chamber is set to Atrium	93; 125; 157; 190; 220;... 400; 440; 470 ms	93 ms

Parameter	Availability	Settings	Nominal
Atrial Tachycardia Detection Rate (page 87)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Assurity and Endurity Family Pacemakers[211]	110; 120; … 200; 225; … 300 bpm	180 bpm

Parameter	Availability	Settings	Nominal
Auditory Duration (page 136)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164) with Patient Notifier Capability (page 190)	2; 4; … 16 s	6 s

Parameter	Availability	Settings	Nominal
Auto Mode Switch (page 86)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Off; DDI; DDIR; VVI; VVIR; DDT; DDTR; VVT; VVTR	DDIR

[211] Available only when chamber is set to Atrium.

Parameter	Availability	Settings	Nominal
AutoSense (page 75)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Atrial: Off; On Ventricular: On	Atrial: On Ventricular: Nonprogrammable
	CRT-Ps (page 164), Dual-Chamber Pacemakers	Atrial: Off; On Ventricular: Off; On	Atrial: Off Ventricular: Off

Parameter	Availability	Settings	Nominal
AV Association Delta (page 101)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	30; 40; … 150 ms	60 ms

Parameter	Availability	Settings	Nominal
AV Interval Delta (page 95)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Off; 30; 40; … 150 ms	Devices with DecisionTx Programming Capability: 60 ms Other devices: Off

Parameter	Availability	Settings	Nominal
Backup Pulse Configuration (page 76)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), with ACap Confirm Capability (page 179), BiVCap Confirm Capability (page 183), V AutoCapture Capability (page 194)	Bipolar (non programmable)	Bipolar
	Single-Chamber ICDs (page 164) with V AutoCapture Capability (page 194)	Bipolar (non programmable)	Bipolar
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164) with ACap Confirm Capability (page 179), BiVCap Confirm Capability (page 183), V AutoCapture Capability (page 194)	Atrial: Bipolar (non programmable) RV and V: Unipolar; Bipolar	Atrial: Bipolar RV and V: Bipolar[212]
	Single-Chamber Pacemakers (page 164) with V AutoCapture Capability (page 194)	Unipolar; Bipolar	Bipolar[213]

Parameter	Availability	Settings	Nominal
Base Rate (page 66)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	30; 35; … 100 **bpm**	60 **bpm**
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	30; 35; … 130; 140; ...170 **bpm**	60 **bpm**

Parameter	Availability	Settings	Nominal
Burst Cycle Length (page 109)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Adaptive: 50; 51; … 100% Fixed 200; 205; … 550 ms	Adaptive: 85%

Parameter	Availability	Settings	Nominal
Cap Confirm (page 73)	Devices with ACap Confirm Capability (page 179)	Atrium: On; Monitor; Off	Atrium: Monitor
	Devices with BiVCap Confirm Capability (page 183)	RV: Setup; On; Monitor; Off LV: Setup; On; Monitor; Off	RV: Off LV: Off

[212] If RV Lead Type is set to Unipolar, then the Backup Pulse Configuration is set to Unipolar.
[213] If RV Lead Type is set to Unipolar, then the Backup Pulse Configuration is set to Unipolar.

Parameter	Availability	Settings	Nominal
Cap Confirm Paced/Sensed AV Delay (page 76)	Devices with BiVCap Confirm Capability (page 183)	50/25; 100/70; 120/100 ms	50/25 ms

Parameter	Availability	Settings	Nominal
Chamber Onset (page 102)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163) with Chamber Onset Discrimination Capability (page 184)	Passive; On; Off	On

Parameter	Availability	Settings	Nominal
Channels, Stored EGMs (page 140)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	1; 2; 3 channels	2 channels
	Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)	1; 2; 3 channels	1 channel

Parameter	Availability	Settings	Nominal
Charge Interval (page 122)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Devices with Battery Model 2356 (page 182) and Battery Model 2555 (page 182): 1; 2; … 6 months Devices with Battery Model 2753 (page 183), Battery Model 2850 (page 183), and Battery Model 2950 (page 183): 4; 5; 6 months	Devices with Battery Model 2356 and Battery Model 2555: 3 months Devices with Battery Model 2753 and Battery Model 2850: 4 months Devices with Battery Model 2950: 6 months

Parameter	Availability	Settings	Nominal
Configuration, Stored EGM (page 141)	All devices	See parameter description for details.	

Parameter	Availability	Settings	Nominal
CorVue Thoracic Impedance Monitoring Feature (page 145)	Devices with CorVue Thoracic Impedance Monitoring Capability (page 184)	On; Off	Off

Parameter	Availability	Settings	Nominal
CorVue Threshold (page 30)	Devices with CorVue Thoracic Impedance Monitoring Capability (page 184)	8; 9; … 18 days	CRT-Ds, Dual Chamber ICDs, Single-Chamber ICDS: 14 days CRT-Ps, Dual-Chamber Pacemakers, Single-Chamber Pacemakers: 16 days

Parameter	Availability	Settings	Nominal
Consecutive High Atrial Rate Cycles, see Number of Cycles (Consecutive High Atrial Rate Cycles)			

Parameter	Availability	Settings	Nominal
Consecutive High Ventricular Rate Cycles, see Number of Cycles (Consecutive High Ventricular Rate Cycles) (page 211)			

Parameter	Availability	Settings	Nominal
Continuous Time in AT/AF (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	30 min; 1; 3; 6; 9; 12; 24 hours	3 hours

Parameter	Availability	Settings	Nominal
Custom, Stored EGM Configuration (page 142)	CRT-Ds (page 163) except those with VectSelect Quartet™ LV Pulse Configuration capability	A tip; A ring; RV tip; RV ring[214]; LV tip; LV ring[215]; RV-coil; Can; SVC	n/a
	CRT-Ds with VectSelect Quartet™ LV Pulse Configuration capability (page 194)	A tip; A ring; RV tip; RV ring; RV-coil; LV Distal tip 1; LV Mid 2; LV Mid 3; Can; LV Proximal 4; SVC	n/a
	Dual-Chamber ICDs (page 163)	A tip; A ring; V tip; V ring[216]; RV-coil; Can; SVC	n/a
	Single-Chamber ICDs (page 164)	V tip; V ring[217]; RV-coil; Can; SVC	n/a

Parameter	Availability	Settings	Nominal
Cycle Count, Hysteresis Rate (page 69)	All devices	1; 2; … 16 cycles	n/a

Parameter	Availability	Settings	Nominal
Decay Delay (page 77)	CRT-Ds (page 163), CRT-Ps (page 164)	Auto[218]; 7 0; 30; 60; 95; 125; 160; 190; 220 ms	Devices with Low Frequency Attenuation Capability (page 189): Atrium Post-Sensed: 0 ms Atrium Post-Paced: 0 ms RV Post-Sensed: 60 ms RV Post-Paced: 0 ms Other devices: Atrium Post-Sensed: 0 ms Atrium Post-Paced: 0 ms RV Post-Sensed: 60 ms RV Post-Paced: Auto
	Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Auto[219];7 0; 30; 60; 95; 125; 160; 190; 220 ms	Devices with Low Frequency Attenuation Capability (page 189): Atrium Post-Sensed: 0 ms Atrium Post-Paced: 0 ms Ventricular Post-Sensed: 60 ms Ventricular Post-Paced: 0 ms Other devices: Atrium Post-Sensed: 0 ms Atrium Post-Paced: 0 ms Ventricular Post-Sensed: 60 ms Ventricular Post-Paced: Auto
	Dual-Chamber Pacemakers, Single-Chamber Pacemakers	Auto[220];7 0; 30; 60; 95; 125; 160; 190; 220 ms	Ventricular Post-Sensed: 60 ms Ventricular Post-Paced: Auto

Parameter	Availability	Settings	Nominal
Delay, MultiPoint Pacing	CRT-Ds, CRT-Ps with MultiPoint Pacing Capability (page 189)	Delay 1: 5; 10; … 80 ms Delay 2: 5; 10; … 50 ms	Delay 1 (Pacing): 5 ms Delay 2 (Pacing): 5 ms

Parameter	Availability	Settings	Nominal
Detection Interval/Rate (page 90)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	This is the full range of settings displayed by the programmer. Depending on other parameter settings, the programmer may not allow all settings to be programmed. VT or VT-1 rate zone: 230; 235; 240; … 590 ms VT-2 rate zone: 230; 235; …	Devices with DecisionTx Programming Capability and Far Field MD Morphology Discrimination Capability (page 187): VT rate zone in 2 Zone Configuration: 350 ms VT-1 rate zone in 3 Zone Configuration: 400 ms

[214] RVring is only available when the RV lead type is Bipolar.
[215] LVring is only available when the LV Lead Type is Bipolar.
[216] V-ring is only available when the Ventricular Lead Type is Bipolar.
[217] V-ring is only available when the Ventricular Lead Type is Bipolar.
[218] The Auto setting is only available for ventricular channels.
[219] The Auto setting is only available for ventricular channels.
[220] The Auto setting is only available for ventricular channels.

		550 ms VF rate zone in 1 Zone (page 123) Zone Configuration: 200; 210; … 430 ms VF rate zone in 2 Zones (page 123) or 3 Zones (page 123) Zone Configuration: 200; 210; … 430 ms	VT-2 rate zone: 330 ms VF rate zone in 1 Zone Configuration: 320 ms VF rate zone in 2 Zones or 3 Zones Zone Configuration: 280 ms Other devices: VT or VT-1 rate zone: 430 ms VT-2 rate zone: 375 ms VF rate zone in 1 Zone Configuration: 360 ms VF rate zone in 2 Zones or 3 Zones Zone Configuration: 330 ms

Parameter	Availability	Settings	Nominal
Diagnosis (page 94)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	If Any; If All; If 2 of 3[221]	Devices with Far Field MD Morphology Discrimination Capability (page 187): Dual Chamber setting: If All Ventricular Only setting: n/a Devices with DecisionTx Programming Capability: Dual-Chamber setting: If All Ventricular Only Setting: If 2 of 3 Other devices: If Any

Parameter	Availability	Settings	Nominal
DynamicTx Over-Current Detection (page 115)	Devices with DynamicTx Over-Current Detection Algorithm Capability (page 185)	On; Off	On

Parameter	Availability	Settings	Nominal
Emergency Shock (page 173)	Devices with Battery Model 2356 (page 182)	Pulse Width Waveform Mode (page 114): 50; 100; … 750 V Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0 J	n/a
	Devices with Battery Model 2555 (page 182) and Battery Model 2950 (page 183)	Pulse Width Waveform Mode: 50; 100; … 800; 830 V Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0 J	n/a
	Devices with Battery Model 2850 (page 183)	Pulse Width Waveform Mode: 50; 100; … 800; 845; 890 V Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0; 40.0 J	n/a
	Devices with Battery Model 2753 (page 183)	Pulse Width Waveform Mode: 50; 100; … 800; 830; 875 V Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; … 30.0; 32.0; 34.0; 36.0; 40.0 J	n/a

Parameter	Availability	Settings	Nominal
Episodal Pacing Mode (page 63)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	DDI; VVI; AAI	DDI

Parameter	Availability	Settings	Nominal
Evaluation Period, AT/AF Burden (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	Daily; Weekly	Daily

[221] Only available when SVT Discrimination is set to Ventricular Only.

Parameter	Availability	Settings	Nominal
Evaluation Period, V. Rate During AT/AF (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	Daily	Non-programmable

Parameter	Availability	Settings	Nominal
Far Field MD/SecureSense Configuration (page 91)	Devices with Far Field MD Morphology Discrimination Capability (page 187) or SecureSense™ RV Lead Noise Discrimination Capability (page 193)	V Tip-Can[222]; RV Tip-Can[223]; RV Coil-Can	RV Coil-Can

Parameter	Availability	Settings	Nominal
High Atrial Rate (page 144)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Single-Chamber Pacemakers (page 164) when Chamber is set to Atrium	125; 150 … 300 bpm	150 bpm

Parameter	Availability	Settings	Nominal
High V Rate EGM Max Duration (page 139)	CRT-Ps (page 164), Dual-Chamber Pacemakers, Single-Chamber Pacemakers	20; 30 s; 1; 2; 3; 4; 5 min	20 s

Parameter	Availability	Settings	Nominal
High V Rate Pre-Trigger Max Duration (page 140)	CRT-Ps, Dual-Chamber Pacemakers, Single-Chamber Pacemakers	2; 10; 14; 20; 30; 40; 50; 60 s	14 s

Parameter	Availability	Settings	Nominal
High Ventricular Rate, see Ventricular Rate Threshold (page 223)			

Parameter	Availability	Settings	Nominal
High V. Rate Threshold (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	60; 70; … 150; 175; 200 bpm	100 bpm

Parameter	Availability	Settings	Nominal
HVLI Monitoring Lower Limit (page 80)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	20; 25; … 80 Ω	20 Ω

Parameter	Availability	Settings	Nominal
HVLI Monitoring Upper Limit (page 80)	CRT-Ds (page 163) (36 J/30 J devices), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	40; 50; … 200 Ω	200 Ω
	CRT-Ds (40 J devices)	40; 50; … 125 Ω	125 Ω

Parameter	Availability	Settings	Nominal
Hysteresis Rate (page 68)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 30; 35; … 95 bpm	Off

[222] This setting is only available in Dual-chamber ICDs and Single-Chamber ICDs.
[223] This setting is only available in CRT-Ds.

	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Off; 30; 35; … 150 **bpm**	Off

Parameter	Availability	Settings	Nominal
Interval Stability (page 101)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Dual Chamber SVT Discrimination Mode (page 92): Off; Passive; On; On w/AVA Ventricular Only SVT Discrimination Mode: Off; Passive; On; On w/SIH	Devices with Far Field MD Morphology Discrimination Capability (page 187): Dual Chamber SVT Discrimination Mode: On w/AVA Ventricular Only SVT Discrimination Mode: Passive Devices with DecisionTx Programming Capability: Dual Chamber SVT Discrimination Mode: On w/AVA Ventricular Only SVT Discrimination Mode: On w/SIH Other devices: Dual Chamber SVT Discrimination Mode: On Ventricular Only SVT Discrimination Mode: Passive

Parameter	Availability	Settings	Nominal
Interval Stability Window Size (page 102)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	8; 9; … 20 intervals	12 intervals

Parameter	Availability	Settings	Nominal
Intervention Duration (page 69)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	1; 2; … 10 min	3 min

Parameter	Availability	Settings	Nominal
Intervention Rate (page 69)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Off; Base Rate; Intrinsic+0; Intrinsic+10; Intrinsic+20; Intrinsic+30; 80; 90 … 120 **bpm**	Off

Parameter	Availability	Settings	Nominal
Interventricular Delay	CRT-Ds (page 163), CRT-Ps (page 164)	10[224]; 15; … 80 ms	n/a

Parameter	Availability	Settings	Nominal
Lead Chamber (page 79)	Single-Chamber Pacemakers (page 164)	Atrium, Ventricle	Ventricle

Parameter	Availability	Settings	Nominal
Lead Monitoring (page 80)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single Chamber ICDs (page 164)	Monitor	Non-programmable

[224] 10 ms is not available when the Ventricular Pacing chamber is set to LV ->- RV.

	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single Chamber Pacemakers (page 164)	Monitor; Polarity Switch[225]	Monitor

Parameter	Availability	Settings	Nominal
Lead Type (page 79)	CRT-Ds (page 163) without Plugged Port Lead Type Capability (page 191)	Atrial: Bipolar RV: Bipolar LV: (without VectSelect Quartet™ LV Pulse Configuration capability (page 194)): Unipolar; Bipolar; Uncoded LV (with VectSelect Quartet™ LV Pulse Configuration capability): Quadripolar; Uncoded	Atrial: Non-programmable RV: Non-programmable LV: (without VectSelect Quartet™ LV Pulse Configuration capability): Uncoded LV (with VectSelect Quartet™ LV Pulse Configuration capability): Quadripolar
	CRT-Ds (page 163) with Plugged Port Lead Type Capability (page 191)	Atrial: Bipolar; Plugged RV: Bipolar LV (without VectSelect Quartet™ LV Pulse Configuration capability): Unipolar; Bipolar; Uncoded; Plugged LV (with VectSelect Quartet™ LV Pulse Configuration capability): Quadripolar; Uncoded; Plugged	Atrial:Bipolar RV: Non-programmable LV (without VectSelect Quartet™ LV Pulse Configuration capability): Uncoded LV (with VectSelect Quartet™ LV Pulse Configuration capability): Quadripolar
	Dual-Chamber ICDs (page 163) without Plugged Port Lead Type Capability	Atrial: Bipolar Ventricular: Bipolar	Atrial: Non-programmable Ventricular: Non-programmable
	Dual-Chamber ICDs with Plugged Port Lead Type Capability	Atrial: Bipolar; Plugged Ventricular: Bipolar	Atrial: Bipolar Ventricular: Non-programmable
	Single-Chamber ICDs (page 164)	Ventricular: Bipolar	Ventricular: Non-programmable
	CRT-Ps (page 164) with VectSelect Quartet™ LV Pulse Configuration capability (page 194)	Atrial: Unipolar, Bipolar, Uncoded, Plugged RV: Unipolar, Bipolar, Uncoded LV: Quadripolar; Uncoded, Plugged	Atrial: Uncoded RV: Uncoded LV: Quadripolar
	CRT-Ps (page 164) without VectSelect Quartet™ LV Pulse Configuration capability	Atrial: Unipolar, Bipolar, Uncoded, Plugged RV: Unipolar, Bipolar, Uncoded LV: Unipolar, Bipolar, Uncoded, Plugged	Atrial: Uncoded RV: Uncoded LV: Uncoded
	Dual-Chamber Pacemakers (page 164)	Atrial: Unipolar, Bipolar, Uncoded, Plugged Ventricular: Unipolar, Bipolar, Uncoded	Atrial: Uncoded Ventricular: Uncoded
	Single Chamber Pacemakers (page 164)	Unipolar, Bipolar, Uncoded	Uncoded

Parameter	Availability	Settings	Nominal
Low Frequency Attenuation (page 79)	Devices with Low Frequency Attenuation Capability (page 189)	On; Off	On

Parameter	Availability	Settings	Nominal
Lower Limit (page 80)	All devices	100; 150; … 500 Ω	200 Ω

Parameter	Availability	Settings	Nominal
Magnet Response (page 62)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Normal; Ignore	Normal

[225] The Polarity Switch setting is not available for the left ventricular lead in CRT-Ps.

	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Off; Battery Test	Battery Test

Parameter	Availability	Settings	Nominal
Max Sensitivity (page 77) with Low Frequency Attenuation (page 79) On	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Atrium: 0.2; 0.3; … 1.0 mV RV Pacemaker: Same as Defib; 0.3; … 2.0 mV RV Defib: 0.3; … 1.0 mV	Atrium: 0.2 mV RV Pacemaker: Same as Defib RV Defib: 0.5 mV
	Single-Chamber ICDs (page 164)	Ventricular Pacemaker: Same as Defib; 0.3; … 2.0 mV Ventricular Defib: 0.3; … 1.0 mV	Ventricular Pacemaker: Same as Defib Ventricular Defib: 0.5 mV

Parameter	Availability	Settings	Nominal
Max Sensitivity (page 77), ICDs and CRT-Ds with Low Frequency Attenuation (page 79) Off	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Atrium: 0.2; 0.3; … 1.0 mV RV Pacemaker: Same as Defib; 0.2; 0.3; … 2.0 mV RV Defib: 0.2; 0.3; … 1.0 mV	Atrium: 0.2 mV RV Pacemaker: Same as Defib RV Defib: 0.3 mV
	Single-Chamber ICDs (page 164)	Ventricular Pacemaker: Same as Defib; 0.2; 0.3; … 2.0 mV Ventricular Defib: 0.2; 0.3; … 1.0 mV	Ventricular Pacemaker: Same as Defib Ventricular Defib: 0.3 mV

Parameter	Availability	Settings	Nominal
Max Sensitivity (page 77), for Pacemakers and CRT-PS	CRT-Ps (page 164), Dual-Chamber Pacemakers	Atrial: 0.2; 0.3; … 1.0 mV Ventricular Pacemaker: 0.2; 0.3; … 2.0 mV	Atrial: 0.2 mV Ventricular Pacemaker: 0.5 mV
	Single-Chamber Pacemakers	Ventricular Pacemaker: 0.2; 0.3; … 2.0 mV	Ventricular Pacemaker: 0.5 mV

Parameter	Availability	Settings	Nominal
Max Sensor Rate (page 64)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	80; 85; … 150 bpm	110 bpm
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	80; 85; … 150; 160; 170; 180 bpm	130 bpm

Parameter	Availability	Settings	Nominal
Max Step (page 111)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	10; 15; … 100 ms	50 ms

Parameter	Availability	Settings	Nominal
Max Track Rate (page 67)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	90; 95; … 130; 140; 150 bpm	110 bpm
	Assurity, Endurity Dual-Chamber Pacemakers (page 164)	90; 95; … 130; 140; …210 bpm	130 bpm
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	90; 95; … 130; 140; …180 bpm	130 bpm

Parameter	Availability	Settings	Nominal
Max Trigger Rate (page 67)	Devices with Ventricular Triggering Capability (page 194)	90; 100; … 150 bpm	130 bpm

Parameter	Availability	Settings	Nominal
Maximum AF Suppression Rate (page 88)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	80; 85; … 150 bpm	110 bpm
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Single-Chamber Pacemakers when Chamber is set to Atrium	80; 85; … 150; 160; …180 bpm	120 bpm

Parameter	Availability	Settings	Nominal
Minimum Burst Cycle Length (page 110)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	150; 155; … 400 ms	200 ms

Parameter	Availability	Settings	Nominal
Mode (page 61)	All devices	See parameter description or Mode Descriptions (page 153) for details.	

Parameter	Availability	Settings	Nominal
Morphology (page 95)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Passive; Off	On

Parameter	Availability	Settings	Nominal
Morphology in AF/A Flutter (V<A Rate Branch: Morphology) (page 95)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	On; Passive; Off	On

Parameter	Availability	Settings	Nominal
Morphology in Sinus Tach (V=A Rate Branch: Morphology) (page 96)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	On; Passive; Off	On

Parameter	Availability	Settings	Nominal
Morphology No. of Matches (page 96)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	3; 4; … 20 complexes	Devices with Far Field MD Morphology Discrimination Capability (page 187): 3 complexes Devices with DecisionTx Programming Capability: 7 complexes Other devices: 5 complexes

Parameter	Availability	Settings	Nominal
Morphology Scoring (page 105)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Off	Off

Parameter	Availability	Settings	Nominal
Morphology Template Pacing Hysteresis (page 97)	Devices with Far Field MD Morphology Discrimination Capability (page 187)	On; Off	CRT-Ds: On Dual-Chamber ICDs, Single-Chamber ICDs: Off

Parameter	Availability	Settings	Nominal
Morphology Type (page 98)	Devices with Far Field MD Morphology Discrimination Capability (page 187)	Far Field; Original MD	Far Field

Parameter	Availability	Settings	Nominal
Morphology Window Size (page 97)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	6; 8; … 20 complexes	Devices with Far Field MD Morphology Discrimination Capability (page 187): 10 complexes; Devices with DecisionTx Programming Capability:12 complexes Other devices: 8 complexes

Parameter	Availability	Settings	Nominal
MRI Base Rate (page 66)	Devices with MR Conditional Programming Capability (page 189)	30; 35; … 120 bpm	85 bpm

Parameter	Availability:	Settings:	Nominal:
	Single-chamber pacemakers with MR Conditional Programming Capability	AOO, VOO, Pacing Off	VOO
	Dual-chamber pacemakers with MR Conditional Programming Capability	AOO, VOO, DOO, Pacing Off	DOO

Parameter	Availability	Settings	Nominal
MRI Paced AV Delay (page 70)	Dual-chamber devices with MR Conditional Programming Capability (page 189)	25; 30; 40; … 120 ms	120 ms

Parameter	Availability	Settings	Nominal
MRI Pulse Amplitude (page 75)	Devices with MR Conditional Programming Capability (page 189)	5.0; 7.5 V	5.0 V

Parameter	Availability	Settings	Nominal
MRI Pulse Configuration (page 58)	Devices with MR Conditional Programming Capability (page 189)	Bipolar	Non-programmable

Parameter	Availability	Settings	Nominal
MRI Pulse Width (page 75)	Devices with MR Conditional Programming Capability (page 189)	1.0 ms	Non-programmable

Parameter	Availability	Settings	Nominal
MultiPoint Pacing LV1 Pulse Configuration (page 58)	CRT-D devices with MultiPoint Pacing Capability (page 189)	Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil	Distal tip 1-Mid 2
	CRT-P Devices with MultiPoint Pacing Capability (page 189)	Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Ring; Distal tip 1-can; Mid 2-Proximal 4; Mid 2-RV Ring;Mid 2-can; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Ring;Mid 3-can; Proximal 4-Mid 2; Proximal 4-RV Ring; Promixal 4-can	Distal tip 1-Mid 2

Parameter	Availability	Settings	Nominal
MultiPoint Pacing LV2 Pulse Configuration (page 80)	CRT-D devices with MultiPoint Pacing Capability (page 189)	Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil	Mid 3-RV Coil
	CRT-P devices with MultiPoint Pacing Capability (page 189)	Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Ring; Distal tip 1-can; Mid 2-Proximal 4; Mid 2-RV Ring;Mid 2-can; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Ring;Mid 3-can; Proximal 4-Mid 2; Proximal 4-RV Ring; Promixal 4-can	Mid-3 RV Ring

Parameter	Availability	Settings	Nominal
MultiPoint Pacing Post-Ventricular Atrial Blanking	Devices with MultiPoint Pacing Capability (page 189)	125; 130; … 260 ms	150 ms

Parameter	Availability	Settings	Nominal
Negative AV Hysteresis/Search (page 72)	CRT-Ds without VectSelect Quartet™ LV Pulse Configuration capability, Dual-Chamber ICDs (page 163), CRT-Ps without VectSelect Quartet™ LV Pulse Configuration capability, Dual-Chamber Pacemakers (page 164)	Off; -10; -20; … -120 ms	Off

Parameter	Availability	Settings	Nominal
No. Intervals (page 90)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	8; 9; … 25; 30; … 100 intervals	Devices with DecisionTx Programming Capability and devices with Far Field MD Morphology Discrimination Capability (page 187): VT rate zone in 2 Zone Configuration: 16 intervals VT-1 rate zone in 3 Zone Configuration: 18 intervals VT-2 rate zone: 16 intervals VF rate zone: 12 intervals Other devices: 12 intervals

Parameter	Availability	Settings	Nominal
Number of Bursts (page 109)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	1; 2; … 15 bursts	3 bursts

Parameter	Availability	Settings	Nominal
Number of Cycles (page 144) (Consecutive High Atrial Rate Cycles)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Single-Chamber Pacemakers (page 164) when Chamber is set to Atrium	2; 3; … 5; 10; … 20 cycles	5 cycles

Parameter	Availability	Settings	Nominal
Number of Cycles (page 143) (Consecutive High Ventricular Rate Cycles)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	2; 3; … 5; 10; … 20 cycles	5 cycles

Parameter	Availability	Settings	Nominal
Number of Notifications (page 136)	Devices with Patient Notifier Capability (page 190)	1; 2; … 16 notifications	4 notifications

Parameter	Availability	Settings	Nominal
Number of Stimuli (page 109)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	2; 3; … 20 stimuli	8 stimuli

Parameter	Availability	Settings	Nominal
Onset Delta (page 103)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Adaptive: 4; 6; … 86% Fixed: 30; 35; … 500 ms	Adaptive: 18% Fixed: 100 ms

Parameter	Availability	Settings	Nominal
Overdrive Pacing Cycles (page 88)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Assurity and Endurity Single-Chamber Pacemakers when Chamber is set to Atrium	15; 20; … 40 cycles	15 cycles

Parameter	Availability	Settings	Nominal
Paced AV Delay (page 70)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	25; 30; 40; … 200; 225; … 300; 350 ms	200 ms

Parameter	Availability	Settings	Nominal
Pacing Margin (page 76)	Devices with BiVCap Confirm Capability (page 183)	0.25; 0.50; … 2.5 V	1.0 V

Parameter	Availability	Settings	Nominal
Percent Pacing Alert Duration (page 137)	Devices with Percent Pacing Alert Capability (page 191)	1; 7; 30; 90 days	7 days

Parameter	Availability	Settings	Nominal
Percentage BiV Pacing Limit (Percent Pacing Less Than) (page 137)	CRT-Ds (page 163), Allure devices	60; 65; … 80; 81; … 100%	90%

Parameter	Availability	Settings	Nominal
Percentage RV/V Pacing Limit (Percent Pacing Greater Than) (page 137)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164), Allure, Assurity, and Endurity devices	0; 5; … 95%	40%

Parameter	Availability	Settings	Nominal
PMT Detection Rate (page 85)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	90; 95; … 150 **bpm**	110 **bpm**
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	90; 95; … 180 **bpm**	130 **bpm**

Parameter	Availability	Settings	Nominal
PMT Response (page 85)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Off; Passive; Atrial Pace	Atrial Pace
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Off; Passive; Atrial Pace; Extend PVARP	Atrial Pace

Parameter	Availability	Settings	Nominal
Post Detection Interval/Rate (page 119)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See parameter description for details.	

Parameter	Availability	Settings	Nominal
Post-Shock Base Rate (page 121)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	30; 35; … 100 **bpm**	60 **bpm**

Parameter	Availability	Settings	Nominal
Post-Shock Duration (page 122)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.5; 1; 2.5; 5; 7.5; 10 min	0.5 min

Parameter	Availability	Settings	Nominal
Post-Shock Mode (page 121)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See parameter description for details.	

Parameter	Availability	Settings	Nominal
Post-Shock Pause (page 121)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	1; 2; … 7 s	2 s

Parameter	Availability	Settings	Nominal
Post-Ventricular Atrial Blanking (page 81)	CRT-Ds (page 163)	60; 70; … 250 ms	70 ms
	Dual-Chamber ICDs (page 163)	60; 70; … 250 ms	60 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	60; 70; … 250 ms	150 ms

Parameter	Availability	Settings	Nominal
Pulse Amplitude (page 75)	CRT-Ds (page 163), CRT-Ps (page 164)	0.25; 0.50; … 4.0; 4.5; … 7.5 V	A: 2.5 V RV: 2.5 V LV: 2.5 V
	Dual-Chamber ICDs (page 163), Dual-Chamber Pacemakers (page 164)	0.25; 0.50; … 4.0; 4.5; … 7.5 V	A: 2.5 V Ventricular: 2.5 V
	Single-Chamber ICDs (page 164), Single-Chamber Pacemakers (page 164)	0.25; 0.50; … 4.0; 4.5; … 7.5 V	Ventricular: 2.5 V

Parameter	Availability	Settings	Nominal
Pulse Amplitude, Fibber Test (page 53)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Burst or Shock-on-T Fibber Mode: 5.0; 7.5 V	Burst or Shock-on-T Fibber Mode: 7.5 V

Parameter	Availability	Settings	Nominal
Pulse Amplitude, NIPS Test (page 57)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.25; 0.50; … 3.75; 4.0; 4.5; … 7.5 V	7.5 V
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	0.25; 0.50; … 3.75; 4.0; 4.5; … 7.5 V	Programmed Pulse Amplitude

Parameter	Availability	Settings	Nominal
Pulse Amplitude, Post-Shock (page 122)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.25; 0.50; … 7.5 V	7.5 V

Parameter	Availability	Settings	Nominal
Pulse Configuration (page 80)	CRT-Ds (page 163) with VectSelect Quartet™ LV Pulse Configuration capability (page 194)	Atrial: Bipolar RV: Bipolar LV: Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil	Atrial: Non-programmable RV: Non-programmable LV: Distal tip 1-Mid 2
	CRT-Ds without VectSelect Quartet™ LV Pulse Configuration capability	Atrial: Bipolar RV: Bipolar LV: Bipolar; LV tip to RV coil; LV ring to RV coil	Atrial: Non-programmable RV: Non-programmable LV: LV tip to RV coil
	Dual-Chamber ICDs (page 163)	Atrial: Bipolar Ventricular: Bipolar	Atrial: Non-programmable Ventricular: Non-programmable
	Single-Chamber ICDs (page 164)	Ventricular: Bipolar	Ventricular: Non-programmable
	CRT-Ps (page 164) with VectSelect Quartet™ LV Pulse Configuration capability	Atrial: Bipolar, Unipolar RV: Bipolar, Unipolar LV: Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Ring; Distal tip 1-Can; Mid 2 – Proximal 4; Mid 2-RV Ring; Mid 2-Can; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Ring; Mid 3-Can; Proximal 4-Mid 2; Proximal 4-RV Ring; Proximal 4-Can	Atrial: Bipolar RV: Bipolar LV: Distal tip 1-Mid 2
	CRT-Ps (page 164) without VectSelect Quartet™ LV Pulse Configuration capability	Atrial: Bipolar; Unipolar RV: Bipolar; Unipolar LV: Bipolar; Unipolar; LV tip to RV ring; LV ring to RV ring	Atrial: Bipolar RV: Bipolar LV: LV tip to RV ring
	Dual-Chamber Pacemakers (page 164)	Atrial: Bipolar; Unipolar Ventricular: Bipolar; Unipolar	Atrial: Bipolar Ventricular: Bipolar
	Single-Chamber Pacemakers (page 164)	Ventricular: Bipolar; Unipolar	Ventricular: Bipolar

Parameter	Availability	Settings	Nominal
Pulse Configuration, NIPS Test (page 58)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Bipolar	Non-programmable
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Unipolar (tip–case); Bipolar (tip–ring)	Same as Pulse Configuration settings

Parameter	Availability	Settings	Nominal
Pulse Duration, Fibber Test (page 53)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.5; 1.0; … 5.0 s	2.0 s

Parameter	Availability	Settings	Nominal
Pulse Width (page 75)	All devices	0.05; 0.1; 0.2; … 1.5 ms	0.5 ms

Parameter	Availability	Settings	Nominal
Pulse Width, Fibber Test (page 53)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	1.0; 1.5 ms	1.5 ms

Parameter	Availability	Settings	Nominal
Pulse Width, NIPS Test (page 57)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.05; 0.1; 0.2; … 1.5 ms	1.0 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	0.05; 0.1; 0.2; … 1.5 ms	Programmed Pulse Width

Parameter	Availability	Settings	Nominal
Pulse Width, Post-Shock (page 122)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	0.05; 0.1; 0.2; … 1.5 ms	1.5 ms

Parameter	Availability	Settings	Nominal
PVARP (page 81)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	125; 150; … 500 ms	275 ms

Parameter	Availability	Settings	Nominal
PVC Response (page 85)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Off; Atrial Pace	Off
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Off; Atrial Pace; Extended PVARP[226]	Off

Parameter	Availability	Settings	Nominal
Ramp (page 111)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Off	Off

[226] Available only in VDD(R) mode.

Parameter	Availability	Settings	Nominal
Ramp Step (page 111)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	5; 10; … 30 ms	10 ms

Parameter	Availability	Settings	Nominal
Rate Branch (page 94)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	See parameter description for details	

Parameter	Availability	Settings	Nominal
Rate Responsive AV Delay (page 70)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Off; Low; Medium; High	Medium
	Anthem Family CRT-Ps, Accent Family, Dual-Chamber Pacemakers	Off; Low; Medium; High	Off
	Allure Family CRT-Ps, Assurity, Endurity Family Dual-Chamber Pacemakers	Off; Low; Medium; High	Medium

Parameter	Availability	Settings	Nominal
Rate Responsive PVARP/V Ref (page 81)	Allure, Assurity, Endurity devices	Off; Low; Medium; High	High
	All other devices		Low

Parameter	Availability	Settings	Nominal
Reaction Time (page 64)	All devices	Very Fast; Fast; Medium; Slow	Fast

Parameter	Availability	Settings	Nominal
Readaptive (page 110)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Off	Off

Parameter	Availability	Settings	Nominal
Recovery Time (page 64)	All devices	Fast; Medium; Slow; Very Slow	Medium

Parameter	Availability	Settings	Nominal
Rest Rate (page 67)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 30; 35; … 95 bpm	Off
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Off; 30; 35; … 150 bpm	Off

Parameter	Availability	Settings	Nominal
RV Polarity (page 114)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Anode(+); Cathode(-)	Anode(+)

Parameter	Availability	Settings	Nominal
S1 Count, Fibber Test (page 53)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	2; 3; … 25 stimuli	8 stimuli

Parameter	Availability	Settings	Nominal
S1 Count, NIPS Test (page 56)	All devices	2; 3; … 25 stimuli	8 stimuli

Parameter	Availability	Settings	Nominal
S1S1, Fibber Test (page 53)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Shock-on-T Fibber Mode: 100; 110; … 800 ms Burst Fibber Mode: 20; 30; … 100 ms	Shock-on-T Fibber Mode: 600 ms Burst Fibber Mode: 30 ms

Parameter	Availability	Settings	Nominal
S1S2, NIPS Test (page 56)	All devices	Off; 100; 110; … 800 ms	Off

Parameter	Availability	Settings	Nominal
S2 Shock Energy/Voltage, Fibber Test (page 53)	Devices with Battery Model 2356 (page 182)	Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; 15.0; … 27.5; 30.0 J Pulse Width Waveform Mode: 50; 100; … 800; 830 V	Tilt Waveform Mode: 2.0 J Pulse Width Waveform Mode: 200 V
	Devices with Battery Model 2555 (page 182)	Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; 15.0; … 27.5; 30.0; 32.0; … 36.0 J Pulse Width Waveform Mode: 50; 100; … 800; 830 V	Tilt Waveform Mode: 2.0 J Pulse Width Waveform Mode: 200 V
	Devices with Battery Model 2753 (page 183)	Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; 15.0; … 27.5; 30.0; 32.0; … 36.0 J Pulse Width Waveform Mode: 50; 100; … 800; 830 V	Tilt Waveform Mode: 2.0 J Pulse Width Waveform Mode: 200 V
	Devices with Battery Model 2850 (page 183)	Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; 15.0; … 27.5; 30.0; 32.0; … 36.0 J Pulse Width Waveform Mode: 50; 100; … 800; 845 V	Tilt Waveform Mode: 2.0 J Pulse Width Waveform Mode: 200 V
	Devices with Battery Model 2950 (page 183)	Tilt Waveform Mode: 0.1; 0.2; … 1.0; 2.0; … 10.0; 12.5; 15.0; … 27.5; 30.0 J Pulse Width Waveform Mode: 50; 100; … 800 V	Tilt Waveform Mode: 2.0 J Pulse Width Waveform Mode: 200 V

Parameter	Availability	Settings	Nominal
S2S3, NIPS Test (page 57)	All devices	Off; 100; 110; … 800 ms	Off

Parameter	Availability	Settings	Nominal
S3S4, NIPS Test (page 57)	All devices	Off; 100; 110; … 800 ms	Off

Parameter	Availability	Settings	Nominal
Scan Step (page 110)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	5; 10; … 30 ms	10 ms

Parameter	Availability	Settings	Nominal
Scanning (page 110)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On (Dec); Off	On (Dec)

Parameter	Availability	Settings	Nominal
Search Cycles, VIP Extension (page 73)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	1; 2; 3 cycles	1 cycle

Parameter	Availability	Settings	Nominal
Search Interval, Cap Confirm/V. AutoCapture (page 76)	Devices with ACap Confirm Capability (page 179), BiVCap Confirm Capability (page 183), V AutoCapture Capability (page 194)	8; 24 hrs	8 hrs

Parameter	Availability	Settings	Nominal
Search Interval, Hysteresis Rate (page 68)	All devices	Off; 1; 5; 10; 15; 30 min	Off

Parameter	Availability	Settings	Nominal
Search Interval, VIP Extension (page 73)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	30 s; 1; 3; 5; 10; 30 min	1 min

Parameter	Availability	Settings	Nominal
SecureSense™ (page 90)	Devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193)	Passive; On; Off	On

Parameter	Availability	Settings	Nominal
SecureSense™ Timeout Until Therapy (page 91)	Devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193)	Off; 15; 30; ... 60; 90 s	Off

Parameter	Availability	Settings	Nominal
Sense Configuration (page 80)	CRT-Ds (page 163)	Atrial: Bipolar Ventricular: RV Bipolar	Non-programmable
	Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Bipolar	Non-programmable
	CRT-Ps (page 164)	Atrium: Bipolar; Unipolar Tip; Unipolar Ring Ventricular: RV Bipolar; RV Unipolar Tip; RV Unipolar Ring; LV Bipolar; LV Unipolar Tip; LV Tip to RV Tip; BV Bipolar; BV Unipolar Tip	Atrium: Bipolar[227] Ventricular: Bipolar[228]
	CRT-Ps (page 164) with VectSelect Quartet™ LV Pulse Configuration capability (page 194)	LV: RV Bipolar; RV Unipolar Tip; RV Unipolar Ring; LV Distal tip 1-Mid2; LV Distal tip 1-Can; LV Distal tip1-RV Tip; BV Bipolar; BV Unipolar Tip	Atrium: Bipolar[229] Ventricular: Bipolar[230]
	Dual-Chamber Pacemakers (page 164)	Atrium: Bipolar; Unipolar Tip; Unipolar Ring Ventricular: Bipolar; Unipolar Tip; Unipolar Ring	Atrium: Bipolar[231] Ventricular: Bipolar[232]

[227] If the A Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[228] If the RV Lead Type is set to Unipolar, the nominal is RV Unipolar Tip.
[229] If the A Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[230] If the RV Lead Type is set to Unipolar, the nominal is RV Unipolar Tip.
[231] If the A Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[232] If the RV Lead Type is set to Unipolar, the nominal is RV Unipolar Tip.

	Single-Chamber Pacemakers (page 164)	Ventricular: Bipolar; Unipolar Tip; Unipolar Ring	Ventricular: Bipolar[233]

Parameter	Availability	Settings	Nominal
Sensed AV Delay (page 70)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	25; 30; 40; … 200; 225; … 325 ms	150 ms

Parameter	Availability	Settings	Nominal
Sensitivity (page 76)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Atrial: Auto[234]; 0.2; 0.3; … 1.0 mV Ventricular: Auto	Atrial: Auto Ventricular: Non-programmable
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	Atrial: Auto[235]; 0.1[236]; 0.2; … 0.5; 0.75; 1.0; ...2.0; 2.5; ...4.0; 5.0 mV Ventricular: Auto[237]; 0.5[238]; 1.0; 1.5; … 5.0; 6.0; … 10; 12.5 mV	Atrial: 0.5 mV[239] Ventricular: 2.0 mV

Parameter	Availability	Settings	Nominal
Sensor (page 63)	All Devices	On; Passive; Off	Passive

Parameter	Availability	Settings	Nominal
Shock Configuration (page 114)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	RV to SVC & Can; RV to Can; RV to SVC[240]	RV to SVC & Can

Parameter	Availability	Settings	Nominal
Shortest AV Delay (page 71)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	25; 30; … 50; 60; … 120 ms	100 ms

Parameter	Availability	Settings	Nominal
Shortest PVARP/V Ref (page 82)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	125; 150; … 475 ms	225 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	125; 150; … 475 ms	175 ms

Parameter	Availability	Settings	Nominal
SIH Count (page 101)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	1; 2; … 8 intervals	2 intervals

[233] If the RV Lead Type is set to Unipolar, the nominal is RV Unipolar Tip.
[234] "Auto" is not a selectable setting but is displayed in the Sensitivity button when the AutoSense parameter is set to On.
[235] "Auto" is not a selectable setting but is displayed in the Sensitivity button when the AutoSense parameter is set to On.
[236] Atrial Sensitivity settings of 0.1 mV can be susceptible to crosstalk.
[237] "Auto" is not a selectable setting but is displayed in the Sensitivity button when the AutoSense parameter is set to On.
[238] Ventricular Sensitivity settings of 0.5 mV can be susceptible to crosstalk.
[239] If the ventricular Lead Type is set to Unipolar, the nominal is 1.0 mV.
[240] The RV to SVC setting is only available in devices with DynamicTx Over-Current Detection algorithm capability.

Parameter	Availability	Settings	Nominal
Sinus Node Recovery Delay (page 58)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	1; 2; … 5 s	1 s

Parameter	Availability	Settings	Nominal
Sinus Redetection (page 119)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Fast (3 intervals); Nominal (5 intervals); Slow (7 intervals)	Nominal (5 intervals)

Parameter	Availability	Settings	Nominal
Slope (page 63)	All devices	1; 2; … 16; Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3)	8

Parameter	Availability	Settings	Nominal
Stability Delta (page 101)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	30; 35; … 500 ms	Devices with DecisionTx Programming Capability and devices with Far Field MD Morphology Discrimination Capability (page 187): 40 ms Other devices: 80 ms

Parameter	Availability	Settings	Nominal
Sudden Onset (page 103)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; Passive; On	Devices with Far Field MD Morphology Discrimination Capability (page 187): Dual Chamber SVT Discrimination Mode: Off Ventricular Only SVT Discrimination Mode: Passive Devices with DecisionTx Programming Capability: Dual Chamber SVT Discrimination Mode: On Ventricular Only SVT Discrimination Mode: On Other devices: Dual Chamber SVT Discrimination Mode: On Ventricular Only SVT Discrimination Mode: Passive

Parameter	Availability	Settings	Nominal
SVT Discrimination (page 91), VT/VT-1/VT-2 Rate Zones	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	On; Off	Devices with DecisionTx Programming Capability and devices with Far Field MD Morphology Discrimination Capability (page 187) VT or VT-1 rate zone: On VT-2 rate zone: On Other Devices: VT or VT-1 rate zone: On VT-2 rate zone: Off

Parameter	Availability	Settings	Nominal
SVT Discrimination in Sinus Tach (page 94)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	On; Off	On

Parameter	Availability	Settings	Nominal
SVT Discrimination Mode (page 92)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Dual Chamber; Ventricular Only	Dual Chamber

	Single-Chamber ICDs (page 164)	Ventricular Only	Non-programmable

Parameter	Availability	Settings	Nominal
SVT Discrimination Timeout (page 92)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 20; 30; 40; 50 s; 1; 2; … 10; 15; … 60 min	Off

Parameter	Availability	Settings	Nominal
SVT Upper Limit (page 93)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 250; 255; … 585 ms; Same as VT-2; Same as VF	Devices with DecisionTx Programming Capability and Far Field Morphology Discrimination Capability (page 187): Same as VF Other devices: 2 Zones Zone Configuration (page 123): Same as VF 3 Zones Zone Configuration (page 123): Same as VT-2

Parameter	Availability	Settings	Nominal
SyncAV CRT Delta	Devices with SyncAV CRT capability (page 193).	Off; -10; -20; … -120 ms	Off

Parameter	Availability	Settings	Nominal
Tachy Therapy Enable/Disable (page 168)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Disabled; Enabled	n/a

Parameter	Availability	Settings	Nominal
Template Auto Update (page 97)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Devices with Far Field MD Morphology Discrimination Capability (page 187): Off; 3; 9; 12 hours; 1; 3; 7; 14; 30 days Other devices: Off; 8 hours; 1; 3; 7; 14; 30 days	Devices with Far Field MD Morphology Discrimination Capability: 3 hours Other CRT-Ds: Off Other Dual-Chamber ICDs, Single-Chamber ICDs: 1 day

Parameter	Availability	Settings	Nominal
Template Match Criteria (page 96)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See Morphology No. of Matches (page 96) and Morphology Window Size (page 97).	

Parameter	Availability	Settings	Nominal
Therapy (page 106)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See parameter description for details	

Parameter	Availability	Settings	Nominal
Therapy After Timeout (page 93)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	VT Therapy; VF Therapy	VT Therapy

Parameter	Availability	Settings	Nominal
Threshold (page 63)	All devices	1.0; 1.5; … 7.0; Auto (-0.5); Auto (+0.0); Auto (+0.5); Auto (+1.0); Auto (+1.5); Auto (+2.0)	Auto (+0.0)

Parameter	Availability	Settings	Nominal
Threshold Start (page 78) for CRT-Ds and ICDs with Low Frequency Attenuation capability (page 189)	CRT-Ds (page 163), CRT-Ps (page 164)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV RV Post-Sensed: 50; 62.5; 75; 100% RV Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV RV Post-Sensed: 50% RV Post-Paced: 1.0 mV
	Dual-Chamber ICDs (page 163)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV Ventricular Post-Sensed: 50% Ventricular Post-Paced: 1.0 mV
	Single-Chamber ICDs (page 164)	Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Ventricular Post-Sensed: 50% Ventricular Post-Paced: 1.0 mV

Parameter	Availability	Settings	Nominal
Threshold Start (page 78) for CRT-Ds and ICDs without Low Frequency Attenuation capability	CRT-Ds (page 163)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV RV Post-Sensed: 50; 62.5; 75; 100% RV Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV RV Post-Sensed: 62.5% RV Post-Paced: Auto
	Dual-Chamber ICDs (page 163)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV Ventricular Post-Sensed: 62.5% Ventricular Post-Paced: Auto
	Single-Chamber ICDs (page 164)	Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Ventricular Post-Sensed: 62.5% Ventricular Post-Paced: Auto

Parameter	Availability	Settings	Nominal
Threshold Start (page 78) for CRT-Ps and Pacemakers	CRT-Ps (page 164)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV RV Post-Sensed: 50; 62.5; 75; 100% RV Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV RV Post-Sensed: 75% RV Post-Paced: Auto
	Dual-Chamber Pacemakers (page 164)	Atrium Post-Sensed: 50; 62.5; 75; 100% Atrium Post-Paced: 0.2; 0.3; … 3.0 mV Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Atrium Post-Sensed: 50% Atrium Post-Paced: 0.8 mV Ventricular Post-Sensed: 75% Ventricular Post-Paced: Auto
	Single-Chamber Pacemakers (page 164)	Ventricular Post-Sensed: 50; 62.5; 75; 100% Ventricular Post-Paced: Auto; 0.2; 0.3; … 3.0 mV	Ventricular Post-Sensed: 75% Ventricular Post-Paced: Auto

Parameter	Availability	Settings	Nominal
Time Between Notifications (page 136)	Devices with Patient Notifier Capability (page 190)	10; 22 hrs	10 hrs

Parameter	Availability	Settings	Nominal
Time to Therapy (page 55)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	3; 4; … 20 s	10 s

Parameter	Availability	Settings	Nominal
Timeout Trigger (page 105)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	2 Zones Zone Configuration: VT Therapy 3 Zones Zone Configuration: VT-2 Therapy; VT-1 & VT-2 Therapy	2 Zones Zone Configuration: Non-programmable 3 Zones Zone Configuration: VT-1 & VT-2 Therapy

Parameter	Availability	Settings	Nominal
Total Time in AT/AF (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	0.5; 1; 3; 6; 9; 12; 24; 36; 48 hrs	6 hrs

Parameter	Availability	Settings	Nominal
Total Time in High V. Rate (page 135)	Devices with AT/AF Alert Triggers Capability (page 180)	1; 3; 6; 9; 12 hrs	6 hrs

Parameter	Availability	Settings	Nominal
Trigger Alert for NSO (page 91)	Devices with SecureSense™ RV Lead Noise Discrimination Capability (page 193)	1 - 5 episodes	5 episodes

Parameter	Availability	Settings	Nominal
Upper Limit (page 80)	All devices	400; 500; 600; 750; 1000; … 2500; 3000 Ω	2000 Ω

Parameter	Availability	Settings	Nominal
V. AutoCapture (page 73)	Devices with V AutoCapture Capability (page 194)	Setup; On; Off	Off

Parameter	Availability	Settings	Nominal
V. AutoCapture Paced/Sensed AV Delay (page 76)	Devices with V AutoCapture Capability (page 194)	50/25; 100/70; 120/100 ms	50/25 ms

Parameter	Availability	Settings	Nominal
V. Noise Reversion Mode (page 63)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163),	Pacing Off; VOO; DOO	Pacing Off
	Single-Chamber ICDs (page 164)	Pacing Off; VOO	Pacing Off
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Pacing Off; VOO, DOO	DOO[241]
	Single-Chamber Pacemakers (page 164)	Pacing Off; VOO	VOO

Parameter	Availability	Settings	Nominal
V. Support Rate, Atrial Fibber Test (page 58)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	Off; 30; 35 … 95 bpm	Off

[241] If the Atrial Lead Type is set to Plugged, then the nominal value is VOO.

Parameter	Availability	Settings	Nominal
V. Support Rate, Atrial NIPS Test (page 58)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Off; 30; 35 … 95 **bpm**	CRT-Ds, Dual-Chamber ICDs: Off CRT-Ps, Dual-Chamber Pacemakers: 50 **bpm**

Parameter	Availability	Settings	Nominal
V. Triggering (page 62)	Devices with Ventricular Triggering Capability (page 194)	On; Off	Off

Parameter	Availability	Settings	Nominal
Ventricular Blanking (page 83)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163)	44; 52 ms	52 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Auto; 12; 16; ... 52 ms	Accent, Accent RF, Anthem, Anthem RF devices: Auto All other devices: 44 ms

Parameter	Availability	Settings	Nominal
Ventricular Intrinsic Preference (VIP) Parameter (page 71)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	Off; On	Off

Parameter	Availability	Settings	Nominal
Ventricular Pace Refractory (page 83)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	125; 160; 190; … 400; 440; 470 ms	250 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	125; 160; 190; … 400; 440; 470; 500 ms	250 ms

Parameter	Availability	Settings	Nominal
Ventricular Pacing	CRT-Ds (page 163), CRT-Ps (page 164)	LV+RV (Simultaneous); LV —> RV; RV —> LV; RV Only	LV+RV (Simultaneous)

Parameter	Availability	Settings	Nominal
Ventricular Rate Threshold (page 143)	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	125; 150 … 300 **bpm**	150 **bpm**

Parameter	Availability	Settings	Nominal
Ventricular Safety Standby (page 84)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	On; Off	On

Parameter	Availability	Settings	Nominal
Ventricular Sense Refractory (page 83)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	125; 157 ms	125 ms
	CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), Single-Chamber Pacemakers (page 164)	125; 157; 160; 190; 220; ... 400; 440; 470; 500 ms	250 ms

Parameter	Availability	Settings	Nominal
VF Shocks (Defib) (page 115)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See parameter description for details.	

Parameter	Availability	Settings	Nominal
Vibration Duration (page 136)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	2; 4; … 16 s	6 s

Parameter	Availability	Settings	Nominal
VIP Extension (page 73)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164)	50; 75; … 150; 160; … 200 ms	100 ms

Parameter	Availability	Settings	Nominal
VT Redetection (page 119)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	6; 7; … 20 intervals	6 intervals

Parameter	Availability	Settings	Nominal
VT Shocks (CVRT) (page 115)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	See parameter description for details.	

Parameter	Availability	Settings	Nominal
VT Therapy Timeout (page 105)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off; 10 s; 20 s; … 120 s; 2.5 min; 3.0 min; … 5.0 min	Off

Parameter	Availability	Settings	Nominal
VT/VF EGM Max Duration (page 139)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	30 s; 1; 2; 3; 4; 5 min	1 min

Parameter	Availability	Settings	Nominal
VT/VF Pre-Trigger Max Duration (page 140)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	2; 10; 14; 20; 30; 40; 50; 60 s	14 s

Parameter	Availability	Settings	Nominal
Waveform (page 114)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Biphasic; Monophasic	Biphasic

Parameter	Availability	Settings	Nominal
Waveform Mode (page 114)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Tilt; Pulse Width	Tilt

Parameter	Availability	Settings	Nominal
Zone Configuration (page 89)	CRT-Ds (page 163), Dual-Chamber ICDs (page 163), Single-Chamber ICDs (page 164)	Off (page 123); 1 Zone (page 123); 2 Zones (page 123); 3 Zones (page 123)	Off

Accent™ Devices Technical Data

The tables below are applicable to the following Accent™ device models:

- Accent SR PM1110
- Accent SR RF PM1210
- Accent DR PM2112
- Accent DR RF PM2210

The technical data below include:

- Shipped and Standard Settings (page 227)
- Operating Parameters Tolerances (page 230)
- NIPS Tolerances (page 231)
- Physical Specifications (page 232)
- Battery Voltage (page 232)
- X-ray Identification (page 232)
- Spare Parts And Accessories (page 232)

Shipped and Standard Settings

Table 93. Shipped and Standard settings for Accent single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[242]
Basic Operation		
Mode	VVI	VVI
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	VOO	VOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Capture & Sense		
V. AutoCapture Pacing	Off	Off
Pulse Amplitude	2.5 V	2.5 V
Pulse Width	0.4 ms	0.4 ms
Sensitivity	2.0 mV	2.0 mV
AutoSense	Off	Off
Max Sensitivity	0.5 mV	0.5 mV
Post-Paced Decay Delay	Auto	Auto
Post-Sensed Decay Delay	60 ms	60 ms
Post-Paced Threshold Start	Auto	Auto
Post-Sensed Threshold Start	75%	75%
Backup Pulse Configuration	Bipolar	Bipolar[243]

[242] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.
[243] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.

Table 93. Shipped and Standard settings for Accent single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[242]
Search Interval	8 hr	8 hr
Leads		
Lead Type	Uncoded	Uncoded
Pulse Configuration	Bipolar	Bipolar[244]
Sense Configuration	Bipolar	Bipolar[245]
Lead Monitoring	Monitor	Monitor
Upper Limit	2000 Ω	2000 Ω
Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
Sense Refractory	250 ms	250 ms
Pace Refractory	250 ms	250 ms
Rate Responsive VREF	Low	Low
Shortest VREF	175 ms	175 ms

Table 94. Shipped and Standard settings for Accent dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[246]
Basic Operation		
Mode	DDD	DDD
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	DOO	DOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Max Tracking Rate	130 bpm	130 bpm
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Delays		
Paced AV Delay	200 ms	200 ms
Sensed AV Delay	150 ms	150 ms
Rate Responsive AV Delay	Off	Off
Shortest AV Delay	100 ms	100 ms
Ventricular Intrinsic Preference (VIP)	Off	Off
VIP Extension	100 ms	100 ms
VIP Search Interval	1 min	1 min
VIP Search Cycles	1 cycle	1 cycle

[244] If the Lead Type is set to Unipolar, the nominal is Unipolar.
[245] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[246] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Table 94. Shipped and Standard settings for Accent dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[246]
Negative AV/PV Hysteresis w/Search	Off	Off
Capture & Sense		
ACap Confirm	Off	Off
V. AutoCapture Pacing	Off	Off
A. Pulse Amplitude	2.5 V	2.5 V
V. Pulse Amplitude	2.5 V	2.5 V
A. Pulse Width	0.4 ms	0.4 ms
V. Pulse Width	0.4 ms	0.4 ms
A. Sensitivity	0.5 mV	0.5 mV[247]
A. Max Sensitivity	0.3 mV	0.3 mV
A. Post-Paced Decay Delay	0 ms	0 ms
A. Post-Sensed Decay Delay	0 ms	0 ms
A. Post-Paced Threshold Start	0.8 mV	0.8 mV
A. Post-Sensed Threshold Start Percentage	50%	50%
A. Post-Sensed Minimum Start Threshold	0.3 mV	0.3 mV
A. AutoSense	Off	Off
V. Sensitivity	2.0 mV	2.0 mV
V. Max Sensitivity	0.5 mV	0.5 mV
V. Post-Sense Decay Delay	60 ms	60 ms
V. Post-Paced Decay Delay	Auto	Auto
V. Post-Sense Threshold Start Percentage	75%	75%
V. Post-Paced Threshold Start	Auto	Auto
V. AutoSense	Off	Off
AutoCapture Pacing		
A. Backup Pulse Configuration	Bipolar	Bipolar
V. Backup Pulse Configuration	Bipolar	Bipolar[248]
A. Search Interval	8 hr	8 hr
V. Search Interval	8 hr	8 hr
V. AutoCapture Paced/Sensed AV Delay	50/25 ms	50/25 ms
Leads		
A. Lead Type	Uncoded	Uncoded
V. Lead Type	Uncoded	Uncoded
A. Pulse Configuration	Bipolar	Bipolar[249]
V. Pulse Configuration	Bipolar	Bipolar[250]
A. Sense Configuration	Bipolar	Bipolar[251]
V. Sense Configuration	Bipolar	Bipolar[252]
A. Lead Monitoring	Monitor	Monitor
V. Lead Monitoring	Monitor	Monitor
A. Upper Limit	2000 Ω	2000 Ω
V. Upper Limit	2000 Ω	2000 Ω
A. Lower Limit	200 Ω	200 Ω
V. Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
A. Refractory (PVARP)	275 ms	275 ms
A. Sense Refractory	93 ms	93 ms

[247] If the A. Lead Type is set to Unipolar, the nominal is 1.0mV.
[248] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.
[249] If the Lead Type is set to Unipolar, the nominal is Unipolar.
[250] If the Lead Type is set to Unipolar, the nominal is Unipolar.
[251] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[252] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.

Table 94. Shipped and Standard settings for Accent dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[246]
A. Pace Refractory	190 ms	190 ms
V. Sense Refractory	250 ms	250 ms
V. Pace Refractory	250 ms	250 ms
Rate Responsive PVARP/VREF	Low	Low
Shortest PVARP/VREF	175 ms	175 ms[253]
Post Ventricular Atrial Blanking (PVAB)	150 ms	150 ms
V. Blanking	Auto	Auto
V. Safety Standby	On	On
PVC Response	Off	Off
PMT Response	Atrial Pace	Atrial Pace
PMT Detection Rate	130 bpm	130 bpm
AT/AF Detection and Response		
Auto Mode Switch	DDIR	DDIR
Atrial Tachycardia Detection Rate	180 bpm	180 bpm
AMS Base Rate	80 bpm	80 bpm
AF Suppression Pacing	Off	Off
Overdrive Pacing Cycles	15 cycles	15 cycles
Maximum AF Suppression Rate	120 bpm	120 bpm

Operating Parameters Tolerances

Table 95. Operating parameter/measurement tolerances single-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Capture & Sense	
Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
Pulse Width	± 0.04 ms
Sensitivity	± 30% or 0.3 mV, whichever is greater[254]
Leads	
Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)

Table 96. Operating parameter/measurement tolerances for dual-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms

[253] If the Mode is set to AAI or AAT, the nominal is 200ms.
[254] Sensitivity is with respect to a 20ms haversine test signal.

Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Max Tracking Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Delays	
Paced AV Delay	± 10 ms
Sensed AV Delay	± 10 ms
Shortest AV Delay	± 5 ms
VIP Search Interval	± 2 sec
Capture & Sense	
A. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
V. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
A. Pulse Width	± 0.04 ms
V. Pulse Width	± 0.04 ms
A. Sensitivity	± 30%[255]
V. Sensitivity	± 30% or 0.3 mV, whichever is greater[256]
AutoCapture Pacing/Cap Confirm	
V. AutoCapture Paced/Sensed AV Delay	± 5 ms
Leads	
A. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
V. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
Refractories & Blanking	
A. Refractory (PVARP)	± 10 ms
A. Absolute Refractory Period	± 10 ms
V. Refractory	± 10 ms
Rate Responsive PVARP/VREF	± 10 ms
Shortest PVARP/VREF	± 10 ms
Post Ventricular Atrial Blanking (PVAB)	± 10 ms
V. Blanking	-4/+10 ms
PMT Detection Rate	± 20 ms
AT/AF Detection & Response	
Atrial Tachycardia Detection Rate	± 15 ms
AMS Base Rate	± 15 ms
Maximum AF Suppression Rate	± 15 ms

NIPS Tolerances

Table 97. NIPS options

Parameter	Tolerance
Coupling Interval	± 10 ms
S1 , S2, S3, and S4 Cycle	± 5 ms
V. Backup Rate (VOO Pacing)	± 15 ms
Sinus Node Recovery Delay	± 1 sec

[255] Sensitivity is with respect to a 20ms haversine test signal.
[256] Sensitivity is with respect to a 20ms haversine test signal.

Physical Specifications

Table 98. Physical Specifications for Accent devices

Specification[257]	PM1110	PM1210	PM2110	PM2210
Case Material	Titanium	Titanium	Titanium	Titanium
Case Coating	None	None	None	None
RF Antenna Material	None	Titanium	None	Titanium
Connector Material	Epoxy	Epoxy	Epoxy	Epoxy
Dimensions (mm) (h x l x t)[258]	42 x 52 x 6	52 x 52 x 6	46 x 52 x 6	52 x 52 x 6
Weight (g)	18	23	19	23
Displacement volume[259] (cm^3)	9.5 ± 0.5	12.8 ± 0.5	10.5 ± 0.5	12.9 ± 0.5
Lead Connector[260]	IS-1[261]	IS-1	IS-1	IS-1

Dimensions and weight values are nominal.

Battery Voltage

Table 99. Battery voltage for devices with Battery Model 2662 (page 182)

Parameter	Data
Battery voltage	3.2 V (beginning of life)
Elective replacement voltage (unloaded)	2.6 V
End-of-life voltage (unloaded)	2.5 V

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 100. X-ray ID codes

Device Model	X-ray ID Model Code
PM1110, PM1210, PM2110, PM2210	HI

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 101. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug

[257] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[258] (h x l x t) = height by length by thickness.
[259] ±0.5 cm^3
[260] Accepts IS-1 short terminal pin leads.
[261] Accepts IS-1 short terminal pin leads.

Allure™, Allure Quadra™, Quadra Allure MP™, and Quadra Allure MP™ RF Devices Technical Data

The tables below are applicable to the following Allure™ device models:

- Allure PM3120
- Allure Quadra PM3140
- Quadra Allure MP PM3160
- Allure RF PM3222
- Allure Quadra RF PM3242
- Quadra Allure MP RF PM3262

The technical data below include:

- Shipped and Standard Settings (page 233)
- Operating Parameters Tolerances (page 235)
- NIPS Tolerances (page 236)
- Physical Specifications (page 237)
- Battery Voltage (page 237)
- X-ray Identification (page 237)
- Spare Parts And Accessories (page 237)

Shipped and Standard Settings

Table 102. Shipped and Standard settings for Allure, Allure Quadra, Quadra Allure MP, and Quadra Allure MP RF devices

Parameter	Shipped Settings	Nominal (Standard) Settings[262]
Basic Operation		
Mode	DDD	DDD
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	DOO	DOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Ventricular Pacing	Simultaneous	Simultaneous
Interventricular Delay	11.7 ms	11.7 ms
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Max Tracking Rate	130 bpm	130 bpm
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Delays		
Paced AV Delay	200 ms	200 ms
Sensed AV Delay	150 ms	150 ms
Rate Responsive AV Delay	Off	Medium
Shortest AV Delay	100 ms	100 ms
Ventricular Intrinsic Preference (VIP)	Off	Off
VIP Extension	100 ms	100 ms

[262] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Table 102. Shipped and Standard settings for Allure, Allure Quadra, Quadra Allure MP, and Quadra Allure MP RF devices

Parameter	Shipped Settings	Nominal (Standard) Settings[262]
VIP Search Interval	1 min	1 min
VIP Search Cycles	1 cycle	1 cycle
Negative AV/Hysteresis w/Search	Off	Off
SyncAV CRT	Off	Off
Capture & Sense		
ACap Confirm	Off	Off
RVCap Confirm	Off	Off
LVCap Confirm	Off	Off
A. Pulse Amplitude	2.5 V	2.5 V
RV. Pulse Amplitude	2.5 V	2.5 V
LV. Pulse Amplitude	2.5 V	2.5 V
A. Pulse Width	0.4 ms	0.4 ms
RV. Pulse Width	0.4 ms	0.4 ms
LV. Pulse Width	0.4 ms	0.4 ms
A. Sensitivity	0.5 mV	0.5 mV[263]
A. Max Sensitivity	0.3 mV	0.3 mV
A. Post-Paced Decay Delay	0 ms	0 ms
A. Post-Sensed Decay Delay	0 ms	0 ms
A. Post-Paced Threshold Start	0.8 mV	0.8 mV
A. Post-Sensed Threshold Start Percentage	50%	50%
A. Post-Sensed Minimum Start Threshold	0.3 mV	0.3 mV
A. AutoSense	Off	Off
RV. Sensitivity	2.0 mV	2.0 mV
RV Max Sensitivity	0.5 mV	0.5 mV
RV. Post-Sense Decay Delay	60 ms	60 ms
RV. Post-Paced Decay Delay	Auto	Auto
RV. Post-Sense Threshold Start Percentage	75%	75%
RV. Post-Paced Threshold Start	Auto	Auto
RV. AutoSense	Off	Off
AutoCapture Pacing		
A. Backup Pulse Configuration	Bipolar	Bipolar
RV. Backup Pulse Configuration	Bipolar	Bipolar[264]
A. Search Interval	8 hr	8 hr
RV. Search Interval	8 hr	8 hr
V. AutoCapture Paced/Sensed AV Delay	50/25 ms	50/25 ms
Leads		
A. Lead Type	Uncoded	Uncoded
RV. Lead Type	Uncoded	Uncoded
LV. Lead Type	Uncoded	Uncoded
A. Pulse Configuration	Bipolar	Bipolar
RV. Pulse Configuration	Bipolar	Bipolar[265]
LV. Pulse Configuration	Allure: Bipolar; Allure Quadra: Distal Tip 1-Mid 2	Allure: Bipolar; Allure Quadra: Distal Tip 1-Mid 2
A. Sense Configuration	Bipolar	Bipolar[266]
V. Sense Configuration	Allure: Bipolar; Allure Quadra: Distal Tip 1-Mid 2	Allure: Bipolar[267]; Allure Quadra: Distal Tip 1-Mid 2

[263] If the A. Lead Type is set to Unipolar, the nominal is 1.0mV.
[264] If the RV Lead Type is set to Unipolar, the nominal is Unipolar.
[265] In Allure devices, if the LV Lead Type and RV Lead Type are set to Unipolar, the nominal is Unipolar. If the LV Lead Type is set to Unipolar or Uncoded and the RV Lead Type is set to Bipolar or Uncoded, the nominal is LV tip to RV ring.
[266] If the A Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[267] If the RV Lead Type is set to Unipolar, the nominal is RV Unipolar Tip.

Table 102. Shipped and Standard settings for Allure, Allure Quadra, Quadra Allure MP, and Quadra Allure MP RF devices

Parameter	Shipped Settings	Nominal (Standard) Settings[262]
A. Lead Monitoring	Monitor	Monitor
V. Lead Monitoring	Monitor	Monitor
A. Upper Limit	2000 Ω	2000 Ω
V. Upper Limit	2000 Ω	2000 Ω
A. Lower Limit	200 Ω	200 Ω
V. Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
A. Refractory (PVARP)	275 ms	275 ms
A. Sense Refractory	93 ms	93 ms
A. Pace Refractory	190 ms	190 ms
V. Sense Refractory	250 ms	250 ms
V. Pace Refractory	250 ms	250 ms
Rate Responsive PVARP/VREF	High	High
Shortest PVARP/VREF	175 ms	175 ms[268]
Post Ventricular Atrial Blanking (PVAB)	150 ms	150 ms
V. Blanking	44 ms	44 ms
V. Safety Standby	On	On
PVC Response	Off	Off
PMT Response	Atrial Pace	Atrial Pace
PMT Detection Rate	130 bpm	130 bpm
AT/AF Detection and Response		
Auto Mode Switch	DDIR	DDIR
Atrial Tachycardia Detection Rate	180 bpm	180 bpm
AMS Base Rate	80 bpm	80 bpm
AF Suppression	Off	Off
Overdrive Pacing Cycles	15 cycles	15 cycles
Maximum AF Suppression Rate	120 bpm	120 bpm

Operating Parameters Tolerances

Table 103. Operating parameter/measurement tolerances for CRT-Ps

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Max Tracking Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Delays	
Paced AV Delay	± 10 ms
Sensed AV Delay	± 10 ms
Shortest AV Delay	± 5 ms
VIP Search Interval	± 2 sec

[268] If the Mode is set to AAI or AAT, the nominal is 200ms.

Table 103. Operating parameter/measurement tolerances for CRT-Ps

Parameter/Measurement	Tolerance
Capture & Sense	
A. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
RV. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
LV. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
A. Pulse Width	± 0.04 ms
RV. Pulse Width	± 0.04 ms
LV. Pulse Width	± 0.04 ms
A. Sensitivity	± 30%[269]
V. Sensitivity	± 30% or 0.3 mV, whichever is greater[270]
AutoCapture Pacing/Cap Confirm	
V. AutoCapture Paced/Sensed AV Delay	± 5 ms
Leads	
A. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
V. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
Refractories & Blanking	
A. Refractory (PVARP)	± 10 ms
A. Absolute Refractory Period	± 10 ms
V. Refractory	± 10 ms
Rate Responsive PVARP/VREF	± 10 ms
Shortest PVARP/VREF	± 10 ms
Post Ventricular Atrial Blanking (PVAB)	± 10 ms
V. Blanking	-4/+10 ms
PMT Detection Rate	± 20 ms
AT/AF Detection & Response	
Atrial Tachycardia Detection Rate	± 15 ms
AMS Base Rate	± 15 ms
Maximum AF Suppression Rate	± 15 ms

NIPS Tolerances

Table 104. NIPS options

Parameter	Tolerance
Coupling Interval	± 10 ms
S1 , S2, S3, and S4 Cycle	± 5 ms
V. Backup Rate (VOO Pacing)	± 15 ms
Sinus Node Recovery Delay	± 1 sec

[269] Sensitivity is with respect to a 20ms haversine test signal.
[270] Sensitivity is with respect to a 20ms haversine test signal.

Physical Specifications

Table 105. Physical Specifications for Allure devices

Specification[271]	PM3120	PM3140	PM3222	PM3242
Case Material	Titanium	Titanium	Titanium	Titanium
Case Coating	None	None	None	None
RF Antenna Material	None	None	Titanium	Titanium
Connector Material	Epoxy	Epoxy	Epoxy	Epoxy
Dimensions (mm) (h x l x t)[272]	55x 59 x 6	56 x 59 x 6	55 x 59 x 6	56 x 59 x 6
Weight (g)	24	26	24	27
Displacement volume[273] (cm^3)	14 ± 0.5	15 ± 0.5	14 ± 0.5	15 ± 0.5
Lead Connector[274]	IS-1[275]	IS-1/IS4-LLLL[276]	IS-1[277]	IS-1/IS4-LLLL[278]

Dimensions and weight values are nominal.

Battery Voltage

Table 106. Battery voltage for devices with Battery Model 2662 (page 182)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.62 V
End-of-life voltage (unloaded)	2.47 V

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 107. X-ray ID codes

Device Model	X-ray ID Model Code
PM3120, PM3140, PM3222, PM3242, PM3160, PM3262	HI

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 108. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug
AC-IS4PP	IS4/DF4 port plug[279]

[271] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[272] (h x l x t) = height by length by thickness.
[273] ±0.5 cm^3
[274] Accepts IS-1 short terminal pin leads.
[275] Accepts IS-1 short terminal pin leads.
[276] Accepts IS-1 short terminal pin leads or IS4-LLLL quadripolar leads.
[277] Accepts IS-1 short terminal pin leads.
[278] Accepts IS-1 short terminal pin leads or IS4-LLLL quadripolar leads.
[279] For use with IS4-LLLL bores.

Anthem™ Devices Technical Data

The tables below are applicable to the following Anthem™ device models:

- Anthem PM3110
- Anthem RF PM3210

The technical data below include:

- Shipped and Standard Settings (page 239)
- Operating Parameters Tolerances (page 241)
- NIPS Tolerances (page 242)
- Physical Specifications (page 242)
- Battery Voltage (page 243)
- X-ray Identification (page 243)
- Spare Parts And Accessories (page 243)

Shipped and Standard Settings

Table 109. Shipped and Standard settings for Anthem devices

Parameter	Shipped Settings	Nominal (Standard) Settings[280]
Basic Operation		
Mode	DDD	DDD
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	DOO	DOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Ventricular Pacing	Simultaneous	Simultaneous
Interventricular Delay	11.7 ms	11.7 ms
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Max Tracking Rate	130 bpm	130 bpm
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Delays		
Paced AV Delay	200 ms	200 ms
Sensed AV Delay	150 ms	150 ms
Rate Responsive AV Delay	Off	Off
Shortest AV Delay	100 ms	100 ms
Ventricular Intrinsic Preference (VIP)	Off	Off
VIP Extension	100 ms	100 ms
VIP Search Interval	1 min	1 min
VIP Search Cycles	1 cycle	1 cycle
Negative AV/PV Hysteresis w/Search	Off	Off
Capture & Sense		
ACap Confirm	Off	Off

[280] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Table 109. Shipped and Standard settings for Anthem devices

Parameter	Shipped Settings	Nominal (Standard) Settings[280]
RVCap Confirm	Off	Off
LVCap Confirm	Off	Off
A. Pulse Amplitude	2.5 V	2.5 V
RV. Pulse Amplitude	2.5 V	2.5 V
LV. Pulse Amplitude	2.5 V	2.5 V
A. Pulse Width	0.4 ms	0.4 ms
RV. Pulse Width	0.4 ms	0.4 ms
LV. Pulse Width	0.4 ms	0.4 ms
A. Sensitivity	0.5 mV	0.5 mV[281]
A. Max Sensitivity	0.3 mV	0.3 mV
A. Post-Paced Decay Delay	0 ms	0 ms
A. Post-Sensed Decay Delay	0 ms	0 ms
A. Post-Paced Threshold Start	0.8 mV	0.8 mV
A. Post-Sensed Threshold Start Percentage	50%	50%
A. Post-Sensed Minimum Start Threshold	0.3 mV	0.3 mV
A. AutoSense	Off	Off
RV Sensitivity	2.0 mV	2.0 mV
RV Max Sensitivity	0.5 mV	0.5 mV
RV Post-Sense Decay Delay	60 ms	60 ms
RV Post-Paced Decay Delay	Auto	Auto
RV Post-Sense Threshold Start Percentage	75%	75%
RV Post-Paced Threshold Start	Auto	Auto
RV AutoSense	Off	Off
AutoCapture Pacing		
A. Backup Pulse Configuration	Bipolar	Bipolar
RV. Backup Pulse Configuration	Bipolar	Bipolar[282]
A. Search Interval	8 hr	8 hr
RV. Search Interval	8 hr	8 hr
V. AutoCapture Paced/Sensed AV Delay	50/25 ms	50/25 ms
Leads		
A. Lead Type	Uncoded	Uncoded
RV. Lead Type	Uncoded	Uncoded
LV. Lead Type	Uncoded	Uncoded
A. Pulse Configuration	Bipolar	Bipolar
RV. Pulse Configuration	Bipolar	Bipolar
LV. Pulse Configuration	Bipolar	Bipolar[283]
A. Sense Configuration	Bipolar	Bipolar[284]
V. Sense Configuration	Bipolar	Bipolar[285]
A. Lead Monitoring	Monitor	Monitor
V. Lead Monitoring	Monitor	Monitor
A. Upper Limit	2000 Ω	2000 Ω
V. Upper Limit	2000 Ω	2000 Ω
A. Lower Limit	200 Ω	200 Ω
V. Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
A. Refractory (PVARP)	275 ms	275 ms

[281] If the A. Lead Type is set to Unipolar, the nominal is 1.0mV.
[282] If the RV Lead Type is set to Unipolar, the nominal is Unipolar.
[283] If the LV Lead Type is set to Unipolar or Uncoded, the nominal is Unipolar Tip.
[284] If the LV Lead Type is set to Unipolar or Uncoded, the nominal is Unipolar Tip.
[285] If the LV Lead Type is set to Unipolar or Uncoded, the nominal is Unipolar Tip.

Table 109. Shipped and Standard settings for Anthem devices

Parameter	Shipped Settings	Nominal (Standard) Settings[280]
A. Sense Refractory	93 ms	93 ms
A. Pace Refractory	190 ms	190 ms
V. Sense Refractory	250 ms	250 ms
V. Pace Refractory	250 ms	250 ms
Rate Responsive PVARP/VREF	Low	Low
Shortest PVARP/VREF	175 ms	175 ms[286]
Post Ventricular Atrial Blanking (PVAB)	150 ms	150 ms
V. Blanking	Auto	Auto
V. Safety Standby	On	On
PVC Response	Atrial Pace	Atrial Pace
PMT Response	Atrial Pace	Atrial Pace
PMT Detection Rate	130 bpm	130 bpm
AT/AF Detection and Response		
Auto Mode Switch	DDIR	DDIR
Atrial Tachycardia Detection Rate	180 bpm	180 bpm
AMS Base Rate	80 bpm	80 bpm
AF Suppression	Off	Off
Overdrive Pacing Cycles	15 cycles	15 cycles
Maximum AF Suppression Rate	120 bpm	120 bpm

Operating Parameters Tolerances

Table 110. Operating parameter/measurement tolerances for CRT-Ps

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Max Tracking Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Delays	
Paced AV Delay	± 10 ms
Sensed AV Delay	± 10 ms
Shortest AV Delay	± 5 ms
VIP Search Interval	± 2 sec
Capture & Sense	
A. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
RV. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
LV. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
A. Pulse Width	± 0.04 ms
RV. Pulse Width	± 0.04 ms

[286] If the Mode is set to AAI or AAT, the nominal is 200ms.

Table 110. Operating parameter/measurement tolerances for CRT-Ps

Parameter/Measurement	Tolerance
LV. Pulse Width	± 0.04 ms
A. Sensitivity	± 30%[287]
V. Sensitivity	± 30% or 0.3 mV, whichever is greater[288]
AutoCapture Pacing/Cap Confirm	
V. AutoCapture Paced/Sensed AV Delay	± 5 ms
Leads	
A. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
V. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
Refractories & Blanking	
A. Refractory (PVARP)	± 10 ms
A. Absolute Refractory Period	± 10 ms
V. Refractory	± 10 ms
Rate Responsive PVARP/VREF	± 10 ms
Shortest PVARP/VREF	± 10 ms
Post Ventricular Atrial Blanking (PVAB)	± 10 ms
V. Blanking	-4/+10 ms
PMT Detection Rate	± 20 ms
AT/AF Detection & Response	
Atrial Tachycardia Detection Rate	± 15 ms
AMS Base Rate	± 15 ms
Maximum AF Suppression Rate	± 15 ms

NIPS Tolerances

Table 111. NIPS options

Parameter	Tolerance
Coupling Interval	± 10 ms
S1 , S2, S3, and S4 Cycle	± 5 ms
V. Backup Rate (VOO Pacing)	± 15 ms
Sinus Node Recovery Delay	± 1 sec

Physical Specifications

Table 112. Physical Specifications for Anthem devices

Specification[289]	PM3110	PM3210
Case Material	Titanium	Titanium
Case Coating	None	None
RF Antenna Material	None	Titanium
Connector Material	Epoxy	Epoxy
Dimensions (mm) (h x l x t)[290]	52 x 52 x 6	57 x 52 x 6
Weight (g)	21	25
Displacement volume[291] (cm^3)	11.5 ± 0.5	13.7 ± 0.5

[287] Sensitivity is with respect to a 20ms haversine test signal.
[288] Sensitivity is with respect to a 20ms haversine test signal.
[289] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[290] (h x l x t) = height by length by thickness.
[291] ±0.5 cm^3

Table 112. Physical Specifications for Anthem devices

Specification[289]	PM3110	PM3210
Lead Connector[292]	IS-1	IS-1

Dimensions and weight values are nominal.

Battery Voltage

Table 113. Battery voltage for devices with Battery Model 2662 (page 182)

Parameter	Data
Battery voltage	3.2 V (beginning of life)
Elective replacement voltage (unloaded)	2.6 V
End-of-life voltage (unloaded)	2.5 V

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 114. X-ray ID codes

Device Model	X-ray ID Model Code
PM3110, PM3210	HI

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 115. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug

[292] Accepts IS-1 short terminal pin leads.

Assurity™ and Assurity MRI™ Devices Technical Data

The tables below are applicable to the following Assurity™ device models:

- Assurity PM1240
- Assurity MRI PM1272
- Assurity PM2240
- Assurity MRI PM2272

The technical data below include:

- Shipped and Standard Settings (page 245)
- Operating Parameters Tolerances (page 248)
- NIPS Tolerances (page 250)
- Physical Specifications (page 250)
- Battery Voltage (page 250)
- X-ray Identification (page 250)
- Spare Parts And Accessories (page 251)

Shipped and Standard Settings

Table 116. Shipped and Standard settings for Assurity single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[293]
Basic Operation		
Mode	VVI	VVI
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	VOO	VOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Capture & Sense		
V. AutoCapture Pacing	Off	Off
Pulse Amplitude	2.5 V	2.5 V
Pulse Width	0.4 ms	0.4 ms
Sensitivity	2.0 mV	2.0 mV
AutoSense	Off	Off
Max Sensitivity	0.5 mV	0.5 mV
Post-Paced Decay Delay	Auto	Auto
Post-Sensed Decay Delay	60 ms	60 ms
Post-Paced Threshold Start	Auto	Auto
Post-Sensed Threshold Start	75%	75%
Backup Pulse Configuration	Bipolar	Bipolar[294]

[293] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.
[294] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.

Table 116. Shipped and Standard settings for Assurity single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[293]
Search Interval	8 hr	8 hr
Leads		
Lead Type	Uncoded	Uncoded
Pulse Configuration	Bipolar	Bipolar[295]
Sense Configuration	Bipolar	Bipolar[296]
Lead Monitoring	Monitor	Monitor
Upper Limit	2000 Ω	2000 Ω
Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
Sense Refractory	250 ms	250 ms
Pace Refractory	250 ms	250 ms
Rate Responsive VREF	Low	Low
Shortest VREF	175 ms	175 ms
MRI Settings[297]		
MRI Mode	VOO	VOO
MRI Base Rate	85 bpm	85 bpm
MRI Pulse Amplitude	5.0 V	5.0 V
MRI Pulse Configuration	Bipolar	Bipolar
MRI Pulse Width	1.0 ms	1.0 ms

Shipped and Standard settings for Assurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[298]
Basic Operation		
Mode	DDD	DDD
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	DOO	DOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Max Tracking Rate	130 bpm	130 bpm
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Delays		
Paced AV Delay	200 ms	200 ms
Sensed AV Delay	150 ms	150 ms

[295] If the Lead Type is set to Unipolar, the nominal is Unipolar.
[296] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.
[297] Available only in devices with MR Conditional Programming Capability.
[298] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Shipped and Standard settings for Assurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[298]
Rate Responsive AV Delay	Off	Off
Shortest AV Delay	100 ms	100 ms
Ventricular Intrinsic Preference (VIP)	Off	Off
VIP Extension	100 ms	100 ms
VIP Search Interval	1 min	1 min
VIP Search Cycles	1 cycle	1 cycle
Negative AV/PV Hysteresis w/Search	Off	Off
Capture & Sense		
ACap Confirm	Off	Off
V. AutoCapture Pacing	Off	Off
A. Pulse Amplitude	2.5 V	2.5 V
V. Pulse Amplitude	2.5 V	2.5 V
A. Pulse Width	0.4 ms	0.4 ms
V. Pulse Width	0.4 ms	0.4 ms
A. Sensitivity	0.5 mV	0.5 mV[299]
A. Max Sensitivity	0.3 mV	0.3 mV
A. Post-Paced Decay Delay	0 ms	0 ms
A. Post-Sensed Decay Delay	0 ms	0 ms
A. Post-Paced Threshold Start	0.8 mV	0.8 mV
A. Post-Sensed Threshold Start Percentage	50%	50%
A. Post-Sensed Minimum Start Threshold	0.3 mV	0.3 mV
A. AutoSense	Off	Off
V. Sensitivity	2.0 mV	2.0 mV
V. Max Sensitivity	0.5 mV	0.5 mV
V. Post-Sense Decay Delay	60 ms	60 ms
V. Post-Paced Decay Delay	Auto	Auto
V. Post-Sense Threshold Start Percentage	75%	75%
V. Post-Paced Threshold Start	Auto	Auto
V. AutoSense	Off	Off
AutoCapture Pacing		
A. Backup Pulse Configuration	Bipolar	Bipolar
V. Backup Pulse Configuration	Bipolar	Bipolar[300]
A. Search Interval	8 hr	8 hr
V. Search Interval	8 hr	8 hr
V. AutoCapture Paced/Sensed AV Delay	50/25 ms	50/25 ms
Leads		
A. Lead Type	Uncoded	Uncoded
V. Lead Type	Uncoded	Uncoded
A. Pulse Configuration	Bipolar	Bipolar
V. Pulse Configuration	Bipolar	Bipolar
A. Sense Configuration	Bipolar	Bipolar[301]
V. Sense Configuration	Bipolar	Bipolar[302]
A. Lead Monitoring	Monitor	Monitor
V. Lead Monitoring	Monitor	Monitor
A. Upper Limit	2000 Ω	2000 Ω
V. Upper Limit	2000 Ω	2000 Ω
A. Lower Limit	200 Ω	200 Ω
V. Lower Limit	200 Ω	200 Ω

[299] If the A. Lead Type is set to Unipolar, the nominal is 1.0mV.
[300] If the RV Lead Type is set to Unipolar, the nominal is Unipolar.
[301] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.
[302] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.

Shipped and Standard settings for Assurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[298]
Refractories & Blanking		
A. Refractory (PVARP)	275 ms	275 ms
A. Sense Refractory	93 ms	93 ms
A. Pace Refractory	190 ms	190 ms
V. Sense Refractory	250 ms	250 ms
V. Pace Refractory	250 ms	250 ms
Rate Responsive PVARP/VREF	High	High
Shortest PVARP/VREF	175 ms	175 ms[303]
Post Ventricular Atrial Blanking (PVAB)	150 ms	150 ms
V. Blanking	44 ms	44 ms
V. Safety Standby	On	On
PVC Response	Off	Off
PMT Response	Atrial Pace	Atrial Pace
PMT Detection Rate	130 bpm	130 bpm
AT/AF Detection and Response		
Auto Mode Switch	DDIR	DDIR
Atrial Tachycardia Detection Rate	180 bpm	180 bpm
AMS Base Rate	80 bpm	80 bpm
AF Suppression Pacing	Off	Off
Overdrive Pacing Cycles	15 cycles	15 cycles
Maximum AF Suppression Rate	120 bpm	120 bpm
MRI Settings[304]		
MRI Mode	DOO	DOO
MRI Base Rate	85 bpm	85 bpm
MRI Pulse Amplitude	5.0 V	5.0 V
MRI Pulse Configuration	Bipolar	Bipolar
MRI Pulse Width	1.0 ms	1.0 ms
MRI Paced AV Delay	120 ms	120 ms

Operating Parameters Tolerances

Table 117. Operating parameter/measurement tolerances single-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Capture & Sense	
Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
Pulse Width	± 0.04 ms
Sensitivity	± 30% or 0.3 mV, whichever is greater[305]

[303] If the Mode is set to AAI or AAT, the nominal is 200ms.
[304] Available only in devices with MR Conditional Programming Capability.
[305] Sensitivity is with respect to a 20ms haversine test signal.

Table 117. Operating parameter/measurement tolerances single-chamber pacemakers

Parameter/Measurement	Tolerance
Leads	
Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)

Table 118. Operating parameter/measurement tolerances for dual-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Max Tracking Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Delays	
Paced AV Delay	± 10 ms
Sensed AV Delay	± 10 ms
Shortest AV Delay	± 5 ms
VIP Search Interval	± 2 sec
Capture & Sense	
A. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
V. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
A. Pulse Width	± 0.04 ms
V. Pulse Width	± 0.04 ms
A. Sensitivity	± 30%[306]
V. Sensitivity	± 30% or 0.3 mV, whichever is greater[307]
AutoCapture Pacing/Cap Confirm	
V. AutoCapture Paced/Sensed AV Delay	± 5 ms
Leads	
A. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
V. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
Refractories & Blanking	
A. Refractory (PVARP)	± 10 ms
A. Absolute Refractory Period	± 10 ms
V. Refractory	± 10 ms
Rate Responsive PVARP/VREF	± 10 ms
Shortest PVARP/VREF	± 10 ms
Post Ventricular Atrial Blanking (PVAB)	± 10 ms
V. Blanking	-4/+10 ms
PMT Detection Rate	± 20 ms

[306] Sensitivity is with respect to a 20ms haversine test signal.
[307] Sensitivity is with respect to a 20ms haversine test signal.

AT/AF Detection & Response	
Atrial Tachycardia Detection Rate	± 15 ms
AMS Base Rate	± 15 ms
Maximum AF Suppression Rate	± 15 ms

NIPS Tolerances

Table 119. NIPS options

Parameter	Tolerance
Coupling Interval	± 10 ms
S1 , S2, S3, and S4 Cycle	± 5 ms
V. Backup Rate (VOO Pacing)	± 15 ms
Sinus Node Recovery Delay	± 1 sec

Physical Specifications

Table 120. Physical Specifications for Assurity devices

Specification[308]	PM1240 PM2240
Case Material	Titanium
Case Coating	None
RF Antenna Material	Titanium
Connector Material	Epoxy
Dimensions (mm) (h x l x t)[309]	47 x 50 x 6
Weight (g)	20
Displacement volume[310] (cm^3)	10.4 ± 0.5
Lead Connector[311]	IS-1[312]

Dimensions and weight values are nominal.

Battery Voltage

Table 121. Battery voltage for Assurity devices with Battery Model 2662 (page 182)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.60 V
End-of-life voltage (unloaded)	2.47 V

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 122. X-ray ID codes

Device Model	X-ray ID Model Code
PM1240, PM2240	HI
PM1272, PM2272	HM MRI

[308] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[309] (h x l x t) = height by length by thickness.
[310] ±0.5 cm^3
[311] Accepts IS-1 short terminal pin leads.
[312] Accepts IS-1 short terminal pin leads.

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 123. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug

Current™, Current™+, Current™ RF, and Current Accel™ Devices Technical Data

The tables below are applicable to the following Current™ device models:

- Current VR 1107-30
- Current VR 1107-36
- Current VR RF 1207-30
- Current VR RF 1207-36
- Current VR CD1207-36Q
- Current+ VR CD1211-36
- Current+ VR CD1211-36Q
- Current Accel VR CD1215-30
- Current Accel VR CD1215-36
- Current Accel VR CD1215-36Q
- Current DR 2107-30
- Current DR 2107-36
- Current DR RF 2207-30
- Current DR RF 2207-36
- Current DR CD2207-36Q
- Current+ DR CD2211-36
- Current+ DR CD2211-36Q
- Current Accel DR CD2215-30
- Current Accel DR CD2215-36
- Current Accel DR CD2215-36Q

  Note

  Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E).

The technical data below include:

- Physical Specifications (page 254)
- Device Configurations (page 255)
- Battery Voltage (page 256)
- Operating Parameters Tolerances (page 256)
- X-ray Identification (page 257)
- Spare Parts And Accessories (page 257)

Physical Specifications

Table 124. Physical specifications for Current 30 J devices

Specification[313]	1107-30	1207-30 CD1215-30	2107-30	2207-30 CD2215-30
Dimensions (cm) (h x l x t)[314]	6.9 x 5.0 x 1.3	7.5 x 5.0 x 1.3	7.0 x 5.0 x 1.3	7.6 x 5.0 x 1.3
Weight (g)	71	73	72	74
Displacement volume (cm^3)	34	37	35	38
Can material	Titanium			
Header material	Epoxy			
Septum material	Silicone			
Stored energy (J)	34			
Noise detection rate	100 or more sensed events per second			
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one IS-1 3.2 mm bipolar lead connector.		High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one or two IS-1 3.2 mm bipolar lead connectors.	
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2356, One cell			

Table 125. Physical specifications for Current 36 J devices

Specification[315]	1107-36	1207-36 CD1211-36 CD1215-36	2107-36	2207-36 CD2211-36 CD2215-36
Dimensions (cm) (h x l x t)[316]	7.0 x 5.0 x 1.4	7.6 x 5.0 x 1.4	7.1 x 5.0 x 1.4	7.7 x 5.0 x 1.4
Weight (g)	76	79	78	80
Displacement volume (cm^3)	38	41	39	42
Can material	Titanium			
Header material	Epoxy			
Septum material	Silicone			
Stored energy (J)	42			
Noise detection rate	100 or more sensed events per second			
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one IS-1 3.2 mm bipolar lead connector.		High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one or two IS-1 3.2 mm bipolar lead connectors.	
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell			

[313] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[314] (h x l x t) = height by length by thickness.
[315] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[316] (h x l x t) = height by length by thickness.

Table 126. Physical specifications for Current 36 J devices with "Q" header

Specification[317]	CD1207-36Q CD1211-36Q CD1215-36Q	CD2207-36Q CD2211-36Q CD2215-36Q
Dimensions (cm) (h x l x t)[318]	7.4 x 5.0 x 1.4	7.4 x 5.0 x 1.4
Weight (g)	79	80
Displacement volume (cm^3)	41	41
Can material	Titanium	
Header material	Epoxy	
Septum material	Silicone	
Stored energy (J)	42	
Noise detection rate	100 or more sensed events per second	
Lead compatibility	High voltage and RV low voltage: one DF4-LLHH lead connector	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector.
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell	

Device Configurations

Table 127. Device configurations

Tachyarrhythmia Configuration	
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off	
Bradyarrhythmia Mode	
Current DR, Current DR RF, Current+ DR, Current Accel DR	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
Current VR, Current VR RF, Current+ VR, Current Accel VR	VVI(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: VOO(R); Additional modes available as temporary modes: VOO
SVT Discrimination Mode[319]	
Current DR, Current DR RF, Current+ DR, Current Accel DR	Ventricular Only, Dual Chamber
Current VR, Current VR RF, Current+ VR, Current Accel VR	Ventricular Only
A Pulse Configuration and Sense Configuration	
Current DR, Current DR RF, Current+ DR, Current Accel DR	Bipolar (A-tip to A-ring)
V Pulse Configuration and Sense Configuration	
All Models	Bipolar (V-tip to V-ring)

[317] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[318] (h x l x t) = height by length by thickness.
[319] Sensing only in the right atrium and right ventricle.

Battery Voltage

Table 128. Battery voltage for devices with Battery Model 2356 (page 182) and Battery Model 2555 (page 182)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.45 V
End-of-life voltage (unloaded)	2.35 V

Operating Parameters Tolerances

Table 129. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay[320]	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[321]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms

[320] Dual-chamber devices only.
[321] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 129. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[322]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 130. X-ray ID codes

Device Model	X-ray ID Model Code
1107-36/30, 2107-36/30	KA
1207-36/30, CD1207-36Q, CD1211-36/36Q, CD1215-36/36Q/30, 2207-36/30, CD2207-36Q, CD2211-36/36Q, CD2215-36/30/36Q	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 131. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[323]
AC-IS4PP	IS4/DF4 port plug

[322] Load > 200ohms.
[323] Dual-chamber ICDs and CRTDs only.

Ellipse™ Devices Technical Data

The tables below are applicable to the following Ellipse™ models:

- Ellipse VR CD1275-36
- Ellipse VR CD1275-36Q
- Ellipse VR CD1311-36
- Ellipse VR CD1311-36Q
- Ellipse VR CD1411-36
- Ellipse VR CD1411-36C
- Ellipse VR CD1411-36Q
- Ellipse VR CD1411-36QC
- Ellipse DR CD2275-36
- Ellipse DR CD2275-36Q
- Ellipse DR CD2311-36
- Ellipse DR CD2311-36Q
- Ellipse DR CD2411-36
- Ellipse DR CD2411-36C
- Ellipse DR CD2411-36Q
- Ellipse DR CD2411-36QC

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E)

Models with the "C" suffix are coated with Parylene.

The technical data below include:

- Physical Specifications (page 260)
- Device Configurations (page 260)
- Battery Voltage (page 260)
- Operating Parameters Tolerances (page 261)
- X-ray Identification (page 262)
- Spare Parts And Accessories (page 262)

Physical Specifications

Table 132. Physical specifications for Ellipse devices

Specification[324]	CD1275-36 CD1311-36 CD1411-36 CD1411-36C	CD2275-36 CD2311-36 CD2411-36 CD2411-36C	CD1275-36Q CD1311-36Q CD1411-36Q CD1411-36QC	CD2275-36Q CD2311-36Q CD2411-36Q CD2411-36QC
Dimensions (cm) (h x l x t)[325]	6.8 x 5.1 x 1.2	6.9 x 5.1 x 1.2	6.6 x 5.1 x 1.2	7.0 x 5.1 x 1.2
Weight (g)	66	66	67	68
Displacement volume (cm^3)	30.6	30.8	30.2	31.3
Can material	Titanium			
Header material	Epoxy			
Septum material	Silicone			
Stored energy (J)	39	39	39	39
Noise detection rate	100 or more sensed events per second			
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one IS-1 3.2 mm bipolar lead connector.	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one or two IS-1 3.2 mm bipolar lead connectors.	High voltage and RV low voltage: one DF4-LLHH lead connector	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2950, One cell			

Device Configurations

Table 133. Device configurations

Tachyarrhythmia Configuration	
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off	
Bradyarrhythmia Mode	
Ellipse DR devices	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
Ellipse VR devices	VVI(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: VOO(R); Additional modes available as temporary modes: VOO
SVT Discrimination Mode[326]	
Ellipse DR devices	Ventricular Only, Dual Chamber
Ellipse VR devices	Ventricular Only
A Pulse Configuration and Sense Configuration	
Ellipse DR devices	Bipolar (A-tip to A-ring)
V Pulse Configuration and Sense Configuration	
All Models	Bipolar (V-tip to V-ring)

Battery Voltage

Table 134. Battery voltage for devices with Battery Model 2950 (page 183)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V

[324] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[325] (h x l x t) = height by length by thickness.
[326] Sensing only in the right atrium and right ventricle.

Table 134. Battery voltage for devices with Battery Model 2950 (page **183**)

Parameter	Data
End-of-life voltage (unloaded)	2.54 V

Operating Parameters Tolerances

Table 135. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay[327]	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[328]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)

[327] Dual-chamber devices only.
[328] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 135. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Voltage Measurement[329]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 136. X-ray ID codes

Device Model	X-ray ID Model Code
CD1275-36/36Q, CD1311-36/36Q, CD1411-36/36C/36Q/36QC, CD2275-36/36Q, CD2311-36/36Q, CD2411-36/36C/36Q/36QC	KF

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 137. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[330]
AC-IS4PP	IS4/DF4 port plug

[329] Load > 200ohms.
[330] Dual-chamber ICDs and CRTDs only.

Endurity™ and Endurity MRI™ Devices Technical Data

The tables below are applicable to the following Endurity™ device models:

- Endurity SR PM1160
- Endurity MRI SR PM1172
- Endurity DR PM2160
- Endurity MRI DR PM2172

The technical data below include:

- Shipped and Standard Settings (page 263)
- Operating Parameters Tolerances (page 266)
- NIPS Tolerances (page 268)
- Physical Specifications (page 268)
- Battery Voltage (page 268)
- X-ray Identification (page 268)
- Spare Parts And Accessories (page 268)

Shipped and Standard Settings

Table 138. Shipped and Standard settings for Endurity single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[331]
Basic Operation		
Mode	VVI	VVI
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	VOO	VOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Capture & Sense		
V. AutoCapture Pacing	Off	Off
Pulse Amplitude	2.5 V	2.5 V
Pulse Width	0.4 ms	0.4 ms
Sensitivity	2.0 mV	2.0 mV
AutoSense	Off	Off
Backup Pulse Configuration	Bipolar	Bipolar[332]
Search Interval	8 hr	8 hr
Leads		
Lead Type	Uncoded	Uncoded
Pulse Configuration	Bipolar	Bipolar[333]
Sense Configuration	Bipolar	Bipolar[334]

[331] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.
[332] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.
[333] If the Lead Type is set to Unipolar, the nominal is Unipolar.
[334] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.

Table 138. Shipped and Standard settings for Endurity single-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[331]
Lead Monitoring	Monitor	Monitor
Upper Limit	2000 Ω	2000 Ω
Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
Sense Refractory	250 ms	250 ms
Pace Refractory	250 ms	250 ms
Rate Responsive VREF	Low	Low
Shortest VREF	175 ms	175 ms
MRI Settings[335]		
MRI Mode	VOO	VOO
MRI Base Rate	85 bpm	85 bpm
MRI Pulse Amplitude	5.0 V	5.0 V
MRI Pulse Configuration	Bipolar	Bipolar
MRI Pulse Width	1.0 ms	1.0 ms

Table 139. Shipped and Standard settings for Endurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[336]
Basic Operation		
Mode	DDD	DDD
Magnet Response	Battery Test	Battery Test
Ventricular Noise Reversion Mode	DOO	DOO
Sensor	Passive	Passive
Max Sensor Rate	130 bpm	130 bpm
Threshold	Auto (+ 0.0)	Auto (+ 0.0)
Slope	Auto (+ 2)	Auto (+ 2)
Reaction Time	Fast	Fast
Recovery Time	Medium	Medium
V. Triggering	Off	Off
Rates		
Base Rate	60 bpm	60 bpm
Rest Rate	Off	Off
Max Tracking Rate	130 bpm	130 bpm
Hysteresis Rate	Off	Off
Search Interval	Off	Off
Cycle Count	1 cycle	1 cycle
Intervention Rate	Off	Off
Intervention Duration	3 min	3 min
Recovery Time	Medium	Medium
Delays		
Paced AV Delay	200 ms	200 ms
Sensed AV Delay	150 ms	150 ms
Rate Responsive AV Delay	Off	Off
Shortest AV Delay	100 ms	100 ms
Ventricular Intrinsic Preference (VIP)	Off	Off
VIP Extension	100 ms	100 ms
VIP Search Interval	1 min	1 min

[335] Available only in devices with MR Conditional Programming Capability.
[336] If parameters have not been previously programmed and are not autoprogrammed, the device will institute these standard or nominal settings.

Table 139. Shipped and Standard settings for Endurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[336]
VIP Search Cycles	1 cycle	1 cycle
Negative AV/PV Hysteresis w/Search	Off	Off
Capture & Sense		
ACap Confirm	Off	Off
V. AutoCapture Pacing	Off	Off
A. Pulse Amplitude	2.5 V	2.5 V
V. Pulse Amplitude	2.5 V	2.5 V
A. Pulse Width	0.4 ms	0.4 ms
V. Pulse Width	0.4 ms	0.4 ms
A. Sensitivity	0.5 mV	0.5 mV[337]
A. Max Sensitivity	0.3 mV	0.3 mV
A. Post-Paced Decay Delay	0 ms	0 ms
A. Post-Sensed Decay Delay	0 ms	0 ms
A. Post-Paced Threshold Start	0.8 mV	0.8 mV
A. Post-Sensed Threshold Start Percentage	50%	50%
A. Post-Sensed Minimum Start Threshold	0.3 mV	0.3 mV
A. AutoSense	Off	Off
V. Sensitivity	2.0 mV	2.0 mV
V. Max Sensitivity	0.5 mV	0.5 mV
V. Post-Sense Decay Delay	60 ms	60 ms
V. Post-Paced Decay Delay	Auto	Auto
V. Post-Sense Threshold Start Percentage	75%	75%
V. Post-Paced Threshold Start	Auto	Auto
V. AutoSense	Off	Off
AutoCapture Pacing		
A. Backup Pulse Configuration	Bipolar	Bipolar
V. Backup Pulse Configuration	Bipolar	Bipolar[338]
A. Search Interval	8 hr	8 hr
V. Search Interval	8 hr	8 hr
V. AutoCapture Paced/Sensed AV Delay	50/25 ms	50/25 ms
Leads		
A. Lead Type	Uncoded	Uncoded
V. Lead Type	Uncoded	Uncoded
A. Pulse Configuration	Bipolar	Bipolar
V. Pulse Configuration	Bipolar	Bipolar
A. Sense Configuration	Bipolar	Bipolar[339]
V. Sense Configuration	Bipolar	Bipolar[340]
A. Lead Monitoring	Monitor	Monitor
V. Lead Monitoring	Monitor	Monitor
A. Upper Limit	2000 Ω	2000 Ω
V. Upper Limit	2000 Ω	2000 Ω
A. Lower Limit	200 Ω	200 Ω
V. Lower Limit	200 Ω	200 Ω
Refractories & Blanking		
A. Refractory (PVARP)	275 ms	275 ms
A. Sense Refractory	93 ms	93 ms
A. Pace Refractory	190 ms	190 ms

[337] If the A. Lead Type is set to Unipolar, the nominal is 1.0mV.
[338] If the RV Lead Type is set to Unipolar, the nominal is Unipolar.
[339] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar.
[340] If the ventricular Lead Type is set to Unipolar, the nominal is Unipolar Tip.

Table 139. Shipped and Standard settings for Endurity dual-chamber pacemakers

Parameter	Shipped Settings	Nominal (Standard) Settings[336]
V. Sense Refractory	250 ms	250 ms
V. Pace Refractory	250 ms	250 ms
Rate Responsive PVARP/VREF	High	High
Shortest PVARP/VREF	175 ms	175 ms[341]
Post Ventricular Atrial Blanking (PVAB)	150 ms	150 ms
V. Blanking	44 ms	44 ms
V. Safety Standby	On	On
PVC Response	Off	Off
PMT Response	Atrial Pace	Atrial Pace
PMT Detection Rate	130 bpm	130 bpm
AT/AF Detection and Response		
Auto Mode Switch	DDIR	DDIR
Atrial Tachycardia Detection Rate	180 bpm	180 bpm
AMS Base Rate	80 bpm	80 bpm
AF Suppression Pacing	Off	Off
Overdrive Pacing Cycles	15 cycles	15 cycles
Maximum AF Suppression Rate	120 bpm	120 bpm
MRI Settings[342]		
MRI Mode	DOO	DOO
MRI Base Rate	85 bpm	85 bpm
MRI Pulse Amplitude	5.0 V	5.0 V
MRI Pulse Configuration	Bipolar	Bipolar
MRI Pulse Width	1.0 ms	1.0 ms
MRI Paced AV Delay	120 ms	120 ms

Operating Parameters Tolerances

Table 140. Operating parameter/measurement tolerances single-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Capture & Sense	
Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
Pulse Width	± 0.04 ms
Sensitivity	± 30% or 0.3 mV, whichever is greater[343]
Leads	
Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)

[341] If the Mode is set to AAI or AAT, the nominal is 200ms.
[342] Available only in devices with MR Conditional Programming Capability.
[343] Sensitivity is with respect to a 20ms haversine test signal.

Table 141. Operating parameter/measurement tolerances for dual-chamber pacemakers

Parameter/Measurement	Tolerance
Basic Operation	
Max Sensor Rate	± 15 ms
Rates	
Base Rate	± 15 ms
Rest Rate	± 15 ms
Max Tracking Rate	± 15 ms
Hysteresis Rate	± 15 ms
Search Interval	± 2 sec
Intervention Rate	± 15 ms
Intervention Duration	± 2 sec
Delays	
Paced AV Delay	± 10 ms
Sensed AV Delay	± 10 ms
Shortest AV Delay	± 5 ms
VIP Search Interval	± 2 sec
Capture & Sense	
A. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
V. Pulse Amplitude	± 20% (BOL to ERI) ± 30% (ERI to EOL)
A. Pulse Width	± 0.04 ms
V. Pulse Width	± 0.04 ms
A. Sensitivity	± 30%[344]
V. Sensitivity	± 30% or 0.3 mV, whichever is greater[345]
AutoCapture Pacing/Cap Confirm	
V. AutoCapture Paced/Sensed AV Delay	± 5 ms
Leads	
A. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
V. Lead Monitoring	± 20% (200 - 2000 Ω) ± 30% (100 - 200 Ω, 2000 - 3000 Ω)
Refractories & Blanking	
A. Refractory (PVARP)	± 10 ms
A. Absolute Refractory Period	± 10 ms
V. Refractory	± 10 ms
Rate Responsive PVARP/VREF	± 10 ms
Shortest PVARP/VREF	± 10 ms
Post Ventricular Atrial Blanking (PVAB)	± 10 ms
V. Blanking	-4/+10 ms
PMT Detection Rate	± 20 ms
AT/AF Detection & Response	
Atrial Tachycardia Detection Rate	± 15 ms
AMS Base Rate	± 15 ms
Maximum AF Suppression Rate	± 15 ms

[344] Sensitivity is with respect to a 20ms haversine test signal.
[345] Sensitivity is with respect to a 20ms haversine test signal.

NIPS Tolerances

Table 142. NIPS options

Parameter	Tolerance
Coupling Interval	± 10 ms
S1 , S2, S3, and S4 Cycle	± 5 ms
V. Backup Rate (VOO Pacing)	± 15 ms
Sinus Node Recovery Delay	± 1 sec

Physical Specifications

Table 143. Physical Specifications for Endurity devices

Specification[346]	PM1160	PM2160
Case Material	Titanium	Titanium
Case Coating	None	None
RF Antenna Material	None	None
Connector Material	Epoxy	Epoxy
Dimensions (mm) (h x l x t)[347]	41 x 50 x 6	46 x 50 x 6
Weight (g)	19	19
Displacement volume[348] (cm^3)	9.7 ± 0.5	10.4 ± 0.5
Lead Connector[349]	IS-1	IS-1

Dimensions and weight values are nominal.

Battery Voltage

Table 144. Battery voltage for devices with Battery Model 2662 (page 182)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.60 V
End-of-life voltage (unloaded)	2.47 V

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 145. X-ray ID codes

Device Model	X-ray ID Model Code
PM1160, PM2160	HI
PM1172, PM2172	HM MRI

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 146. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver

[346] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[347] (h x l x t) = height by length by thickness.
[348] ±0.5 cm^3
[349] Accepts IS-1 short terminal pin leads.

Table 146. Spare parts and accessories

Model Number	Device Description
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-IP-2	IS-1 receptacle plug

Fortify™ Devices Technical Data

The tables below are applicable to the following Fortify™ device models:

- Fortify VR CD1231-40
- Fortify VR CD1231-40Q
- Fortify DR CD2231-40
- Fortify DR CD2231-40Q

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E).

The technical data below include:

- Physical Specifications (page 271)
- Device Configurations (page 271)
- Battery Voltage (page 272)
- Operating Parameters Tolerances (page 272)
- X-ray Identification (page 273)
- Spare Parts And Accessories (page 273)

Physical Specifications

Table 147. Physical specifications for Fortify devices

Specification[350]	CD1231-40	CD2231-40	CD1231-40Q	CD2231-40Q
Dimensions (cm) (h x l x t)[351]	7.3 x 4.0 x 1.4	7.4 x 4.0 x 1.4	7.1 x 4.0 x 1.4	7.1 x 4.0 x 1.4
Weight (g)	76	76	75	75
Displacement volume (cm^3)	35	35	35	35
Can material	Titanium			
Header material	Epoxy			
Septum material	Silicone			
Stored energy (J)	45	45	45	45
Noise detection rate	100 or more sensed events per second			
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one IS-1 3.2 mm bipolar lead connector.	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one or two IS-1 3.2 mm bipolar lead connectors.	High voltage and RV low voltage: one DF4-LLHH lead connector	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2850, One cell			

Device Configurations

Table 148. Device configurations

Tachyarrhythmia Configuration	
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off	
Bradyarrhythmia Mode	
Fortify DR	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT

[350] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[351] (h x l x t) = height by length by thickness.

Fortify VR	VVI(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: VOO(R); Additional modes available as temporary modes: VOO
SVT Discrimination Mode[352]	
Fortify DR	Dual Chamber, Ventricular Only
Fortify VR	Ventricular Only
A Pulse Configuration and Sense Configuration	
Fortify DR	Bipolar (A-tip to A-ring)
V Pulse Configuration and Sense Configuration	
All Models	Bipolar (V-tip to V-ring)

Battery Voltage

Table 149. Battery voltage for devices with Battery Model 2850 (page **183**)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V
End-of-life voltage (unloaded)	2.54 V

Operating Parameters Tolerances

Table 150. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay[353]	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[354]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms

[352] Sensing only in the right atrium and right ventricle.
[353] Dual-chamber devices only.
[354] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 150. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[355]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 151. X-ray ID codes

Device Model	X-ray ID Model Code
CD1231-40/40Q, CD2231-40/40Q	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 152. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[356]
AC-IS4PP	IS4/DF4 port plug

[355] Load > 200ohms.
[356] Dual-chamber ICDs and CRTDs only.

Fortify Assura™ Devices Technical Data

The tables below are applicable to the following Fortify Assura™ device models:

- Fortify Assura VR CD1257-40
- Fortify Assura VR CD1257-40Q
- Fortify Assura VR CD1357-40
- Fortify Assura VR CD1357-40C
- Fortify Assura VR CD1357-40Q
- Fortify Assura VR CD1357-40QC
- Fortify Assura DR CD2257-40
- Fortify Assura DR CD2257-40Q
- Fortify Assura DR CD2357-40
- Fortify Assura DR CD2357-40C
- Fortify Assura DR CD2357-40Q
- Fortify Assura DR CD2357-40QC

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connector cavities comply with ISO 27186:2010(E).

Models with the "C" suffix are coated with Parylene.

The technical data below include:

- Physical Specifications (page 275)
- Device Configurations (page 276)
- Battery Voltage (page 276)
- Operating Parameters Tolerances (page 276)
- X-ray Identification (page 277)
- Spare Parts And Accessories (page 277)

Physical Specifications

Table 153. Physical specifications for Fortify Assura devices

Specification[357]	CD1257-40 CD1357-40 CD1357-40C	CD2257-40 CD2357-40 CD2357-40C	CD1257-40Q CD1357-40Q CD1357-40QC	CD2257-40Q CD2357-40Q CD2357-40QC
Dimensions (cm) (h x l x t)[358]	7.3 x 4.0 x 1.4	7.4 x 4.0 x 1.4	7.1 x 4.0 x 1.4	7.1 x 4.0 x 1.4
Weight (g)	76	76	75	75
Displacement volume (cm^3)	35	35	35	35
Can material	Titanium			
Header material	Epoxy			
Septum material	Silicone			
Stored energy (J)	45	45	45	45
Noise detection rate	100 or more sensed events per second			
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one IS-1 3.2 mm bipolar lead connector.	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one or two IS-1 3.2 mm bipolar lead connectors.	High voltage and RV low voltage: one DF4-LLHH lead connector	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2850, One cell			

[357] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[358] (h x l x t) = height by length by thickness.

Device Configurations

Table 154. Device configurations

Tachyarrhythmia Configuration	
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off	
Bradyarrhythmia Mode	
Fortify Assura DR	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
Fortify Assura VR	VVI(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: VOO(R); Additional modes available as temporary modes: VOO
SVT Discrimination Mode[359]	
Fortify Assura DR	Ventricular Only, Dual Chamber
Fortify Assura VR	Ventricular Only
A Pulse Configuration and Sense Configuration	
Fortify Assura DR Fortify ST DR	Bipolar (A-tip to A-ring)
V Pulse Configuration and Sense Configuration	
All Models	Bipolar (V-tip to V-ring)

Battery Voltage

Table 155. Battery voltage for devices with Battery Model 2850 (page 183)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V
End-of-life voltage (unloaded)	2.54 V

Operating Parameters Tolerances

Table 156. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay[360]	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[361]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω

[359] Sensing only in the right atrium and right ventricle.
[360] Dual-chamber devices only.
[361] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 156. Operating parameter/measurement tolerances

Parameter/Measurement	Tolerance
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[362]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 157. X-ray ID codes

Device Model	X-ray ID Model Code
CD1257-40/40Q, CD1357-40/40C/40Q/40QC, CD2257-40/40Q, CD2357-40/40C/40Q/40QC	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 158. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet

[362] Load > 200ohms.

Table 158. Spare parts and accessories

Model Number	Device Description
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[363]
AC-IS4PP	IS4/DF4 port plug

[363] Dual-chamber ICDs and CRTDs only.

Promote™, Promote™ RF, Promote Accel™, Promote™+, Promote™ Q, and Promote Quadra™ Devices Technical Data

The tables below are applicable to the following Promote™ device models:

- Promote 3107-30
- Promote 3107-36
- Promote 3107-36Q
- Promote RF 3207-30
- Promote RF 3207-36
- Promote CD3207-36Q
- Promote+ CD3211-36
- Promote+ CD3211-36Q
- Promote Accel CD3215-30
- Promote Accel CD3215-36
- Promote Accel CD3215-36Q
- Promote Q CD3221-36
- Promote Quadra CD3245-40
- Promote Quadra CD3245-40Q

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E).
Models CD3221-36 and CD3245-40/40Q use an IS4-LLLL LV pacing lead and support a programmable LV pacing vector. St. Jude Medical's IS4 connector cavities comply with ISO27186:2010(E).

The technical data below include:

- Physical Specifications (page 280)
- Device Configurations (page 281)
- Battery Voltage (page 282)
- Operating Parameters Tolerances (page 282)
- X-ray Identification (page 283)
- Spare Parts And Accessories (page 283)

Physical Specifications

Table 159. Physical specifications for Promote devices

Specification[364]	3107-30	3107-36	3107-36Q
Dimensions (cm) (h x l x t)[365]	7.4 x 5.0 x 1.3	7.5 x 5.0 x 1.4	7.3 x 5.1 x 1.4
Weight (g)	74	80	82
Displacement volume (cm^3)	37	41	40
Can material	Titanium		
Header material	Epoxy		
Septum material	Silicone		
Stored energy (J)	34	42	42
Noise detection rate	100 or more sensed events per second		
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one, two or three IS-1 3.2 mm bipolar (RA, RV, and LV) lead connectors OR one or two IS-1 3.2 mm bipolar (RA and RV) lead connectors and one IS-1 3.2 mm unipolar (LV) lead connector.		High voltage and RV low voltage: one DF4-LLHH lead connector. RA and LV low voltage: one or two IS-1 3.2 mm bipolar lead connectors OR one IS-1 3.2 mm bipolar (RA) lead connector and one IS-1 3.2 mm unipolar (LV) lead connector.
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell		Lithium/silver vanadium oxide; Greatbatch Medical, Model 2356, One cell

Table 160. Physical specifications for Promote, Promote RF, Promote+, Promote Accel devices

Specification[366]	3207-36 CD3211-36 CD3215-36	3207-30 CD3215-30	CD3207-36Q CD3211-36Q CD3215-36Q
Dimensions (cm) (h x l x t)[367]	8.1 x 5.0 x 1.4	8.0 x 5.0 x 1.3	7.5 x 5.0 x 1.4
Weight (g)	82	76	82
Displacement volume (cm^3)	43	39	42
Can material	Titanium		
Header material	Epoxy		
Septum material	Silicone		
Stored energy (J)	42	34	42
Noise detection rate	100 or more sensed events per second		
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one, two or three IS-1 3.2 mm bipolar (RA, RV, and LV) lead connectors OR one or two IS-1 3.2 mm bipolar (RA and RV) lead connectors and one IS-1 3.2 mm unipolar (LV) lead connector.		High voltage and RV low voltage: one DF4-LLHH lead connector. RA and LV low voltage: one or two IS-1 3.2 mm bipolar lead connectors OR one IS-1 3.2 mm bipolar (RA) lead connector and one IS-1 3.2 mm unipolar (LV) lead connector.
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2356, One cell	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell

[364] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[365] (h x l x t) = height by length by thickness.
[366] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[367] (h x l x t) = height by length by thickness.

Table 161. Physical specifications for Promote Q, Promote Quadra devices

Specification[368]	CD3221-36	CD3245-40	CD3245-40Q
Dimensions (cm) (h x l x t)[369]	8.5 x 5.0 x 1.4	8.1 x 5.1 x 1.5	7.4 x 5.1 x 1.5
Weight (g)	88	88	87
Displacement volume (cm^3)	49	46	44
Can material	Titanium		
Header material	Epoxy		
Septum material	Silicone		
Stored energy (J)	42	45	45
Noise detection rate	100 or more sensed events per second		
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. RA and RV Low voltage: one or two IS-1 3.2 mm bipolar lead connectors. LV low voltage: one IS-4-LLLL quadripolar lead connector.		High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector. LV low voltage: one IS4-LLLL quadripolar lead connector.
Battery	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2555, One cell	Lithium/silver vanadium oxide; Greatbatch Medical, Model 2753, One cell	

Device Configurations

Table 162. Device configurations

Tachyarrhythmia Configuration	
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off	
Bradyarrhythmia Mode	
All Promote devices except those with Ventricular Triggering Capability	AAI(R), VVI(R), DDI(R), DDD(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
Promote devices with Ventricular Triggering Capability (page 194)	AAI(R), VVI(R), VVT(R) DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[370]	
Ventricular Only, Dual Chamber	
A Pulse Configuration and Sense Configuration	
Bipolar (A-tip to A-ring)	
RV Pulse Configuration and Sense Configuration	
Bipolar (RV-tip to RV-ring)	
LV Pulse Configuration (CRT-Ds with VectSelect Quartet™ LV Pulse Configuration Capability (page 194))	
Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil	
LV Pulse Configuration (CRT-Ds without VectSelect Quartet™ LV Pulse Configuration Capability)	
Bipolar (LV-tip to LV-ring), LV-tip to RV-coil, LV-ring to RV-coil	

[368] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[369] (h x l x t) = height by length by thickness.
[370] Sensing only in the right atrium and right ventricle.

Battery Voltage

Table 163. Battery voltage for devices with Battery Model 2356 (page 182) and Battery Model 2555 (page 182)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.45 V
End-of-life voltage (unloaded)	2.35 V

Table 164. Battery voltage for devices with Battery Model 2753

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V
End-of-life voltage (unloaded)	2.54 V

Operating Parameters Tolerances

Table 165. Operating parameter/measurement tolerances for CRT-Ds

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[371]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms

[371] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 165. Operating parameter/measurement tolerances for CRT-Ds

Parameter/Measurement	Tolerance
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[372]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

X-ray ID codes

Device Model	X-ray ID Model Code
3107-36/36Q/30	KA
3207-36/30, CD3207-36Q, CD3211-36/36Q CD3215-36/36Q/30, CD3221-36, CD3245-40/40Q	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 166. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[373]
AC-IS4PP	IS4/DF4 port plug

[372] Load > 200ohms.
[373] Dual-chamber ICDs and CRTDs only.

Quadra Assura™, and Quadra Assura MP™ Devices Technical Data

The tables below are applicable to the following Quadra Assura™ device models:

- Quadra Assura CD3265-40
- Quadra Assura CD3265-40Q
- Quadra Assura CD3365-40
- Quadra Assura CD3365-40C
- Quadra Assura CD3365-40Q
- Quadra Assura CD3365-40QC
- Quadra Assura MP CD3269-40
- Quadra Assura MP CD3269-40Q
- Quadra Assura MP CD3369-40
- Quadra Assura MP CD3369-40C
- Quadra Assura MP CD3369-40Q
- Quadra Assura MP CD3369-40QC

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E).
Models CD3265-40, CD3265-40Q, CD3365-40, CD3365-40C, CD3365-40Q, and CD3365-40QC use an IS4-LLLL LV pacing lead and supports ten programmable LV pacing vector. Models CD3269-40, CD3269-40Q, CD3369-40, CD3369-40C, CD3369-40Q, and CD3369-40QC use an IS4-LLLL LV pacing lead and supports ten programmable LV pacing vectors, and support multiple LV pacing pulses (MultiPoint™ Pacing). St. Jude Medical's IS4 connector cavities comply with ISO27186:2010(E).

Models with the "C" suffix are coated with Parylene.

The technical data below include:

- Physical Specifications (page 286)
- Device Configurations (page 286)
- Battery Voltage (page 287)
- Operating Parameters Tolerances (page 287)
- X-ray Identification (page 288)
- Spare Parts And Accessories (page 288)

Physical Specifications

Table 167. Physical specifications for Quadra Assura devices

Specification[374]	CD3265-40 CD3269-40 CD3365-40 CD3365-40C CD3369-40 CD3369-40C	CD3265-40Q CD3269-40Q CD3365-40Q CD3365-40QC CD3369-40Q CD3369-40QC
Dimensions (cm) (h x l x t)[375]	8.3 x 4.1 x 1.4	7.6 x 4.1 x 1.4
Weight (g)	83	81
Displacement volume (cm^3)	4038	
Can material	Titanium	
Header material	Epoxy	
Septum material	Silicone	
Stored energy (J)	45	45
Noise detection rate	100 or more sensed events per second	
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. RA and RV Low voltage: one or two IS-1 3.2 mm bipolar lead connectors. LV low voltage: one IS-4-LLLL quadripolar lead connector.	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector. LV low voltage: one IS4-LLLL quadripolar lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2850, One cell	

Device Configurations

Table 168. Device configurations

Tachyarrhythmia Configuration
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off
Bradyarrhythmia Mode
AAI(R), VVI(R), VVT(R) DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[376]
Ventricular Only, Dual Chamber
A Pulse Configuration and Sense Configuration
Bipolar (A-tip to A-ring)
RV Pulse Configuration and Sense Configuration
Bipolar (RV-tip to RV-ring)
LV Pulse Configuration (CRT-Ds with VectSelect Quartet™ LV Pulse Configuration Capability (page 194))
Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil
LV Pulse Configuration (CRT-Ds without VectSelect Quartet™ LV Pulse Configuration Capability)
Bipolar (LV-tip to LV-ring), LV-tip to RV-coil, LV-ring to RV-coil
LV1 Pulse Configuration (CRT-Ds with VectSelect Quartet , Auto VectSelect, and MultiPoint Pacing Capability)
Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil

[374] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[375] (h x l x t) = height by length by thickness.
[376] Sensing only in the right atrium and right ventricle.

LV2 Pulse Configuration (CRT-Ds with VectSelect Quartet, Auto VectSelect, and MultiPoint Pacing Capability)
Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil

Battery Voltage

Table 169. Battery voltage for devices with Battery Model 2850 (page **183**)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V
End-of-life voltage (unloaded)	2.54 V

Operating Parameters Tolerances

Table 170. Operating parameter/measurement tolerances for CRT-Ds

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[377]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)

[377] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.

Table 170. Operating parameter/measurement tolerances for CRT-Ds

Parameter/Measurement	Tolerance
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[378]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

Table 171. X-ray ID codes

Device Model	X-ray ID Model Code
CD3265-40/40Q, CD3365-40/40C/40Q/40QC, CD3269-40/40Q, CD3369-40/40C/40Q/40QC	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 172. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[379]
AC-IS4PP	IS4/DF4 port plug

[378] Load > 200ohms.
[379] Dual-chamber ICDs and CRTDs only.

Unify™, Unify Assura™, Unify Quadra™ Devices Technical Data

The tables below are applicable to the following Unify™ device models:

- Unify CD3231-40
- Unify CD3231-40Q
- Unify Quadra CD3249-40
- Unify Quadra CD3249-40Q
- Unify Assura CD3257-40
- Unify Assura CD3257-40Q
- Unify Assura CD3357-40
- Unify Assura CD3357-40C
- Unify Assura CD3357-40Q
- Unify Assura CD3357-40QC

Note

Models with the "Q" suffix are functionally equivalent in all respects to the same model without the "Q" suffix, except for the header. Models without the "Q" suffix use DF-1 lead connectors for the high-voltage leads, and models with the "Q" suffix use a single DF4-LLHH lead connector for the high-voltage leads and for the low voltage RV lead. DF4 connector cavities comply with ISO 27186:2010(E).
Models CD3249-40 and CD3249-40Q use an IS4-LLLL LV pacing lead and support a programmable LV pacing vector. St. Jude Medical's IS4 connector cavities comply with ISO27186:2010(E).

Models with the "C" suffix are coated with Parylene.

The technical data below include:

- Physical Specifications (page 289)
- Device Configurations (page 290)
- Battery Voltage (page 290)
- Operating Parameters Tolerances (page 291)
- X-ray Identification (page 291)
- Spare Parts And Accessories (page 292)

Physical Specifications

Table 173. Physical specifications for Unify, Unify Assura devices

Specification[380]	CD3231-40 CD3257-40 CD3357-40 CD3357-40C	CD3231-40Q CD3257-40Q CD3357-40Q CD3357-40QC
Dimensions (cm) (h x l x t)[381]	7.9 x 4.0 x 1.4	7.3 x 4.0 x 1.4
Weight (g)	78	77
Displacement volume (cm^3)	36	36
Can material	Titanium	
Header material	Epoxy	
Septum material	Silicone	
Stored energy (J)	45	45
Noise detection rate	100 or more sensed events per second	
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. Low voltage: one, two or three IS-1 3.2 mm bipolar (RA, RV, and LV) lead connectors OR one or two IS-1 3.2 mm bipolar (RA and RV) lead connectors and one IS-1 3.2 mm unipolar (LV) lead connector.	High voltage and RV low voltage: one DF4-LLHH lead connector. RA and LV low voltage: one or two IS-1 3.2 mm bipolar lead connectors OR one IS-1 3.2 mm bipolar (RA) lead connector and one IS-1 3.2 mm unipolar (LV) lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2850, One cell	

[380] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[381] (h x l x t) = height by length by thickness.

Table 174. Physical specifications for Unify Quadra devices

Specification[382]	CD3249-40	CD3249-40Q
Dimensions (cm) (h x l x t)[383]	8.3 x 4.1 x 1.4	7.6 x 4.1 x 1.4
Weight (g)	83	81
Displacement volume (cm^3)	40	38
Can material	Titanium	
Header material	Epoxy	
Septum material	Silicone	
Stored energy (J)	45	45
Noise detection rate	100 or more sensed events per second	
Lead compatibility	High voltage: one or two DF-1 3.2 mm lead connectors. RA and RV Low voltage: one or two IS-1 3.2 mm bipolar lead connectors. LV low voltage: one IS-4-LLLL quadripolar lead connector.	High voltage and RV low voltage: one DF4-LLHH lead connector. RA low voltage: one IS-1 3.2 mm bipolar lead connector. LV low voltage: one IS4-LLLL quadripolar lead connector.
Battery	Silver vanadium oxide/carbon monofluoride; Greatbatch Medical, Model 2850, One cell	

Device Configurations

Table 175. Device configurations

Tachyarrhythmia Configuration
Defibrillator with No Tachycardia Response (1 Zone: VF); Defibrillator with Tachycardia Response - Single Tachycardia Discrimination (2 Zones: VT, VF); Defibrillator with Tachycardia Response - Two Tachycardia Rate Discrimination (3 Zones: VT-1, VT-2, VF); Off
Bradyarrhythmia Mode
AAI(R), VVI(R), VVT(R) DDI(R), DDD(R), DDT(R), Pacer Off; Additional modes available in the tachyarrhythmia therapies Off configuration: AOO(R), VOO(R), DOO(R); Additional modes available as temporary modes: AOO, VOO, DOO, AAT
SVT Discrimination Mode[384]
Ventricular Only, Dual Chamber
A Pulse Configuration and Sense Configuration
Bipolar (A-tip to A-ring)
RV Pulse Configuration and Sense Configuration
Bipolar (RV-tip to RV-ring)
LV Pulse Configuration (CRT-Ds with VectSelect Quartet™ LV Pulse Configuration Capability (page 194))
Distal tip 1-Mid 2; Distal tip 1-Proximal 4; Distal tip 1-RV Coil; Mid 2-Proximal 4; Mid 2-RV Coil; Mid 3-Mid 2; Mid 3-Proximal 4; Mid 3-RV Coil; Proximal 4-Mid 2; Proximal 4-RV Coil
LV Pulse Configuration (CRT-Ds without VectSelect Quartet™ LV Pulse Configuration Capability)
Bipolar (LV-tip to LV-ring), LV-tip to RV-coil, LV-ring to RV-coil

Battery Voltage

Table 176. Battery voltage for devices with Battery Model 2850 (page **183**)

Parameter	Data
Battery voltage	3.20 V (beginning of life)
Elective replacement voltage (unloaded)	2.59 V
End-of-life voltage (unloaded)	2.54 V

[382] The dimensions, weight, and displacement volume are nominal values based on engineering model measurements.
[383] (h x l x t) = height by length by thickness.
[384] Sensing only in the right atrium and right ventricle.

Operating Parameters Tolerances

Table 177. Operating parameter/measurement tolerances for CRT-Ds

Parameter/Measurement	Tolerance
Pacing Parameters	
Paced AV Delay	± 10 ms
Pace Refractory Period	± 10 ms
Pacing Interval	± 15 ms
Pacing Pulse Width	± 40 µs
Pace Pulse Amplitude[385]	± 25% (BOL to ERI) ± 30% (ERI to EOL)
Sense Parameters	
Sensing Refractory Periods	± 5 ms
Cardioversion/Defibrillation Parameters	
Post-Shock Refractory Period	± 50 ms
Shock Pulse Width	± 40 µs
Output Impedance	< 3 Ω
HV Lead Impedance	± 15% at 50 Ω
Cap Charge Time	± 0.15 s
Stored Voltage	± 5%
Delivered Energy:	
at Max Energy	± 10%
20 J < to < Max Energy	± 15%
5 J < to < 20 J	± 20%
1 J < to < 5 J	± 30%
Arrhythmia Detection Parameters	
Detection Intervals	± 10 ms
SVT/VT Therapy Timers	± 3 s
Interval Stability Delta	± 10 ms
AV Delta	± 10 ms
Sudden Onset Delta	± 10 ms
Arrhythmia Induction Parameters	
Post Therapy Pacing Pause	± 0.25 s
Burst Fibber Interval	± 15 ms
Shock-on-T	± 5 ms
NIPS Interval	± 15 ms
ATP Pacing Interval	± 5 ms (fixed) ± 3% (adaptive)
Burst Fibber Pulse Amplitude	± 15%
Diagnostics / Real-Time Status Data	
Sensed Interval	± 10 ms
Minimum/Maximum Cycle Length	± 10 ms
Pacing Lead Impedance (2 & 4 V)	± 15% (200 to <=1000 Ω) ± 20% (1000 <=2000 Ω)
Pacing Voltage Measurement[386]	± 15% or ± 100 mV (whichever is greater)

X-ray Identification

Each pulse generator has an X-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and a two-letter model code shown in the following table.

[385] Pulse width of 0.5 ms into 500 ohms at 37°C with telemetry inactive.
[386] Load > 200ohms.

Table 178. X-ray ID codes

Device Model	X-ray ID Model Code
CD3231-40/40Q, CD3249-40/40Q, CD3257-40/40Q, CD3357-40/40C/40Q/40QC	KC

Spare Parts and Accessories

Only the accessories shown in the following table are approved for use with these devices.

Table 179. Spare parts and accessories

Model Number	Device Description
442-2	Torque driver
AC-0130	Silicone oil
424	Medical adhesive
AC-0160	Magnet
AC-DP-3	DF-1 receptacle plug
AC-IP-2	IS-1 receptacle plug[387]
AC-IS4PP	IS4/DF4 port plug

[387] Dual-chamber ICDs and CRTDs only.

Clinician Use Information for Bradycardia Devices

This section contains information for CRT-Ps (page 164), Dual-Chamber Pacemakers (page 164), and Single-Chamber Pacemakers (page 164). For information on CRT-Ds (page 163), Dual-Chamber ICDs (page 163), and Single-Chamber ICDs (page 164), see Clinician Use Information for Tachycardia Devices (page 315).

Contents:

- Device Longevity (page 293)
- Elective Replacement Indicator (ERI) (page 312)
- End-of-Life (page 313)

Device Longevity

Many individual factors affect pulse generator service life, such as, programmed parameters, percentage of time paced, enabling of MultiPoint™ Pacing (MPP™) feature, internal impedance, etc. The projected longevity data in the following tables 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. Battery status should be checked after parameter programming so that ERI can be detected well before EOL.

ERI precedes EOL by a wide margin of safety, not less than three months under normal circumstances.

The test data were calculated with Sensor set to Passive and Pulse Width (page 53) set to 0.4 ms (unless otherwise noted).

Accent™ SR Model PM1110 Projected Time From Implant to EOL

Table 180. Accent™ SR Model PM1110 Projected Time From Implant to EOL

	Pulse Amplitude	RV 500 Ω	RV 750 Ω	RV 1000 Ω
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	1.0 V	13.2	13.6	13.8
ERI to EOL in Months (Mean)	1.0 V	6.4	6.6	6.7
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	12.9	13.8	14.3
	RV 3.5 V	9.1	10.6	11.5
ERI to EOL in Months (Mean)	RV 2.5 V	6.3	6.7	7.0
	RV 3.5 V	4.6	5.2	5.7
Pacing at 60 **bpm**, 10% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	16.1	16.2	16.3
	RV 3.5 V	15.3	15.7	15.9
ERI to EOL in Months (Mean)	RV 2.5 V	7.8	7.8	7.9
	RV 3.5 V	7.4	7.6	7.7

Endurity Model PM1160 and Endurity Model MRI Model PM1172 Projected Time From Implant to EOL

Table 181. Endurity Model PM1160 and Endurity MRI Model PM1172 Projected Time From Implant to EOL

	Pulse Amplitude	RV 500 Ω	RV 750 Ω	RV 1000 Ω
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	1.0 V	15.0	15.5	15.9
ERI to EOL in Months (Mean)	1.0 V	9.8	10.1	10.3
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	14.4	15.6	16.3
	RV 3.5 V	9.9	11.6	12.8
ERI to EOL in Months (Mean)	RV 2.5 V	9.5	10.2	10.7
	RV 3.5 V	6.7	7.8	8.5
Pacing at 60 **bpm**, 10% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	18.5	18.7	18.8
	RV 3.5 V	17.5	17.9	18.2

Table 181. Endurity Model PM1160 and Endurity MRI Model PM1172 Projected Time From Implant to EOL

	Pulse Amplitude	RV 500 Ω	RV 750 Ω	RV 1000 Ω
ERI to EOL in Months (Mean)	RV 2.5 V	12.0	12.1	12.2
	RV 3.5 V	11.4	11.4	11.8

Accent SR RF Model PM1210 Projected Time From Implant to EOL

Table 182. Accent SR RF Model PM1210 Projected Time From Implant to EOL

	Pulse Amplitude	RV 500 Ω	RV 750 Ω	RV 1000 Ω
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	1.0 V	12.9	13.3	13.5
ERI to EOL in Months (Mean)	1.0 V	6.3	6.4	6.5
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	12.5	13.4	13.9
	RV 3.5 V	8.9	10.3	11.2
ERI to EOL in Months (Mean)	RV 2.5 V	6.1	6.5	6.8
	RV 3.5 V	4.5	5.1	5.6
Pacing at 60 **bpm**, 10% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	15.5	15.7	15.7
	RV 3.5 V	14.8	15.1	15.3
ERI to EOL in Months (Mean)	RV 2.5 V	7.5	7.6	7.6
	RV 3.5 V	7.2	7.3	7.4

Assurity Model PM1240 and Assurity MRI Model PM1272 Projected Time From Implant to EOL

Table 183. Assurity Model PM1240 and Assurity MRI Model PM1272 Projected Time From Implant to EOL

	Pulse Amplitude	RV 500 Ω	RV 750 Ω	RV 1000 Ω
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	1.0 V	14.5	15.0	15.3
ERI to EOL in Months (Mean)	1.0 V	9.5	9.8	10.0
Pacing at 60 **bpm**, 100% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	13.9	15.0	15.7
	RV 3.5 V	9.7	11.3	12.4
ERI to EOL in Months (Mean)	RV 2.5 V	9.2	10.0	10.3
	RV 3.5 V	6.5	7.6	8.3
Pacing at 60 **bpm**, 10% VVI Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV 2.5 V	17.7	17.9	18.0
	RV 3.5 V	16.8	17.2	17.5
ERI to EOL in Months (Mean)	RV 2.5 V	11.6	11.7	11.7
	RV 3.5 V	11.0	11.3	11.4

Accent DR Model PM2110 Projected Time From Implant to EOL

Table 184. Accent DR Model PM2110 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω	A 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω

Table 184. Accent DR Model PM2110 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω	A 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 1.0 V	9.3	10.1	10.5
ERI to EOL in Months (Mean)	A 2.5 V RV 1.0 V	4.6	5.0	5.1
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	9.2	10.2	10.8
	A 3.5 V RV 3.5 V	5.8	7.0	7.9
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	4.6	5.0	5.3
	A 3.5 V RV 3.5 V	3.1	3.6	4.0
Pacing at 60 bpm, 100% RA, 10% RV DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	10.7	11.4	11.9
	A 3.5 V RV 3.5 V	7.8	8.9	9.7
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	5.3	5.6	5.8
	A 3.5 V RV 3.5 V	4.0	4.5	4.8

Endurity Model PM2160, and Endurity MRI Model 2172 Projected Time From Implant to EOL

Table 185. Endurity Model PM2160 and Endurity MRI PM2172 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω	A 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 1.0 V	9.9	10.7	11.2
ERI to EOL in Months (Mean)	A 2.5 V RV 1.0 V	6.6	7.1	7.4
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	9.7	10.8	11.5
	A 3.5 V RV 3.5 V	6.0	7.3	8.3
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	6.5	7.2	7.6
	A 3.5 V RV 3.5 V	4.2	5.0	5.6
Pacing at 60 bpm, 100% RA, 10% RV DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	11.4	12.3	12.7
	A 3.5 V RV 3.5 V	8.2	9.5	10.3
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	7.6	8.1	8.4
	A 3.5 V RV 3.5 V	5.6	6.3	6.9

Accent DR RF Model PM2210 Projected Time From Implant to EOL

Table 186. Accent DR Model PM2110 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω	A 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 1.0 V	9.1	9.8	10.2
ERI to EOL in Months (Mean)	A 2.5 V RV 1.0 V	4.6	4.9	5.1
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	8.9	9.9	10.5
	A 3.5 V RV 3.5 V	5.7	6.8	7.7
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	4.5	4.9	5.2
	A 3.5 V RV 3.5 V	3.0	3.6	3.9
Pacing at 60 bpm, 100% RA, 10% RV DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	10.4	11.1	11.5
	A 3.5 V RV 3.5 V	7.6	8.7	9.5
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	5.2	5.5	5.7
	A 3.5 V RV 3.5 V	3.9	4.4	4.7

Assurity Model PM2240 and Assurity MRI Model PM2272 Projected Time From Implant to EOL

Table 187. Assurity Model PM2240 and Assurity MRI Model PM2272 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω	A 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter On, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 1.0 V	9.6	10.4	10.9
ERI to EOL in Months (Mean)	A 2.5 V RV 1.0 V	6.9	6.4	7.2
Pacing at 60 bpm, 100% DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	9.4	10.5	11.2
	A 3.5 V RV 3.5 V	5.9	7.1	8.1
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	6.3	7.0	7.4
	A 3.5 V RV 3.5 V	4.1	5.0	5.5
Pacing at 60 bpm, 100% RA, 10% RV DDD Pacing, AutoCapture parameter Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V	11.1	11.9	12.3
	A 3.5 V RV 3.5 V	8.0	9.2	10.0
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V	7.4	7.9	8.2
	A 3.5 V RV 3.5 V	5.5	6.2	6.7

Anthem Model PM3110 Projected Time From Implant to EOL

Table 188. Anthem Model PM3110 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 750 Ω RV 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, Cap Confirm Off				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	7.9	9.0	9.8
	A 3.5 V RV 3.5 V LV 3.5 V	4.5	5.6	6.5
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	4.0	4.5	4.9
	A 3.5 V RV 3.5 V LV 3.5 V	2.5	3.0	3.4

Allure Models PM3120 and PM3140 Projected Time From Implant to EOL

Table 189. Allure Models PM3120 and PM3140 Projected Time From Implant to EOL

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 750 Ω RV 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, Cap Confirm Off				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	8.2	9.4	10.2
	A 3.5 V RV 3.5 V LV 3.5 V	4.5	5.7	6.7
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.6	7.5	8.1
	A 3.5 V RV 3.5 V LV 3.5 V	4.0	4.9	5.5

Table 190. Allure Models PM3120 and PM3140 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, Cap Confirm Off			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	7.0	5.6
	A 3.5 V RV 3.5 V LV 3.5 V	3.7	2.6
	A 5.0 V RV 5.0 V LV 5.0 V	2.7	1.9

Table 190. Allure Models PM3120 and PM3140 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	5.8	4.8
	A 3.5 V RV 3.5 V LV 3.5 V	3.5	2.7
	A 5.0 V RV 5.0 V LV 5.0 V	2.7	2.1

Anthem RF Model PM3210 Projected Time From Implant to EOL

Table 191. Anthem RF Model PM3210 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 750 Ω RV 750 Ω LV 750 Ω	A 1000 Ω RV 1000 Ω LV 1000 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, Cap Confirm Off[388]				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	7.7	8.8	9.5
	A 3.5 V RV 3.5 V LV 3.5 V	4.4	5.5	6.4
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	4.0	4.4	4.8
	A 3.5 V RV 3.5 V LV 3.5 V	2.5	3.0	3.4

Table 192. Anthem RF Model PM3210 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, Cap Confirm Off			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.7	5.4
	A 3.5 V RV 3.5 V LV 3.5 V	3.6	2.6
	A 5.0 V RV 5.0 V LV 5.0 V	2.7	1.9

[388] Calculated with a Pulse Width of 0.5 ms.

Table 192. Anthem RF Model PM3210 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	3.5	2.9
	A 3.5 V RV 3.5 V LV 3.5 V	2.2	1.7
	A 5.0 V RV 5.0 V LV 5.0 V	1.7	1.3

Allure RF Models PM3222 and PM3242 Projected Time From Implant to EOL

Table 193. Allure RF Models PM3222 and PM3242 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 750 Ω RV 750 Ω RV 750 Ω	A 1000 Ω RV 1000 Ω RV 1000 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, Cap Confirm Off[389]				
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	8.0	9.2	10
	A 3.5 V RV 3.5 V LV 3.5 V	4.5	5.6	6.5
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.5	7.3	7.9
	A 3.5 V RV 3.5 V LV 3.5 V	4.0	4.8	5.5

Table 194. Allure RF Models PM3222 and PM3242 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, Cap Confirm Off[390]			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.8	5.5
	A 3.5 V RV 3.5 V LV 3.5 V	3.6	2.6
	A 5.0 V RV 5.0 V LV 5.0 V	2.7	1.9

[389] Calculated with a Pulse Width of 0.4 ms.
[390] Calculated with a Pulse Width of 0.5 ms.

Table 194. Allure RF Models PM3222 and PM3242 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	A 500 Ω RV 500 Ω LV 500 Ω	A 300 Ω RV 300 Ω LV 300 Ω
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	5.7	4.7
	A 3.5 V RV 3.5 V LV 3.5 V	3.4	2.7
	A 5.0 V RV 5.0 V LV 5.0 V	2.7	2.1

Quadra Allure MP Model PM3160 Projected Time From Implant to EOL

Table 195. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP OFF, 100% A Pacing, Pulse Width 0.4 ms, Cap Confirm Off, Stored EGMs On			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	8.2	9.4
	A 3.5 V RV 3.5 V LV 3.5 V	4.5	5.7
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.6	7.5
	A 3.5 V RV 3.5 V LV 3.5 V	4.0	4.9

Table 196. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, Pulse Width 0.4 ms, Cap Confirm Off, Stored EGMs On			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV1 2.5 V LV2 2.5 V	6.8	8.0
	A 3.5 V RV 3.5 V LV1 3.5 V LV2 3.5 V	3.6	4.6
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV1 2.5 V LV2 2.5 V	6.8	8.0
	A 3.5 V RV 3.5 V LV1 3.5 V LV2 3.5 V	3.6	4.6

Table 197. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

Table 197. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% VVI Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV - 2.5 V	14.3	15.5	15.9
	RV - 3.5 V	9.8	11.5	12.3
	RV - 5.0 V	8.1	9.8	10.6
ERI to EOL in Months (Mean)	RV - 2.5 V	11.1	12.0	12.4
	RV - 3.5 V	7.8	9.1	9.6
	RV - 5.0 V	6.6	7.8	8.4

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.8	8.0	8.6
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.6	4.6	5.2
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.3	3.0	3.5
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.6	7.5	7.9
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	4.0	4.8	5.3
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	3.2	3.8	4.2

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.4	7.6	8.2
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.3	4.3	4.8
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.0	2.7	3.1
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.3	7.2	7.6
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.7	4.6	5.0

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	3.0	3.6	3.9

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 0% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.6	6.8	7.4
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.2	5.3	5.9
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.2	5.3	5.8
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	6.3	7.2	7.6
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.3	6.2	6.7
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.8	5.7	6.2

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 15% A Pacing, 0.4 ms Pulse Width Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.5	6.7	7.3
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.2	5.3	5.8
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.0	5.1	5.7
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	6.2	7.1	7.5
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.2	6.1	6.6
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.7	5.6	6.0

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 50% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.3	6.5	7.1
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.1	5.2	5.7
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.8	4.8	5.3
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.9	6.8	7.3
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.0	5.9	6.4
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.3	5.2	5.6

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.1	6.3	6.8
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	3.9	5.0	5.5
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.4	4.4	4.9
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.6	6.5	7.0
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.8	5.7	6.1
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.9	4.7	5.2

Table 198. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω

Table 198. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP OFF, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On		
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV - 2.5 V	7.0
	A - 3.5 V RV - 3.5 V LV - 3.5 V	3.7
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV - 2.5 V	5.8
	A - 3.5 V RV - 3.5 V LV - 3.5 V	3.5

Table 199. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On		
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.8
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 3.5 V	2.9
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.8
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.4

Table 200. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.8	7.3	7.8
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	2.9	4.1	4.6
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	1.8	2.7	3.0

Table 200. Quadra Allure MP Model PM3160 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.8	7.0	7.4
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.4	4.5	4.8
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.7	3.6	3.9

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm, 100% DDD-BiV Pacing, MPP ON, 15% A Pacing, 0.4ms Pulse Width, Cap Confirm Off, Stored EGM On, 3 hours Telemetry Session at Implant, 20 minutes in clinic telemetry usage				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	4.9	6.0	6.6
	A - 2.5 V RV - 2.5 V LV1 - 3.5 V LV2 - 3.5 V	4.5	5.6	6.2
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.8	4.8	5.3
	A - 3.5 V RV - 3.5 V LV1 - 5.0 V LV2 - 5.0 V	3.2	4.1	4.6
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.7	6.6	7.0
	A - 2.5 V RV - 2.5 V LV1 - 3.5 V LV2 - 3.5 V	5.5	6.3	6.7
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	4.4	5.3	5.7
	A - 3.5 V RV - 3.5 V LV1 - 5.0 V LV2 - 5.0 V	4.0	4.8	5.2

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm, 100% DDD-BiV Pacing, MPP ON, 15% A Pacing, 0.4ms Pulse Width, Cap Confirm On, Stored EGM On, 3 hours Telemetry Session at Implant, 20 minutes in clinic telemetry usage				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.0 V LV1 - 3.0 V LV2 - 3.0 V	5.0	6.1	6.6
	A - 2.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	4.6	5.7	6.2
	A - 3.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	4.5	5.6	6.1
	A - 3.5 V RV - 2.0 V LV1 - 5.0 V LV2 - 5.0 V	3.6	4.6	5.1
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.0 V LV1 - 3.0 V LV2 - 3.0 V	5.8	6.7	7.1
	A - 2.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	5.5	6.4	6.8
	A - 3.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	5.4	6.2	6.7
	A - 3.5 V RV - 2.0 V LV1 - 5.0 V LV2 - 5.0 V	4.7	5.6	6.0

Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL

Table 201. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP OFF, 100% A Pacing, Pulse Width 0.4 ms, Cap Confirm Off, Stored EGMs On			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	8.0	9.2
	A 3.5 V RV 3.5 V LV 3.5 V	4.5	5.6
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV 2.5 V	6.5	7.3
	A 3.5 V RV 3.5 V LV 3.5 V	4.0	4.8

Table 202. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω

Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, Pulse Width 0.4 ms, Cap Confirm Off, Stored EGMs On			
Implant to ERI in Years (Mean)	A 2.5 V RV 2.5 V LV1 2.5 V LV2 2.5 V	6.7	7.9
	A 3.5 V RV 3.5 V LV1 3.5 V LV2 3.5 V	3.6	4.6
ERI to EOL in Months (Mean)	A 2.5 V RV 2.5 V LV1 2.5 V LV2 2.5 V	6.5	7.4
	A 3.5 V RV 3.5 V LV1 3.5 V LV2 3.5 V	4.0	4.8

Table 203. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (60 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% VVI Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	RV - 2.5 V	13.9	15.0	15.4
	RV - 3.5 V	9.6	11.2	11.9
	RV - 5.0 V	8.0	9.6	10.4
ERI to EOL in Months (Mean)	RV - 2.5 V	10.8	11.6	12.0
	RV - 3.5 V	7.7	8.9	9.4
	RV - 5.0 V	6.5	7.7	8.2

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.7	7.9	8.4
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.6	4.6	5.1
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.2	3.0	3.4
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.5	7.4	7.7
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	4.0	4.8	5.2
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	3.2	3.8	4.1

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.3	7.5	8.0
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.3	4.2	4.7
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.0	2.7	3.1
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	6.2	7.1	7.5
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.7	4.5	4.9
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	3.0	3.6	3.9

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 0% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.5	6.7	7.2
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.2	5.3	5.8
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.1	5.2	5.7
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	6.2	7.1	7.5
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.2	6.1	6.5
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.8	5.7	6.1

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 15% A Pacing, 0.4 ms Pulse Width Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.4	6.6	7.2
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.1	5.2	5.7
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.0	5.0	5.6
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	6.1	7.0	7.4
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.1	6.0	6.5
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.6	5.5	5.9

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 50% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.3	6.4	7.0
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.0	5.1	5.6
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.7	4.7	5.3
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.8	6.7	7.2
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	5.0	5.8	6.3
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	4.2	5.1	5.5

	Pulse Amplitude	500 Ω	750 Ω	900 Ω

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 60 bpm, 100% DDD BiV Pacing, MPP ON, 100% A Pacing, 0.4 ms Pulse Width, Cap Confirm Off, Stored EGMs On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.0	6.2	6.7
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	3.9	4.9	5.4
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.4	4.4	4.9
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.5	6.4	6.8
	A - 2.5 V RV - 2.5 V LV1 - 5.0 V LV2 - 5.0 V	4.7	5.7	6.1
	A - 3.5 V RV - 3.5 V LV1 - 4.0 V LV2 - 4.0 V	3.9	4.7	5.1

Table 204. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP OFF, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On		
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV - 2.5 V	76.8
	A - 3.5 V RV - 3.5 V LV - 3.5 V	3.6
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV - 2.5 V	5.7
	A - 3.5 V RV - 3.5 V LV - 3.5 V	3.4

Table 205. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On		
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.7
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 3.5 V	2.8

Table 205. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.7
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.4

Table 206. Quadra Allure MP RF Model PM3262 Projected Time From Implant to EOL (70 bpm)

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm,100% DDD-BiV Pacing, MPP ON, 100% A Pacing, 0.5 ms Pulse Width, Cap Confirm Off, Stored EGMS On				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.7	6.8	7.3
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	2.8	3.7	4.2
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	1.8	2.4	2.7
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 2.5 V LV2 - 2.5 V	5.7	6.6	6.9
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.4	4.2	4.5
	A - 5.0 V RV - 5.0 V LV1 - 5.0 V LV2 - 5.0 V	2.8	3.3	3.6

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm, 100% DDD-BiV Pacing, MPP ON, 15% A Pacing, 0.4ms Pulse Width, Cap Confirm Off, Stored EGM On, 3 hours Telemetry Session at Implant, 20 minutes in clinic telemetry usage				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	4.8	5.9	6.4
	A - 2.5 V RV - 2.5 V LV1 - 3.5 V LV2 - 3.5 V	4.4	5.5	6.0
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	3.7	4.7	5.2
	A - 3.5 V RV - 3.5 V LV1 - 5.0 V LV2 - 5.0 V	3.1	4.0	4.5

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.5 V LV1 - 3.0 V LV2 - 3.0 V	5.7	6.5	6.9
	A - 2.5 V RV - 2.5 V LV1 - 3.5 V LV2 - 3.5 V	5.4	6.2	6.6
	A - 3.5 V RV - 3.5 V LV1 - 3.5 V LV2 - 3.5 V	4.4	5.2	5.7
	A - 3.5 V RV - 3.5 V LV1 - 5.0 V LV2 - 5.0 V	4.0	4.8	5.2

	Pulse Amplitude	500 Ω	750 Ω	900 Ω
Pacing at 70 bpm, 100% DDD-BiV Pacing, MPP ON, 15% A Pacing, 0.4ms Pulse Width, Cap Confirm On, Stored EGM On, 3 hours Telemetry Session at Implant, 20 minutes in clinic telemetry usage				
Implant to ERI in Years (Mean)	A - 2.5 V RV - 2.0 V LV1 - 3.0 V LV2 - 3.0 V	4.9	6.0	6.5
	A - 2.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	4.5	5.6	6.1
	A - 3.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	4.4	5.5	6.0
	A - 3.5 V RV - 2.0 V LV1 - 5.0 V LV2 - 5.0 V	3.6	4.6	5.1
ERI to EOL in Months (Mean)	A - 2.5 V RV - 2.0 V LV1 - 3.0 V LV2 - 3.0 V	5.7	6.6	7.0
	A - 2.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	5.5	6.4	6.8
	A - 3.5 V RV - 2.0 V LV1 - 3.5 V LV2 - 3.5 V	5.3	6.2	6.6
	A - 3.5 V RV - 2.0 V LV1 - 5.0 V LV2 - 5.0 V	4.7	5.6	6.0

Elective Replacement Indicator (ERI)

ERI (used synonymously with RRT) is the point at which the battery voltage can only maintain adequate operation for a nominal period of six months before End-of-Life (EOL) for models PM1160, PM1240, PM1260, PM2160, PM2240, PM2260, PM3120, PM3140, PM3160, PM3222, PM3242, and PM3262 and for three months before End-of-Life (EOL) for all other St. Jude Medical™ pacemakers and CRT-Ps.

When the device exhibits signs of ERI, described below, replace it expeditiously. There are a number of indicators to this condition:

- The pacing interval increases by 100 ms over the Base Rate to reduce current drain. The difference between the programmed Base Rate (page 66) and actual pacing rates at ERI are shown in Programmed Pacing Rates and Actual Pacing Rates at ERI (page 313).

- The programmer displays an alert that the device has detected ERI
- The Battery & Leads (page 37) window displays a Clear ERI (page 313) button.
- The Sensor is programmed Off.
- The **battery voltage** has decreased to 2.6 V.
- The Magnet Rate (page 38) measures approximately 85.0 **bpm** or less.
- The following features no longer operate at ERI:
  - NIPS Test (page 55)
  - AF Suppression™ Algorithm (page 87)

Clear ERI

Select the Clear ERI button from the Battery & Leads (page 37) window if you suspect that ERI is premature. ERI may be artificially reported under such conditions as extreme cold temperatures or exposure to EMI sources such as electrocautery and defibrillation.

WARNING

At ERI, the nominal life of Allure, Assurity, and Endurity devices is approximately six months. The nominal life of other devices is approximately three months. The device should be replaced expeditiously.

CAUTION

High output settings or high rates may shorten the time to ERI.

If the programmer shows an ERI warning message, fully evaluate the device.

Note

Autoprogrammed Parameters. The programmed parameters that were autoprogrammed at ERI are not restored to their initial settings when Clear ERI is selected. Interrogate and reprogram the device.

Programmed Pacing Rates and Actual Pacing Rates at ERI

Table 207. Programmed pacing rates and actual pacing rates (in **bpm**) at ERI

Programmed Rate	Actual Rate at ERI (100 ms interval increase)	Programmed Rate	Actual Rate at ERI (100 ms interval increase)
45	41.9	110	93.0
50	46.2	115	96.5
55	50.4	120	100.0
60	54.5	125	103.4
65	58.6	130	106.8
70	62.7	135	110.2
75	66.7	140	113.5
80	70.6	145	116.8
85	74.4	150	120.0
90	78.3	155	123.2
95	82.0	160	126.3
100	85.7	165	129.4
105	89.4	170	132.5

End-of-Life

In most pacers and CRT-Ps, EOL occurs when the battery voltage has fallen to below 2.5 V. In Assurity, Endurity, Allure, Allure Quadra, and Quadra Allure MP devices, EOL is 2.47 V.

Clinician Use Information for Tachycardia Devices

This section contains information for CRT-Ds, Dual-Chamber ICDs, and Single-Chamber ICDs. For information on CRT-Ps, Dual-Chamber Pacemakers, and Single-Chamber Pacemakers, see Clinician Use Information for Bradycardia Devices.

Contents:

- Patient Selection and Treatment (page 315)
- Detailed Device Description (page 315)
- Implanting The Pulse Generator (page 319)
- Patient Follow-up (page 321)
- Factors That Affect Device Longevity (page 322)
- Device Longevity Tables (page 323)

Patient Selection and Treatment

Device selection. Before implanting a device, assess the patient's current and anticipated clinical needs. Select a device that will fulfill those needs.

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

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

- Determine the maximum rate of the patient's normal rhythm
- Identify any supraventricular tachy\-arrhythmias
- Identify exercise-induced tachy\-arrhythmias

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

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

Drug-resistant supraventricular tachyarrhythmias (SVTs) may initiate frequent unwanted device therapy. A careful choice of programming options is necessary for such patients.

Antiarrhythmic drug therapy. If the patient is being treated with antiarrhythmic or cardiac drugs, the patient should be on a maintenance drug dose, rather than a loading dose, at the time of pulse generator implantation. Changes in a patient's antiarrhythmic drug (or any other medication that affects the patient's normal cardiac rate or conduction) can affect the rate of tachy\-arrhythmia and/or efficacy of therapy. If changes to drug therapy are made, repeated arrhythmia inductions are recommended to verify pulse generator detection and conversion. The pulse generator may also need to be reprogrammed.

Direct any questions regarding the individualization of patient therapy to St. Jude Medical.

Patient Counseling Information

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

- Persons administering CPR may experience the presence of voltage on the patient's body surface (tingling) when the patient's ICD or CRT-D system delivers a shock
- Encourage patients to use ID cards (issued by St. Jude Medical) and/or ID bracelets documenting their ICD or CRT-D system

Discuss the information in the patient manual with patients and their families before and after pulse generator implantation so they are fully familiar with operation of the device.

Patient Information

Information for the patient is available in a separate booklet packaged with each device from St. Jude Medical. Copies can be obtained by contacting St. Jude Medical. This information should be given to each patient with their first implantable defibrillator and/or at follow-up, as deemed appropriate.

Detailed Device Description

Pulse Generator Headers

The pulse generator headers are shown below. A description of the lead receptacles is in the table below.

Table 208. CRT-D headers (see table for legend)

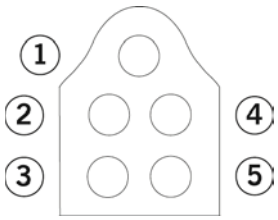
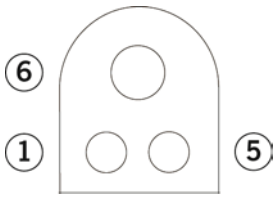
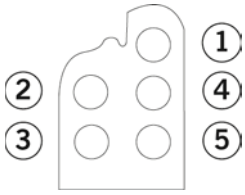
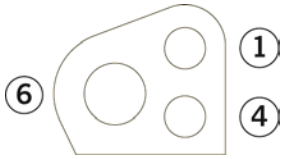
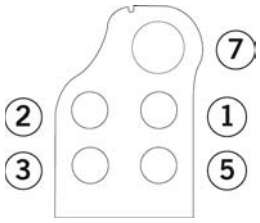
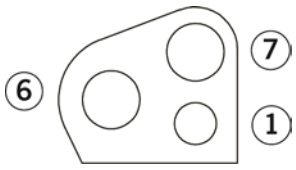
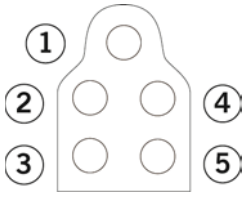
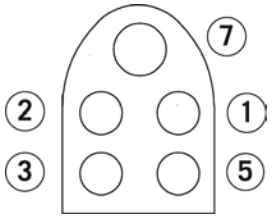
 Promote™ 3107-36/30	 Promote 3107-36Q
 Promote RF 3207-36/30 Promote+ CD3211-36 Promote Accel™ CD3215-36/30	 Promote CD3207-36Q Promote+ CD3211-36Q Promote Accel CD3215-36Q Unify™ CD3231-40Q Unify Assura™ CD3257-40Q, CD3357-40Q, CD3357-40QC
 Promote Q CD3221-36	 Promote Quadra™ CD3245-40Q Unify Quadra™ CD3249-40Q Quadra Assura™ CD3265-40Q, CD3365-40Q, CD3365-40QC Quadra Assura MP™ CD3269-40Q, CD3369-40Q, CD3369-40QC
 Unify CD3231-40 Unify Assura CD3257-40, CD3357-40, CD3357-40C	 Promote Quadra CD3245-40 Unify Quadra CD3249-40 Quadra Assura CD3265-40, CD3365-40, CD3365-40C Quadra Assura MP™ CD3269-40, CD3369-40, CD3369-40C

Table 209. Dual-chamber ICD headers (see table for legend)

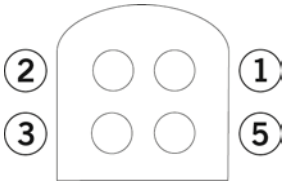
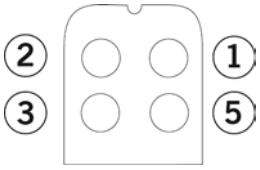
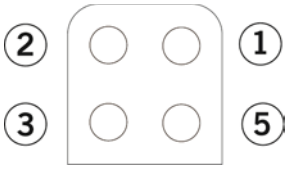
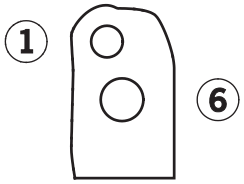
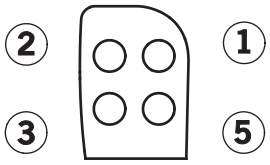
 Current™ 2107-36/30	 Current DR RF 2207-36/30 Current+ DR CD2211-36 Current Accel™ CD2215-36/30
 Current DR CD2207-36Q Current+ DR CD2211-36Q Current Accel DR CD2215-36Q Fortify™ CD2231-40Q Fortify Assura™ DR CD2257-40Q, CD2357-40Q, CD2357-40QC	 Fortify DR CD2231-40 Fortify Assura DR CD2257-40, CD2357-40, CD2357-40C
 Ellipse™ DR CD2275-36Q, CD2311-36Q, CD2411-36Q, CD2411-36QC	 Ellipse DR CD2275-36, CD2311-36, CD2411-36, CD2411-36C

Table 210. Single-chamber ICD headers (see table for legend)

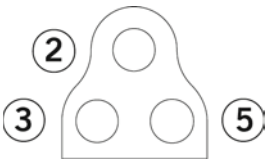
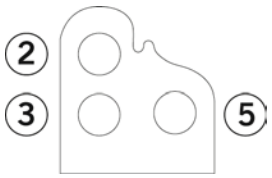
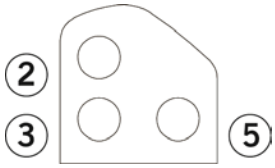
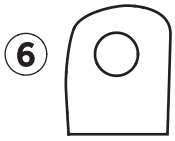
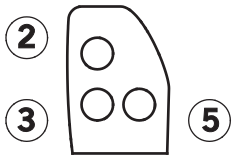
 Current VR 1107-36/30	 Current VR RF 1207-36/30 Current+ VR CD1211-36 Current Accel VR CD1215-36/30
 Current VR CD1207-36Q Current+ VR CD1211-36Q Current Accel VR CD1215-36Q Fortify VR CD1231-40Q Fortify Assura VR CD1257-40Q, CD1357-40, CD1357-40C	 Fortify VR CD1231-40 Fortify Assura VR CD1257-40Q, CD1357-40Q, CD1357-40QC
 Ellipse VR CD1275-36Q, CD1311-36Q, CD1411-36Q, CD1411-36QC	 Ellipse VR CD1275-36, CD1311-36, CD1411-36, CD1411-36C

Table 211. Lead receptacles

Legend Number	Receptacle	Lead Type	Connector Cavity Size
1	A (IS-1 Bi) SENSE/PACE OR PLUG	Bipolar endocardial; IS-1 plug (when no atrial lead is used)	IS-1[391] in-line bipolar
2	SVC (DF-1) OR PLUG	Defibrillation; DF-1 plug (when only one defibrillation electrode is used)	DF-1[392]
3	RV (DF-1)	Defibrillation	DF-1
4	LV (IS-1 Bi) PACE OR PLUG	Bipolar or unipolar left ventricular; IS-1 plug (when no left ventricular lead is used)	IS-1 in-line bipolar or unipolar
5	V or RV (IS-1 Bi) SENSE/PACE	Bipolar endocardial	IS-1 in-line bipolar
6	RV/SVC (DF4-LLHH)[393] RV SENSE/PACE RV/SVC DEFIB	Defibrillation and bipolar endocardial	DF4-LLHH
7	LV (IS4-LLLL)[394] PACE	Four electrode, bipolar left ventricle	IS4-LLLL

Note

When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.

The DF4-LLHH lead receptacle can only be used with DF4-LLHH leads that combine the RV and SVC defibrillation coils and the RV sense/pace electrode into a single connector.

[391] St. Jude Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3.
[392] St. Jude Medical DF-1 connector cavities comply with the international connector standard: ISO 5841-3.
[393] St. Jude Medical's DF4 connector cavities comply with ISO 27186:2010(E).
[394] St. Jude Medical's IS4 connector cavities comply with ISO27186:2010(E).

The IS4-LLLL lead receptacle can only be used with IS4-LLLL leads that combine four LV sense/pace electrodes into a single connector

Implanting the Pulse Generator

This section describes the recommended procedures for handling, implanting, and testing the pulse generator.

Choosing the Implant Site

The pulse generator can be implanted in either the pectoral region or the abdominal region, at the physician's discretion.

Pectoral Placement

Before deciding to implant the pulse generator pectorally, assess patients on a case-by-case basis to ensure their suitability for pectoral implantation. If the device is implanted pectorally, a single incision may be used to form the pocket and provide access for transvenous lead placement. Use short leads of appropriate length to avoid the necessity of coiling extra lead length in the pocket.

Submuscular

For access to the cephalic and subclavian veins, make a single incision over the delta-pectoral groove. To avoid interfering with left shoulder motion, place the pulse generator medial to the humeral head.

Subcutaneous

For access to the cephalic vein, make a long, transverse incision. To ensure that the leads are far enough from the axilla, place the device as far medially as possible. Place the device in the pocket so that the upper edge is inferior to the incision. To prevent migration, anchor the device to the pectoral muscle using the suture holes in the device header.

Abdominal Placement

Abdominal placement is recommended for patients who have had previous pectoral surgery or for whom the physician decides that pectoral placement is undesirable for anatomical reasons. Use leads longer than 75 cm with devices implanted abdominally.

Implanting the Leads

Refer to the information supplied with the leads for implantation information, indications, and possible complications.

Testing at Implant

Due to the nature of the implantation procedure, the physician and support staff should be familiar with all of the components of the system and the material in this manual before beginning the procedure.

After implanting the leads, test the lead systems. Because of the difference in capacitance between the pulse generator and an external stimulation device, we strongly recommend device-based testing. However, you may want to use a single, initial test using an external stimulation device to screen for patients with a high defibrillation threshold before you open the pulse generator package.

For information on device-based testing, see Performing Device-Based Testing (page 320). If an implant support device is used, we strongly recommend that supplemental testing be done with the pulse generator.

WARNING

Due to the nature of the procedure, a separate standby external defibrillator should always be immediately available.

Forming the Pocket and Connecting the Leads

1. If it has not already been done, prepare a pocket for the pulse generator.

   WARNING

   To avoid any risk of accidental shock, make sure that tachyarrhythmia therapies are off before handling the pulse generator. Do not program the pulse generator on until it is inserted in the pocket.

   WARNING

   For reliable data transmission, implant the pulse generator at a depth not to exceed 5 cm. For patient comfort, do not implant the pulse generator within 1.25 cm of bone unless you cannot avoid it.

2. Insert the lead pins into their receptacles, past the setscrew opening.

   If necessary, use sterile lubricant on the insulated shoulder of the lead connectors.

   Properly inserted, the plug heads protrude only a few millimeters from the header. Do not use forceps or other tools to insert the plug as these can damage its silicone insulation.

   Note

   When connecting leads to the pulse generator, make sure that you plug the correct lead into the correct lead receptacle. For sensing and pacing, this is important to ensure that atrial and ventricular signals are correctly recorded and that pacing pulses are delivered in the desired chamber.

WARNING

If you are using a single defibrillation lead with only one defibrillation coil, make sure that the lead is in the receptacle for the RV (DF-1) lead. Lubricate and insert the DF-1 plug into the receptacle for the SVC (DF-1) lead. If the lead is not in the RV receptacle, the can and the lead will have the same polarity and there will be no current flow.

WARNING

When the DF4-LLHH lead receptacle is plugged, disable tachyarrhythmia therapy.

Note

For IS4/DF4 leads and lead receptacles, do not use silicone oil, mineral oil, or any substance other than sterile saline, water, or heparinized saline as a lubricant. For IS-1 and DF-1 leads and lead receptacles the use of a lubricant is optional.

Use and fasten the appropriate lead receptacle plug in an unused lead receptacle. Refer to Spare Parts and Accessories for a list of available lead receptacle plugs.

For dual-chamber and CRT-D devices, if you are not using an atrial sense/pace lead, lubricate and insert an IS-1 receptacle plug into the receptacle for the atrial sense/pace lead.

For CRT-D devices, if you are not using a left ventricular pacing lead, lubricate and insert an IS-1 plug into the receptacle for the LV lead.

3. Carefully insert the tip of the torque driver into the setscrew and turn the handle clockwise until you hear at least three clicks.

   Setscrews are installed in the pulse generator at the time it is shipped. Exercise caution when turning the setscrew, which may be backed out of the connector if turned counterclockwise for more than two rotations.
4. Coil any excess lead length underneath the pulse generator in the implant pocket.

Performing Device-Based Testing

Table 212. Recommended thresholds and amplitudes

Parameter	Acute	Chronic
LV pacing capture threshold	< 3 V	< 5 V
RV pacing capture threshold	< 2 V	< 5 V
Atrial pacing capture threshold	< 2 V	< 5 V
R-wave amplitude	5 mV or greater	2 mV or greater
P-wave amplitude	2 mV or greater	1 mV or greater

1. Implant the leads and pulse generator. See Forming the Pocket and Connecting the Leads. (page 319)
2. Use the programmer to interrogate the pulse generator.
3. Measure pacing capture thresholds, pacing lead impedances and R-wave and P-wave amplitudes and store the data for trending analysis (see table above).

   Note

   Very small-amplitude signals during tachycardia or fibrillation may result in prolonged arrhythmia detection times or inability to detect an arrhythmia.

   Incorrect pacing thresholds may result if you insert a DF4 connector into an IS4 receptacle. Absence of a real-time EGM may result if you insert an IS4 connector into a DF4 receptacle. Refer to the real-time EGMs and impedance measurements to confirm the proper lead connections.
4. Check the sensing lead(s) real-time EGM for discontinuity or any artifact that might indicate lead damage.

   Note that tapping the device header with an instrument or finger may produce artifacts on the real-time EGM.
5. Set the high-voltage waveform tilt or pulse width to the desired value.

   If the waveform is Fixed PW, you should deliver an emergency shock of at least 200 V to evaluate the lead impedance before programming the pulse width. If the waveform is Fixed Tilt, no impedance calculation is required.

   CAUTION

   Do not implant the pulse generator if the acute defibrillation lead impedance is less than 20 Ω or the lead impedance of chronic leads is less than 15 Ω . Damage to the device may result if high-voltage therapy is delivered into an impedance of less than 15 Ω .
6. Set up the device configuration parameters as desired and program the device On.

7. Induce ventricular fibrillation and monitor detection and therapy delivery. Adjust voltage and repeat until defibrillation threshold is determined.

   WARNING

   For effective defibrillation, place the device in the pocket before arrhythmia induction or defibrillation testing.

   If you are using the programmer's device-based testing function, note that if the desired therapy voltage is not reached before the time delay has elapsed (in Timed mode) or therapy has been requested (in Manual mode), therapy delivery is postponed until the therapy voltage has been reached.

   If energy requirements are excessive, the defibrillation leads may need to be repositioned, or the device reprogrammed to a different waveform, tilt, pulse width or polarity, or a different lead system chosen. If an SVC electrode is implanted, it can also be reprogrammed Off or On.

   The energy requirement for reliable arrhythmia termination should be at least 10 J less than the pulse generator's maximum output. This equates to a voltage requirement for termination of no more than approximately 640 to 685 V, depending on programmed waveform, pulse width, and defibrillation lead impedance.

   The choice of defibrillation lead system should be based on clinical factors and energy requirements. If energy requirements cannot be met with a given lead system, or if acute defibrillation lead impedance is low, a different lead system may alleviate the problem.

   If the patient's condition permits, it is recommended that redetection be assessed after a failed shock at implant or predischarge testing.

   If the R-wave amplitude is very small, detection times may be prolonged or the device may be unable to detect an arrhythmia.

   If an arrhythmia is induced but the real-time EGM does not indicate that tachyarrhythmia intervals are being counted, the R-wave amplitude may be too low or the programmed tachyarrhythmia detection rate may be higher than the induced rate.

8. When testing is finished, go to the Capture Testing screen to evaluate the pacing capture thresholds. The capture threshold trends update automatically.

   The unloaded battery voltage, signal amplitude, and pacing lead impedance trends are automatically updated by the device once a month.

9. Set up the device configuration and parameters as described in the appropriate reference manual.

   Refer to the patient's electrophysiology (EP) study and documented spontaneous arrhythmia episodes for program\-ming detection criteria.

10. Confirm bradycardia sensing and pacing as described in the next section.

Confirming Bradycardia Sensing and Pacing

St. Jude Medical recommends that operating room testing include confirmation of bradycardia sensing and pacing at the programmed parameters.

1. Program tachyarrhythmia therapies Off and confirm appropriate sensing during intrinsic conduction.
2. Program the device to DDD or VVI pacing and set the pacing rate and (in DDD mode) AV Delay so the pulse generator paces 100% of the time.
3. If the real-time EGM shows T-waves that appear to be over half the size of the QRS complex and if the device is not pacing at the programmed rate (indicating T-wave sensing), increase the Decay Delay or Threshold Start.

Confirming Parameter Settings

At the end of the programming session, interrogate the device and confirm that the final parameter settings are correct.

Testing Before Hospital Discharge

If appropriate, use noninvasive stimulation to induce the clinical arrhythmias and confirm the appropriateness of the device's programmed settings. Review the performance of the morphology template, if applicable.

Test the Patient Notifier. This will help familiarize the patient with the vibration they will feel when a Patient Notifier is delivered.

Take a chest X-ray to provide a basis for comparison should later changes in shock efficacy or lead impedance make the lead system suspect.

Clinical and animal studies have shown that the high-voltage lead impedance drops significantly in the first seven days post-implant. Over the next few weeks, it gradually returns to near-implant level. In view of the recovery of the lead impedance level, no concomitant adjustment to the high-voltage pulse width is recommended during this period.

Patient Follow-Up

Patients who receive a pulse generator should be seen for follow-up every three months. If the patient experiences a spontaneous episode, it may be deemed appropriate for the patient to return for follow-up immediately.

A follow-up visit should include (at a minimum):

- Review of the FastPath™ Summary screen
- Review of stored and real-time EGMs
- Review of morphology template performance (if applicable)
- Review of sensing amplitude and pacing thresholds

- Confirmation that the final parameter settings are correct

Progression or changes over time in the patient's underlying heart or systemic disease may necessitate a re-evaluation of the patient's clinical arrhythmias and reprogramming of device detection and therapy parameters. Stored EGMs obtained during follow-up visits can help determine when to return to the electrophysiology laboratory, as in the case of an observed change in the VT rate. Device settings should be re-evaluated if the patient's antiarrhythmic medication is changed.

Depending on clinical circumstances and the patient's level of understanding, it may be advisable to give the patient a magnet for emergency use.

The delivery of a high-voltage shock into a damaged lead system may result in device failure, including the inability to deliver therapy or pace, inappropriate shocks, and/or premature battery depletion. Carefully monitor the lead system integrity during patient follow-up for insulation damage or fractures which may result in secondary device failure due to the arcing of current back to the device can.

Device Longevity

Elective Replacement Indicator (ERI)

The unloaded battery voltage determines whether a pulse generator should be replaced. Check the voltage at each follow-up visit. For a discussion of unloaded battery voltage, see the appropriate reference manual.

Immediately following a high-voltage charge, the battery voltage may be much lower than its normal value. A battery voltage measured within approximately four hours of a high-voltage charge should, therefore, not be used for elective replacement determination unless it is at or below the elective replacement indicator (ERI) value.

Normal Battery Condition

An unloaded battery voltage of more than ERI indicates that the device is not currently in need of replacement and that it will operate according to the specifications listed in this manual.

ERI to EOL Battery Condition

The pulse generator will continue to operate according to specifications in the range, except for a change in the pacing amplitude and high-voltage charge time.

Note the EOL measurement of the device. Careful monitoring of the battery voltage is strongly advised until the pulse generator can be replaced.

> WARNING
>
> **Replace the pulse generator within three months of reaching the ERI indication. (This assumes that regular follow-up visits occur every three months, thereby taking into account the possibility that the battery reached the ERI level sometime in the previous three months and still has approximately three months remaining at this battery level.) Replace the pulse generator immediately upon reaching ERI if there is frequent high-voltage charging and/or one or more of the pacing outputs are programmed above 2.5 V.**
>
> Note
>
> In Ellipse devices, the ATP While Charging parameter is disabled at ERI.

Past EOL Battery Condition

If the battery voltage is the EOL value or less, explant the pulse generator immediately or program it to all therapies off until it can be replaced. Below the EOL value, the pulse generator will continue to function, but some operating parameters will be out of specification. Pacing lead impedance may read higher than actual, and the 2.5 V pacing setting is no longer regulated. High-voltage charge times will be extended. If the capacitors take longer than 28 s to reach the programmed voltage, charging stops and the pulse generator delivers whatever voltage is present on the capacitors. When the battery voltage drops below EOL the pulse generator could oversense; therefore, some device functions are automatically disabled, including ATP, arrhythmia induction, and capture testing.

There is no guarantee that the pulse generator will deliver a high-voltage shock with a battery voltage of less than the Past EOL value.

Factors That Affect Device Longevity

Many factors affect the longevity of the pulse generator, such as frequency of high-voltage charging, increase in pacing output parameters such as enabling of the MultiPoint™ Pacing (MPP™) feature, decrease in pacing lead impedance, etc. In some cases, this may cause the period from ERI to EOL to decrease to less than three months. Battery status should be checked after parameter programming so that ERI can be detected well before EOL.

The longevity calculations in the following tables represent a device programmed with the Patient Notifier at nominal settings and with one notification sequence delivered at ERI. When a device is programmed with the Patient Notifier at nominal settings, each Patient Notifier sequence delivered depletes the battery by 0.1%. For example, with the Patient Notifier at nominal settings, the impact to device longevity for each notification sequence delivered is 4 days with no pacing, 3 days with 100% pacing in VVI pacing mode, 2 days with 100% pacing in DDD pacing mode, and <1 day with 100% pacing in DDD pacing mode with biventricular pacing and no atrial pacing.

When a device is programmed with the Patient Notifier at maximum settings, each Patient Notifier sequence delivered depletes the battery by 1%. For example, when the Patient Notifier is at maximum settings, the impact to device longevity for each notification sequence delivered is 1.2 months with no pacing, 1.0 months with 100% pacing in VVI pacing mode, 0.8 months with 100% pacing in

DDD pacing mode, and 0.5 months with 100% pacing in DDD pacing mode with biventricular pacing and no atrial pacing. For information on programming the Patient Notifier parameters, see Alert Notification (page 133).

Device Longevity Tables

The following tables list the projected device longevity.

- Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (page 323)
- Battery longevity for Promote Quadra 40 J devices (page 328)
- Battery longevity for Unify Quadra 40 J devices (page 331)
- Battery longevity for Unify 40 J devices (page 333)
- Battery longevity for Fortify Assura DR 40 J devices (page 335)
- Battery longevity for Fortify DR 40 J devices (page 335)
- Battery longevity for Fortify Assura VR 40 J devices (page 339)
- Battery longevity for Fortify VR 40 J devices (page 339)
- Battery longevity for Promote Q 36 J devices (page 341)
- Battery longevity for Promote, Promote+, Promote RF, Promote Accel 36 J devices (page 342)
- Battery longevity for Ellipse DR 36 J devices (page 343)
- Battery longevity for Ellipse VR 36 J devices (page 345)
- Battery longevity for Current DR, Current+ DR, Current DR RF, Current Accel DR 36 J devices (page 347)
- Battery longevity for Current VR, Current+ VR, Current VR RF, Current Accel VR 36 J devices (page 348)
- Battery longevity for Promote, Promote RF, Promote Accel 30 J devices (page 348)
- Battery longevity for Current DR, Current DR RF, Current Accel DR 30 J devices (page 347)
- Battery longevity for Current VR, Current VR RF, Current Accel VR 30 J devices (page 350)

Battery Longevity for Quadra Assura™, Quadra Assura MP™, and Unify Assura™ 40 J Devices

Table 213. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[395]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.8 yr	10.1 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.2 mo	18.5 mo	17.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.2 yr	9.5 yr	8.3 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.5 mo	16.4 mo	14.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	9.9 yr	8.9 yr	7.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.0 mo	15.4 mo	13.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP OFF, RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	9.2 yr	7.9 yr	6.1 yr	None
2.59-2.54	ERI to EOL	18.9 mo	15.9 mo	13.7 mo	10.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.2 yr	10.7 yr	None

[395] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.

Table 213. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[395]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.1 mo	18.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.5 yr	10.1 yr	9.2 yr	None
2.59-2.54	ERI to EOL	18.9 mo	18.0 mo	17.3 mo	15.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.3 yr	9.6 yr	8.5 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.6 mo	16.6 mo	14.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP OFF, RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	9.9 yr	8.9 yr	7.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.0 mo	15.4 mo	13.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.8 yr	9.0 yr	7.6 yr	5.9 yr	None
2.59-2.54	ERI to EOL	18.5 mo	15.5 mo	13.4 mo	10.5mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	9.5 yr	8.4 yr	6.9 yr	None
2.59-2.54	ERI to EOL	18.5 mo	16.3 mo	14.7 mo	12.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.8 yr	6.9 yr	5.0 yr	3.3 yr	None
2.59-2.54	ERI to EOL	18.5 mo	12.1 mo	9.0 mo	5.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	7.8 yr	6.1 yr	4.2 yr	None
2.59-2.54	ERI to EOL	18.5 mo	13.6 mo	10.8 mo	7.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.1 yr	5.7 yr	4.0 yr	2.5 yr	None
2.59-2.54	ERI to EOL	17.3 mo	10.1 mo	7.2 mo	4.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 500 Ω						

Table 213. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[395]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
3.20-2.59	Normal	10.1 yr	6.6 yr	5.0 yr	3.3 yr	None
2.59-2.54	ERI to EOL	17.3 mo	11.7 mo	8.8 mo	5.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	9.3 yr	8.0 yr	6.2 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.2 mo	5.0 mo	4.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	9.9 yr	8.9 yr	7.5 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.3 mo	5.2 mo	4.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP ON, RA/RV/LV1/LV2 2.5 V, 0.5 ms, 60 bpm, 500 Ω[396]						
3.20-2.59	Normal	10.5 yr	9.1 yr	8.0 yr	6.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.0 mo	15.4 mo	13.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP ON, RA/RV/LV1/LV2 2.5 V, 0.5 ms, 60 bpm, 900 Ω[397]						
3.20-2.59	Normal	10.5 yr	9.6 yr	8.8 yr	7.5 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.6 mo	16.6 mo	14.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP ON, RV 2.5 V, LV1/LV2 5.0 V, 0.5 ms, 60 bpm, 500 Ω[398]						
3.20-2.59	Normal	10.5 yr	7.8 yr	6.2 yr	4.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	15.9 mo	13.7 mo	10.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP ON, RV 2.5 V, LV1/LV2 5.0 V, 0.5 ms, 60 bpm, 900 Ω[399]						
3.20-2.59	Normal	10.5 yr	8.6 yr	7.3 yr	5.6 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.0 mo	15.4 mo	13.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[400]						
3.20-2.59	Normal	11.1 yr	9.9 yr	9.1 yr	7.8 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.0 mo	15.7 mo	13.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[401]						

[396] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[397] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[398] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[399] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[400] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.

Table 213. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[395]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
3.20-2.59	Normal	11.1 yr	10.3 yr	9.8 yr	8.8 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.7 mo	16.9 mo	15.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Table 214. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[402]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.9 yr	10.3 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.3 mo	18.7 mo	17.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.3 yr	9.7 yr	8.6 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.7 mo	16.6 mo	14.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.0 yr	9.1 yr	7.7 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.2 mo	15.7 mo	13.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP OFF, RV 2.5 V, LV 5.0 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	9.4 yr	8.1 yr	6.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	16.2 mo	14.2 mo	11.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.3 yr	10.8 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.2 mo	18.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	18.1 mo	17.5 mo	16.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.4 yr	9.8 yr	8.8 yr	None

[401] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[402] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.

Table 214. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[402]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	18.9 mo	17.8 mo	16.9 mo	15.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP OFF, RV 2.5 V, LV 5.0 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.0 yr	9.1 yr	7.7 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.1 mo	15.7 mo	13.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.4 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.8 yr	9.1 yr	7.9 yr	6.2 yr	None
2.59-2.54	ERI to EOL	18.5 mo	15.8 mo	13.8 mo	11.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.4 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	9.6 yr	8.7 yr	7.2 yr	None
2.59-2.54	ERI to EOL	18.5 mo	16.6 mo	15.0 mo	12.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.4 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.8 yr	7.2 yr	5.3 yr	3.6 yr	None
2.59-2.54	ERI to EOL	18.5 mo	12.6 mo	9.5 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.4 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	8.0 yr	6.4 yr	4.6 yr	None
2.59-2.54	ERI to EOL	18.5 mo	14.0 mo	11.3 mo	8.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.4 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.1 yr	6.0 yr	4.3 yr	2.7 yr	None
2.59-2.54	ERI to EOL	17.3 mo	10.6 mo	7.7 mo	4.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.4 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.1 yr	6.9 yr	5.3 yr	3.6 yr	None
2.59-2.54	ERI to EOL	17.3 mo	12.2 mo	9.4 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.4 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	9.4 yr	8.2 yr	6.5 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.3 mo	5.0 mo	4.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.4 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						

Table 214. Battery longevity for Quadra Assura, Quadra Assura MP, Unify Assura 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[402]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
3.20-2.59	Normal	11.1 yr	10.0 yr	9.2 yr	7.8 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.3 mo	5.2 mo	4.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP ON, RA/RV/LV1/LV2 2.5 V, 0.4 ms, 60 bpm, 500 Ω[403]						
3.20-2.59	Normal	10.5 yr	9.2 yr	8.2 yr	6.7 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.2 mo	15.7 mo	13.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP ON, RA/RV/LV1/LV2 2.5 V, 0.4 ms, 60 bpm, 900 Ω[404]						
3.20-2.59	Normal	10.5 yr	9.6 yr	8.9 yr	7.7 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.8 mo	16.8 mo	15.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP ON, RV 2.5 V, LV1/LV2 5.0 V, 0.4 ms, 60 bpm, 500 Ω[405]						
3.20-2.59	Normal	10.5 yr	8.0 yr	6.5 yr	4.7 yr	None
2.59-2.54	ERI to EOL	18.9 mo	16.2 mo	14.2 mo	11.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), MPP ON, RV 2.5 V, LV1/LV2 5.0 V, 0.4 ms, 60 bpm, 900 Ω[406]						
3.20-2.59	Normal	10.5 yr	8.8 yr	7.6 yr	6.0 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.2 mo	15.7 mo	13.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.4 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[407]						
3.20-2.59	Normal	11.1 yr	10.0 yr	9.3 yr	8.1 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.2 mo	16.0 mo	14.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, MPP OFF, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.4 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[408]						
3.20-2.59	Normal	11.1 yr	10.4 yr	9.9 yr	9.1 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.8 mo	17.1 mo	15.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Promote Quadra™ 40 J Devices

Table 215. Battery longevity for Promote Quadra 40 J devices

Battery	Battery	Approximate Duration[409]	Recommended

[403] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[404] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[405] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[406] MultiPoint™ Pacing enabled, devices with MultiPoint™ Pacing Capability only.
[407] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[408] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.

Voltage Range	Condition	No pacing	25% pacing	50% pacing	100% pacing	Action
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	12.6 yr	12.2 yr	11.8 yr	11.0 yr	None
2.59-2.54	ERI to EOL	24.0 mo	23.3 mo	22.5 mo	21.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.5 yr	10.7 yr	10.1 yr	9.0 yr	None
2.59-2.54	ERI to EOL	22.0 mo	20.7 mo	19.5 mo	17.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.5 yr	10.4 yr	9.4 yr	8.0 yr	None
2.59-2.54	ERI to EOL	22.0 mo	20.0 mo	18.3 mo	15.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.5 yr	9.7 yr	8.4 yr	6.6 yr	None
2.59-2.54	ERI to EOL	22.0 mo	18.8 mo	16.4 mo	13.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	12.6 yr	12.4 yr	12.1 yr	11.7 yr	None
2.59-2.54	ERI to EOL	24.0 mo	23.6 mo	23.2 mo	22.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.5 yr	11.1 yr	10.6 yr	9.9 yr	None
2.59-2.54	ERI to EOL	22.0 mo	21.2 mo	20.5 mo	19.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.5 yr	10.8 yr	10.2 yr	9.2 yr	None
2.59-2.54	ERI to EOL	22.0 mo	20.8 mo	19.7 mo	17.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.5 yr	10.4 yr	9.4 yr	8.0 yr	None
2.59-2.54	ERI to EOL	22.0 mo	20.0 mo	18.3 mo	15.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	11.1 yr	9.3 yr	8.1 yr	6.4 yr	None
2.59-2.54	ERI to EOL	21.3 mo	18.1 mo	15.8 mo	12.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 500 Ω						

[409] Longevity is calculated based on three charges per year and eighteen months from the date of manufacture.

Table 215. Battery longevity for Promote Quadra 40 J devices

Battery	Battery	Approximate Duration[409]				Recommended
3.20-2.59	Normal	11.1 yr	9.9 yr	8.9 yr	7.4 yr	None
2.59-2.54	ERI to EOL	21.3 mo	19.1 mo	17.3 mo	14.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	11.1 yr	7.2 yr	5.4 yr	3.6 yr	None
2.59-2.54	ERI to EOL	21.3 mo	14.3 mo	10.7 mo	7.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	8.2 yr	6.5 yr	4.6 yr	None
2.59-2.54	ERI to EOL	21.3 mo	16.0 mo	12.8 mo	9.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.3 yr	6.1 yr	4.3 yr	2.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	12.0 mo	8.6 mo	5.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.3 yr	7.0 yr	5.3 yr	3.6 yr	None
2.59-2.54	ERI to EOL	20.0 mo	13.8 mo	10.6 mo	7.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.5 yr	9.8 yr	8.5 yr	6.7 yr	None
2.59-2.54	ERI to EOL	6.6 mo	6.3 mo	6.0 mo	5.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.5 yr	10.4 yr	9.5 yr	8.1 yr	None
2.59-2.54	ERI to EOL	6.6 mo	6.4 mo	6.2 mo	5.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[410]						
3.20-2.59	Normal	11.5 yr	10.4 yr	9.7 yr	8.5 yr	None
2.59-2.54	ERI to EOL	22.0 mo	20.1 mo	18.7 mo	16.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[411]						
3.20-2.59	Normal	11.5 yr	10.8 yr	10.4 yr	9.5 yr	None

[410] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[411] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.

Table 215. Battery longevity for Promote Quadra 40 J devices

Battery	Battery	Approximate Duration[409]				Recommended
2.59-2.54	ERI to EOL	22.0 mo	20.9 mo	20.0 mo	18.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Unify Quadra™ 40 J Devices

Table 216. Battery longevity for Unify Quadra 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[412]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.9 yr	10.4 yr	9.9 yr	9.1 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.3 mo	19.5 mo	18.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.2 yr	9.4 yr	8.7 yr	7.6 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.5 mo	17.2 mo	15.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.2 yr	9.0 yr	8.1 yr	6.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.2 mo	13.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.2 yr	8.4 yr	7.2 yr	5.5 yr	None
2.59-2.54	ERI to EOL	20.0 mo	16.8 mo	14.4 mo	11.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.9 yr	10.5 yr	10.2 yr	9.7 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.6 mo	20.1 mo	19.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.2 yr	9.7 yr	9.2 yr	8.4 yr	None
2.59-2.54	ERI to EOL	20.0 mo	19.1 mo	18.2 mo	16.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.2 yr	9.4 yr	8.8 yr	7.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.6 mo	17.4 mo	15.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[412] Shelf life duration is 18 months. Three maximum charges per year.

Table 216. Battery longevity for Unify Quadra 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[412]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.2 yr	9.0 yr	8.1 yr	6.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.1 mo	13.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.0 yr	8.2 yr	7.0 yr	5.4 yr	None
2.59-2.54	ERI to EOL	19.5 mo	16.3 mo	14.0 mo	10.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.0 yr	8.7 yr	7.7 yr	6.3 yr	None
2.59-2.54	ERI to EOL	19.5 mo	17.2 mo	15.4 mo	12.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	10.0 yr	6.3 yr	4.6 yr	3.0 yr	None
2.59-2.54	ERI to EOL	19.5 mo	12.7 mo	9.4 mo	6.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	10.0 yr	7.1 yr	5.5 yr	3.8 yr	None
2.59-2.54	ERI to EOL	19.5 mo	14.3 mo	11.3 mo	7.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	9.3 yr	5.2 yr	3.6 yr	2.3 yr	None
2.59-2.54	ERI to EOL	18.3mo	10.6 mo	7.5 mo	4.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	9.3 yr	6.1 yr	4.5 yr	3.0 yr	None
2.59-2.54	ERI to EOL	18.3mo	12.3 mo	9.2 mo	6.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.2 yr	8.5 yr	7.3 yr	5.6 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.5 mo	5.2 mo	4.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.2 yr	9.1 yr	8.2 yr	6.8 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.6 mo	5.4 mo	5.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V

Table 216. Battery longevity for Unify Quadra 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[412]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.54-2.40	past EOL	N/A	N/A	N/A		Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[413]						
3.20-2.59	Normal	10.2 yr	9.1 yr	8.3 yr	7.1 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.6 mo	14.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[414]						
3.20-2.59	Normal	10.2 yr	9.5 yr	8.9 yr	8.0 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.7 mo	17.7 mo	16.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Unify™ 40 J Devices

Table 217. Battery longevity for Unify 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[415]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	10.3 yr	9.9 yr	9.1 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.3 mo	19.5 mo	18.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.1 yr	9.3 yr	8.6 yr	7.5 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.5 mo	17.2 mo	15.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.1 yr	9.0 yr	8.1 yr	6.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.2 mo	13.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.1 yr	8.4 yr	7.1 yr	5.5 yr	None
2.59-2.54	ERI to EOL	20.0 mo	16.8 mo	14.4 mo	11.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.8 yr	10.5 yr	10.2 yr	9.6 yr	None

[413] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[414] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[415] Longevity is calculated based on three charges per year and eighteen months from the date of manufacture.

Table 217. Battery longevity for Unify 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[415]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	21.2 mo	20.6 mo	20.1 mo	19.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.1 yr	9.6 yr	9.1 yr	8.3 yr	None
2.59-2.54	ERI to EOL	20.0 mo	19.0 mo	18.2 mo	16.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.1 yr	9.4 yr	8.7 yr	7.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.7 mo	17.4 mo	15.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.1 yr	9.0 yr	8.0 yr	6.7 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.1 mo	13.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	9.9 yr	8.1 yr	6.9 yr	5.3 yr	None
2.59-2.54	ERI to EOL	19.5 mo	16.3 mo	14.0 mo	10.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	9.9 yr	8.6 yr	7.7 yr	6.3 yr	None
2.59-2.54	ERI to EOL	19.5 mo	17.2 mo	15.4 mo	12.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	9.9 yr	6.2 yr	4.6 yr	3.0 yr	None
2.59-2.54	ERI to EOL	19.5 mo	12.7 mo	9.4 mo	6.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 3.5 V, LV 3.5 V, A 3.5 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	9.9 yr	7.1 yr	5.5 yr	3.8 yr	None
2.59-2.54	ERI to EOL	19.5 mo	14.3 mo	11.3 mo	7.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 300 Ω						
3.20-2.59	Normal	9.2 yr	5.2 yr	3.6 yr	2.2 yr	None
2.59-2.54	ERI to EOL	18.3mo	10.6 mo	7.5 mo	4.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 5.0 V, LV 5.0 V, A 5.0 V, 0.5 ms, 70 bpm, 500 Ω						
3.20-2.59	Normal	9.2 yr	6.0 yr	4.5 yr	3.0 yr	None

Table 217. Battery longevity for Unify 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[415]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	18.3mo	12.3 mo	9.2 mo	6.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.1 yr	8.4 yr	7.2 yr	5.6 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.5 mo	5.2 mo	4.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 3.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.1 yr	9.0 yr	8.1 yr	6.8 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.6 mo	5.4 mo	5.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[416]						
3.20-2.59	Normal	10.1 yr	9.0 yr	8.3 yr	7.1 yr	None
2.59-2.54	ERI to EOL	20.0 mo	17.9 mo	16.6 mo	14.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[417]						
3.20-2.59	Normal	10.1 yr	9.4 yr	8.9 yr	8.0 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.7 mo	17.7 mo	16.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Fortify Assura™ DR 40 J Devices

Table 218. Battery longevity for Fortify Assura DR 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[418]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.8 yr	10.1 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.2 mo	18.5 mo	17.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.2 yr	9.5 yr	8.3 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.5 mo	16.4 mo	14.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[416] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[417] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[418] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.

Table 218. Battery longevity for Fortify Assura DR 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[418]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.2 yr	10.7 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.1 mo	18.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.5 yr	10.1 yr	9.2 yr	None
2.59-2.54	ERI to EOL	18.9 mo	18.0 mo	17.3 mo	15.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.2 yr	9.5 yr	8.3 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.4 mo	5.3 mo	5.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.5 yr	10.1 yr	9.2 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.4 mo	5.4 mo	5.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[419]						
3.20-2.59	Normal	10.8 yr	10.1 yr	9.6 yr	8.7 yr	None
2.59-2.54	ERI to EOL	18.4 mo	17.3 mo	16.5 mo	15.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[420]						
3.20-2.59	Normal	10.8 yr	10.3 yr	10.0 yr	9.3 yr	None
2.59-2.54	ERI to EOL	18.4 mo	17.7 mo	17.1 mo	16.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Table 219. Battery longevity for Fortify Assura DR 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[421]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.9 yr	10.3 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.3 mo	18.7 mo	17.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						

[419] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[420] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[421] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.

Table 219. Battery longevity for Fortify Assura DR 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[421]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
3.20-2.59	Normal	11.1 yr	10.3 yr	9.7 yr	8.6 yr	None
2.59-2.54	ERI to EOL	18.9 mo	17.7 mo	16.6 mo	14.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.3 yr	10.8 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.2 mo	18.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.4 yr	None
2.59-2.54	ERI to EOL	18.9 mo	18.1 mo	17.5 mo	16.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.3 yr	9.7 yr	8.6 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.4 mo	5.3 mo	5.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.4 yr	None
2.59-2.54	ERI to EOL	5.5 mo	5.4 mo	5.4 mo	5.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.4 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[422]						
3.20-2.59	Normal	10.8 yr	10.1 yr	9.7 yr	8.9 yr	None
2.59-2.54	ERI to EOL	18.4 mo	17.4 mo	16.7 mo	15.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.4 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[423]						
3.20-2.59	Normal	10.8 yr	10.3 yr	10.0 yr	9.4 yr	None
2.59-2.54	ERI to EOL	18.4 mo	17.7 mo	17.2 mo	16.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Fortify™ DR 40 J Devices

Table 220. Battery longevity for Fortify DR 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[424]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	10.3 yr	9.9 yr	9.1 yr	None

[422] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[423] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[424] Longevity is calculated based on three charges per year and eighteen months from the date of manufacture.

Table 220. Battery longevity for Fortify DR 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[424]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	21.2 mo	20.3 mo	19.5 mo	18.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.1 yr	9.3 yr	8.6 yr	7.5 yr	None
2.59-2.54	ERI to EOL	20.0 mo	18.5 mo	17.2 mo	15.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.8 yr	10.5 yr	10.2 yr	9.6 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.6 mo	20.1 mo	19.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.1 yr	9.6 yr	9.1 yr	8.3 yr	None
2.59-2.54	ERI to EOL	20.0 mo	19.0 mo	18.2 mo	16.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.1 yr	9.3 yr	8.6 yr	7.5 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.6 mo	5.5 mo	5.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.1 yr	9.6 yr	9.1 yr	8.3 yr	None
2.59-2.54	ERI to EOL	5.7 mo	5.7 mo	5.6 mo	5.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V AutoCapture On[425]						
3.20-2.59	Normal	9.8 yr	9.2 yr	8.7 yr	7.9 yr	None
2.59-2.54	ERI to EOL	19.5 mo	18.3 mo	17.4 mo	15.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[426]						
3.20-2.59	Normal	9.8 yr	9.4 yr	9.0 yr	8.4 yr	None
2.59-2.54	ERI to EOL	19.5 mo	18.7 mo	18.0 mo	16.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[425] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[426] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.

Battery Longevity for Fortify Assura™ VR 40 J Devices

Table 221. Battery longevity for Fortify Assura VR 40 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[427]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.8 yr	10.1 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.2 mo	18.5 mo	17.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.2 yr	10.7 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.1 mo	18.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.8 yr	10.1 yr	None
2.59-2.54	ERI to EOL	5.6 mo	5.5 mo	5.5 mo	5.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.2 yr	10.7 yr	None
2.59-2.54	ERI to EOL	5.6 mo	5.6 mo	5.5 mo	5.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 500 Ω, V. AutoCapture parameter On[428]						
3.20-2.59	Normal	11.4 yr	11.1 yr	10.8 yr	10.4 yr	None
2.59-2.54	ERI to EOL	19.4 mo	18.9 mo	18.5 mo	17.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 900 Ω, V. AutoCapture parameter On[429]						
3.20-2.59	Normal	11.4 yr	11.2 yr	11.0 yr	10.7 yr	None
2.59-2.54	ERI to EOL	19.4 mo	19.1 mo	18.8 mo	18.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Table 222. Battery longevity for Fortify Assura VR 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[430]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.9 yr	10.3 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.3 mo	18.7 mo	17.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V

[427] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.
[428] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[429] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[430] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 16 days for each additional month of shelf time.

Table 222. Battery longevity for Fortify Assura VR 40 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[430]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.3 yr	10.8 yr	None
2.59-2.54	ERI to EOL	19.9 mo	19.5 mo	19.2 mo	18.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.7 yr	11.3 yr	10.9 yr	10.3 yr	None
2.59-2.54	ERI to EOL	5.6 mo	5.5 mo	5.5 mo	5.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.7 yr	11.5 yr	11.3 yr	10.8 yr	None
2.59-2.54	ERI to EOL	5.6 mo	5.6 mo	5.5 mo	5.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.4 ms, 60 bpm, 500 Ω, V. AutoCapture parameter On[431]						
3.20-2.59	Normal	11.4 yr	11.1 yr	10.9 yr	10.5 yr	None
2.59-2.54	ERI to EOL	19.4 mo	19.0 mo	18.6 mo	18.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.4 ms, 60 bpm, 900 Ω, V. AutoCapture parameter On[432]						
3.20-2.59	Normal	11.4 yr	11.2 yr	11.0 yr	10.7 yr	None
2.59-2.54	ERI to EOL	19.4 mo	19.1 mo	18.8 mo	18.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Fortify™ VR 40 J Devices

Table 223. Battery longevity for Fortify VR 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[433]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.8 yr	10.3 yr	9.9 yr	9.1 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.3 mo	19.5 mo	18.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.8 yr	10.5 yr	10.2 yr	9.6 yr	None
2.59-2.54	ERI to EOL	21.2 mo	20.6 mo	20.1 mo	19.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[431] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[432] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[433] Longevity is calculated based on three charges per year and eighteen months from the date of manufacture.

Table 223. Battery longevity for Fortify VR 40 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[433]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.8 yr	10.3 yr	9.9 yr	9.1 yr	None
2.59-2.54	ERI to EOL	5.8 mo	5.7 mo	5.7 mo	5.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.8 yr	10.5 yr	10.2 yr	9.6 yr	None
2.59-2.54	ERI to EOL	5.8 mo	5.8 mo	5.7 mo	5.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, RV 1.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V AutoCapture On[434]						
3.20-2.59	Normal	10.5 yr	10.1 yr	9.9 yr	9.4 yr	None
2.59-2.54	ERI to EOL	20.6	20.0 mo	19.5 mo	18.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, RV 1.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[435]						
3.20-2.59	Normal	10.5 yr	10.2 yr	10.0 yr	9.6 yr	None
2.59-2.54	ERI to EOL	20.6 mo	20.1 mo	19.8 mo	19.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Promote™ Q 36 J Devices

Table 224. Battery longevity for Promote Q 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[436]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	7.8 yr	7.3 yr	6.8 yr	6.1 yr	None
2.59-2.54	ERI to EOL	9.8 mo	9.1 mo	8.5 mo	7.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	7.8 yr	7.0 yr	6.4 yr	5.5 yr	None
2.59-2.54	ERI to EOL	9.8 mo	8.8 mo	8.0 mo	6.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	7.8yr	7.0 yr	5.8 yr	4.6 yr	None
2.59-2.54	ERI to EOL	9.8 mo	8.3 mo	7.2 mo	5.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[434] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[435] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[436] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.

Table 224. Battery longevity for Promote Q 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[436]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	7.8 yr	7.5 yr	7.2 yr	6.6 yr	None
2.59-2.54	ERI to EOL	9.8 mo	9.4 mo	9.0 mo	8.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	7.8 yr	7.3 yr	6.9 yr	6.2 yr	None
2.59-2.54	ERI to EOL	9.8 mo	9.2 mo	8.6 mo	7.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	7.6 yr	6.9 yr	6.3 yr	5.3 yr	None
2.59-2.54	ERI to EOL	9.7 mo	8.6 mo	7.9 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[437]						
3.20-2.59	Normal	7.8 yr	7.1 yr	6.6 yr	5.8 yr	None
2.59-2.54	ERI to EOL	9.8 mo	8.9 mo	8.2 mo	7.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[438]						
3.20-2.59	Normal	7.8 yr	7.4 yr	7.0 yr	6.4 yr	None
2.59-2.54	ERI to EOL	9.8 mo	9.3 mo	8.8 mo	8.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Promote™, Promote™+, Promote™ RF, Promote Accel™ 36 J Devices

Table 225. Battery longevity for Promote, Promote+, Promote RF, Promote Accel 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[439]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	8.2 yr	7.5 yr	7.0 yr	6.1 yr	None
2.45-2.35	ERI to EOL	10.2 mo	9.3 mo	8.6 mo	7.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	8.2 yr	7.2 yr	6.5 yr	5.4 yr	None
2.45-2.35	ERI to EOL	10.2 mo	8.9 mo	8.0 mo	6.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V

[437] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[438] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[439] Shelf life duration is 18 months. Four maximum charges per year as well as monthly charging during the battery's mid-life voltage range.

Table 225. Battery longevity for Promote, Promote+, Promote RF, Promote Accel 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[439]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	8.2 yr	6.7 yr	5.7 yr	4.4 yr	None
2.45-2.35	ERI to EOL	10.2 mo	8.3 mo	7.0 mo	5.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	8.2 yr	7.7 yr	7.3 yr	6.6 yr	None
2.45-2.35	ERI to EOL	10.2 mo	9.6 mo	9.0 mo	8.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	8.2 yr	7.5 yr	7.0 yr	6.1 yr	None
2.45-2.35	ERI to EOL	10.2 mo	9.3 mo	8.6 mo	7.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	8.2 yr	7.2 yr	6.4 yr	5.3 yr	None
2.45-2.35	ERI to EOL	10.2 mo	8.9 mo	7.9 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[440]						
3.20-2.45	Normal	8.1 yr	7.4 yr	6.9 yr	5.9 yr	None
2.45-2.35	ERI to EOL	10.0 mo	9.2 mo	8.5 mo	7.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[441]						
3.20-2.45	Normal	8.1 yr	7.7 yr	7.3 yr	6.6 yr	None
2.45-2.35	ERI to EOL	10.0 mo	9.5 mo	9.0 mo	8.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Ellipse™ DR 36 J Devices

Table 226. Battery longevity for Ellipse DR 36 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[442]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.1 yr	9.4 yr	None

[440] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[441] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[442] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 18 days for each additional month of shelf time.

Table 226. Battery longevity for Ellipse DR 36 J devices (calculated at 0.5 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[442]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.8 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.4 yr	9.6 yr	8.9 yr	7.7 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.6 mo	6.4 mo	6.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	9.9 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.9 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.4 yr	9.9 yr	9.4 yr	8.6 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.7 mo	6.6 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.4 yr	9.6 yr	8.9 yr	7.7 yr	None
2.59-2.54	ERI to EOL	3.9 mo	3.9 mo	3.8 mo	3.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.4 yr	9.9 yr	9.4 yr	8.6 yr	None
2.59-2.54	ERI to EOL	3.9 mo	3.9 mo	3.9 mo	3.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[443]						
3.20-2.59	Normal	10.1 yr	9.4 yr	8.9 yr	8.1 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.6 mo	6.5 mo	6.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[444]						
3.20-2.59	Normal	10.1 yr	9.6 yr	9.3 yr	8.7 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.7 mo	6.6 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Table 227. Battery longevity for Ellipse DR 36 J devices (calculated at 0.4 ms Pulse Width)

Battery	Battery	Approximate Duration[445]	Recommended

[443] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[444] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[445] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 18 days for each additional month of shelf time.

Voltage Range	Condition	No pacing	25% pacing	50% pacing	100% pacing	Action
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.5 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.8 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	10.4 yr	9.6 yr	9.0 yr	8.0 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.7 mo	6.5 mo	6.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	10.1 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.9 mo	6.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	10.4 yr	9.9 yr	9.5 yr	8.8 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.7 mo	6.6 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.4 yr	9.6 yr	9.0 yr	8.0 yr	None
2.59-2.54	ERI to EOL	3.9 mo	3.9 mo	3.8 mo	3.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.4 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	10.4 yr	9.9 yr	9.5 yr	8.8 yr	None
2.59-2.54	ERI to EOL	3.9 mo	3.9 mo	3.9 mo	3.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.4 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[446]						
3.20-2.59	Normal	10.1 yr	9.5 yr	9.0 yr	8.3 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.6 mo	6.5 mo	6.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
***Pacing parameters*: DDD, RV 1.0 V, A 2.0 V, 0.4 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[447]**						
3.20-2.59	Normal	10.1 yr	9.7 yr	9.4 yr	8.8 yr	None
2.59-2.54	ERI to EOL	6.8 mo	6.7 mo	6.6 mo	6.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Ellipse™ VR 36 J Devices

Table 228. Battery longevity for Ellipse VR 36 J devices (calculated at 0.5 ms Pulse Width)

Battery	Battery	Approximate Duration[448]	Recommended

[446] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[447] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.

Voltage Range	Condition	No pacing	25% pacing	50% pacing	100% pacing	Action
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.1 yr	9.4 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.8 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	9.9 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.9 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.1 yr	9.4 yr	None
2.59-2.54	ERI to EOL	4.0 mo	4.0 mo	3.9 mo	3.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	9.9 yr	None
2.59-2.54	ERI to EOL	4.0 mo	4.0 mo	4.0 mo	3.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 500 Ω, V. AutoCapture parameter On[449]						
3.20-2.59	Normal	10.7 yr	10.4 yr	10.1 yr	9.7 yr	None
2.59-2.54	ERI to EOL	6.9 mo	6.8 mo	6.8 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 900 Ω, V. AutoCapture parameter On[450]						
3.20-2.59	Normal	10.7 yr	10.5 yr	10.3 yr	9.9 yr	None
2.59-2.54	ERI to EOL	6.9 mo	6.9 mo	6.8 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Table 229. Battery longevity for Ellipse VR 36 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[451]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.5 yr	None
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.8 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	10.1 yr	None

[448] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 18 days for each additional month of shelf time.
[449] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[450] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[451] Longevity is calculated based on six months from the date of manufacture, two hours of RF communication time at implant, standard device testing (four charges at implant), and recommended capacitor maintenance. Device longevity decreases by 18 days for each additional month of shelf time.

Table 229. Battery longevity for Ellipse VR 36 J devices (calculated at 0.4 ms Pulse Width)

Battery Voltage Range	Battery Condition	Approximate Duration[451]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.59-2.54	ERI to EOL	7.0 mo	6.9 mo	6.9 mo	6.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 500 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.6 yr	10.2 yr	9.5 yr	None
2.59-2.54	ERI to EOL	4.0 mo	4.0 mo	3.9 mo	3.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.4 ms, 60 bpm, 900 Ω, Two HV charges monthly after ERI						
3.20-2.59	Normal	11.1 yr	10.8 yr	10.5 yr	10.1 yr	None
2.59-2.54	ERI to EOL	4.0 mo	4.0 mo	4.0 mo	3.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.4 ms, 60 bpm, 500 Ω, V. AutoCapture parameter On[452]						
3.20-2.59	Normal	10.7 yr	10.4 yr	10.2 yr	9.7 yr	None
2.59-2.54	ERI to EOL	6.9 mo	6.9 mo	6.8 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.4 ms, 60 bpm, 900 Ω, V. AutoCapture parameter On[453]						
3.20-2.59	Normal	10.7 yr	10.5 yr	10.3 yr	10.0 yr	None
2.59-2.54	ERI to EOL	6.9 mo	6.9 mo	6.8 mo	6.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.54-2.40	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Current™ DR, Current™+ DR, Current™ DR RF, Current Accel™ DR 36 J Devices

Table 230. Battery longevity for Current DR, Current+ DR, Current DR RF, Current Accel DR 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[454]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	8.2 yr	7.5 yr	7.0 yr	6.1 yr	None
2.45-2.35	ERI to EOL	10.2 mo	9.3 mo	8.6 mo	7.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	8.2 yr	7.7 yr	7.3 yr	6.6 yr	None
2.45-2.35	ERI to EOL	10.2 mo	9.6 mo	9.0 mo	8.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[455]						
3.20-2.45	Normal	8.1 yr	7.7 yr	7.4 yr	6.8 yr	None

[452] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[453] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[454] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.
[455] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.

Table 230. Battery longevity for Current DR, Current+ DR, Current DR RF, Current Accel DR 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[454]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.45-2.35	ERI to EOL	10.0 mo	9.6 mo	9.1 mo	8.4 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[456]						
3.20-2.45	Normal	8.1 yr	7.8 yr	7.6 yr	7.2 yr	None
2.45-2.35	ERI to EOL	10.0 mo	9.7 mo	9.4 mo	8.9 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Current™ VR, Current™+ VR, Current™ VR RF, Current Accel VR 36 J Devices

Table 231. Battery longevity for Current VR, Current+ VR, Current VR RF, Current Accel VR 36 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[457]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	8.4 yr	8.0 yr	7.6 yr	7.0 yr	None
2.45-2.35	ERI to EOL	11.1 mo	10.5 mo	10.0 mo	9.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	8.4 yr	8.1 yr	7.8 yr	7.4 yr	None
2.45-2.35	ERI to EOL	11.1 mo	10.7 mo	10.3 mo	9.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 500 Ω, V. AutoCapture parameter On[458]						
3.20-2.45	Normal	8.3 yr	8.1 yr	7.9 yr	7.5 yr	None
2.45-2.35	ERI to EOL	10.9 mo	10.7 mo	10.4 mo	9.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 1.0 V, 0.5 ms, 60 bpm, 900 Ω, V. AutoCapture parameter On[459]						
3.20-2.45	Normal	8.3 yr	8.2 yr	8.0 yr	7.7 yr	None
2.45-2.35	ERI to EOL	10.9 mo	10.7 mo	10.5 mo	10.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Promote™, Promote™ RF, Promote Accel™ 30 J Devices

Table 232. Battery longevity for Promote, Promote RF, Promote Accel 30 J devices

Battery	Battery	Approximate Duration[460]	Recommended

[456] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[457] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.
[458] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[459] V. AutoCapture™ parameter is available in devices with V AutoCapture Capability only.
[460] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.

Voltage Range	Condition	No pacing	25% pacing	50% pacing	100% pacing	Action
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	6.5 yr	5.9 yr	5.4 yr	4.6 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.3 mo	6.6 mo	5.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	6.5 yr	5.7 yr	5.1 yr	4.2 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.1 mo	6.3 mo	5.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	6.5 yr	5.4 yr	4.6 yr	3.5 yr	None
2.45-2.35	ERI to EOL	8.2 mo	6.6 mo	5.5 mo	4.2 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	6.5 yr	6.1 yr	5.7 yr	5.0 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.5 mo	7.0 mo	6.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.5 V, LV 2.5 V, A 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	6.5 yr	6.0 yr	5.5 yr	4.7 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.4 mo	6.7 mo	5.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV (no atrial pacing), RV 2.5 V, LV 5.0 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	6.5 yr	5.7 yr	5.1 yr	4.2 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.1 mo	6.2 mo	5.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[461]						
3.20-2.45	Normal	5.9 yr	5.4 yr	5.0 yr	4.4 yr	None
2.45-2.35	ERI to EOL	7.9 mo	7.3 mo	6.7 mo	5.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD-BiV, RV 2.0 V, LV 2.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/RVCap Confirm/LVCap Confirm On[462]						
3.20-2.45	Normal	5.9 yr	5.6 yr	5.3 yr	4.8 yr	None
2.45-2.35	ERI to EOL	7.9 mo	7.5 mo	7.1 mo	6.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

[461] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.
[462] RVCap™ Confirm, LVCap™ Confirm, and ACap™ Confirm are available in models with ACap Confirm Capability and BiVCap™ Confirm Capability only.

Battery Longevity for Current™ DR, Current™ DR RF, and Current Accel™ DR 30 J Devices

Table 233. Battery longevity for Current DR, Current DR RF, Current Accel DR 30 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[463]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	6.5 yr	5.9 yr	5.4 yr	4.6 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.3 mo	6.6 mo	5.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	6.5 yr	6.1 yr	5.7 yr	5.0 yr	None
2.45-2.35	ERI to EOL	8.2 mo	7.5 mo	7.0 mo	6.1 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[464]						
3.20-2.45	Normal	5.9 yr	5.7 yr	5.4 yr	5.0 yr	None
2.45-2.35	ERI to EOL	7.9 mo	7.5 mo	7.2 mo	6.6 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[465]						
3.20-2.45	Normal	5.9 yr	5.8 yr	5.6 yr	5.3 yr	None
2.45-2.35	ERI to EOL	7.9 mo	7.7 mo	7.4 mo	7.0 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Battery Longevity for Current™ VR, Current™ VR RF, Current Accel™ VR 30 J Devices

Table 234. Battery longevity for Current VR, Current VR RF, Current Accel VR 30 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[466]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 500 Ω						
3.20-2.45	Normal	6.7 yr	6.4 yr	6.1 yr	5.6 yr	None
2.45-2.35	ERI to EOL	9.0 mo	8.5 mo	8.1 mo	7.3 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: VVI, 2.5 V, 0.5 ms, 60 bpm, 900 Ω						
3.20-2.45	Normal	6.7 yr	6.5 yr	6.3 yr	5.9 yr	None
2.45-2.35	ERI to EOL	9.0 mo	8.6 mo	8.4 mo	7.8 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 500 Ω, ACap Confirm/V. AutoCapture parameter On[467]						
3.20-2.45	Normal	6.5 yr	6.4 yr	6.2 yr	6.0 yr	None
2.45-2.35	ERI to EOL	9.3 mo	9.1 mo	8.9 mo	8.5 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V

[463] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.
[464] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[465] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.
[466] Longevity is calculated based on four charges per year and eighteen months from the date of manufacture.
[467] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.

Table 234. Battery longevity for Current VR, Current VR RF, Current Accel VR 30 J devices

Battery Voltage Range	Battery Condition	Approximate Duration[466]				Recommended Action
		No pacing	25% pacing	50% pacing	100% pacing	
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately
Pacing parameters: DDD, RV 1.0 V, A 2.0 V, 0.5 ms, 60 bpm, 900 Ω, ACap Confirm/V. AutoCapture parameter On[468]						
3.20-2.45	Normal	6.5 yr	6.4 yr	6.3 yr	6.1 yr	None
2.45-2.35	ERI to EOL	9.3 mo	9.2 mo	9.0 mo	8.7 mo	Replace within 3 mo, or immediately if frequently charging or pacing amplitude(s) > 2.5 V
2.35-2.25	past EOL	N/A	N/A	N/A	N/A	Replace immediately

Using a Magnet

The pulse generator contains a giant magneto resistor (GMR) that, when activated, prevents delivery of tachyarrhythmia therapy. Bradycardia pacing is not affected.

The GMR is activated in the presence of a strong magnetic field. A magnet placed over the pulse generator can, therefore, be used to prevent the delivery of therapy if a programmer is not available to turn the device off.

The pulse generator can be programmed to ignore the GMR. Therapies would then be delivered in the normal manner in response to detected arrhythmias. Magnet application would have no effect on operation.

The pulse generator does not emit an audible tone when a magnet is placed over it.

The effectiveness of magnets varies. If one magnet does not interrupt operation of the pulse generator, place a second magnet on top of the first or try a different magnet. Pressing firmly on the magnet to decrease the distance between the magnet and the pulse generator may also help.

CAUTION

The magnet is for temporary inhibition of tachyarrhythmia therapy. If inhibition is required for longer than eight hours, disable tachyarrhythmia therapy (Enable/Disable Tachy Therapy) or program tachyarrhythmia therapy Off.

CAUTION

The presence of both a magnet and the programming wand near the implanted device may interfere with telemetry and cause a loss of communication with the programmer. If you need to communicate with the device and use a magnet simultaneously (for example, to confirm proper magnet placement by telemetry), first position the magnet over the device and then place the wand over the device. If the magnet is brought close to the device while communication is already in progress, the programmer may, in rare cases, not detect the presence of the magnet and a device reset may occur.

If arrhythmia intervals were detected before the magnet was applied, detection is interrupted while the magnet is in place. Detection resumes when the magnet is removed.

Bradycardia pacing is not affected by magnet application.

Explanting the Pulse Generator

WARNING

Before explanting the system or disconnecting the leads from a pulse generator, disable Tachy Therapy or program the pulse generator to tachyarrhythmia therapy Off.

In the event of the patient's death, deactivate the pulse generator before post-mortem examination.

If a lead or adapter is explanted, be careful not to damage it during removal.

Before returning the explanted pulse generator to St. Jude Medical, clean it with disinfectant solution, but do not submerge it. Fluid in the lead receptacles of the pulse generator or adapter impedes analysis of the product.

WARNING

Pulse generators contain sealed chemical power cells and capacitors and therefore should never be incinerated.

[468] ACap™ Confirm and V. AutoCapture™ parameters are available in devices with ACap Confirm Capability and V AutoCapture Capability only.

Out-of-Service/Explant/Patient Death Form

Whenever a pulse generator is explanted, or if any of the leads or adapters are replaced or capped, complete an Out-of-Service/Explant/Patient Death form and return it to St. Jude Medical with the explanted products. If possible, send along a printout of the programmed settings of the pulse generator. For information on printing reports, see the appropriate reference manual.

Clinical Studies

Contents:

- Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study) (page 353)
- Performance of Chamber Onset and Far Field Morphology SVT Discriminators (page 365)
- Detect Fluid Early from IntrA-thoracic Impedance MoniToring (DEFEAT-PE STUDY) (page 368)
- Promote™ Q CRT-D and Quartet™ Left Ventricular Heart Lead Study (page 372)
- DecisionTx™ Programming (page 387)
- Acute IEGM Studies (page 388)
- ADOPT-A Study (page 391)
- AF Suppression™/CRT-D Study (page 394)
- Automaticity Clinical Investigation (page 399)
- DEFINITE Trial (page 402)
- Frontier II: Summary of Clinical Investigations (page 406)
- PAVE Study (page 411)
- RHYTHM ICD Study (page 414)
- RHYTHM ICD Study: V-V Optimization Phase (page 421)
- Zephyr IDE Clinical Trial (page 423)
- MultiPoint™ Pacing IDE Study (page 425)

Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study)

Summary of Clinical Study

The Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study) was conducted under an IDE (investigational device exemption).

The purpose of the MRI study was to assess the safety and efficacy of the Accent MRI pacemaker system in a patient population indicated for implant of a pacemaker within and outside of the MRI environment.

The Accent MRI pacemaker was not pursued for approval but instead the next generation version Assurity MRI and Endurity MRI pacemakers were approved. The Assurity MRI™ and the Endurity MRI™ pacemakers utilize a MRI filter and MRI settings which are identical to the MRI filter and parameter set incorporated in the Accent MRI pacemakers. In addition, all other device components which could have an impact on compatibility with the magnetic resonance environment are unchanged from the Accent MRI pacemaker; therefore all Accent MRI endpoint data collected during the study that provided reasonable assurance of safety and effectiveness within and outside of an MRI environment is applicable to the Assurity MRI and Endurity MRI devices.

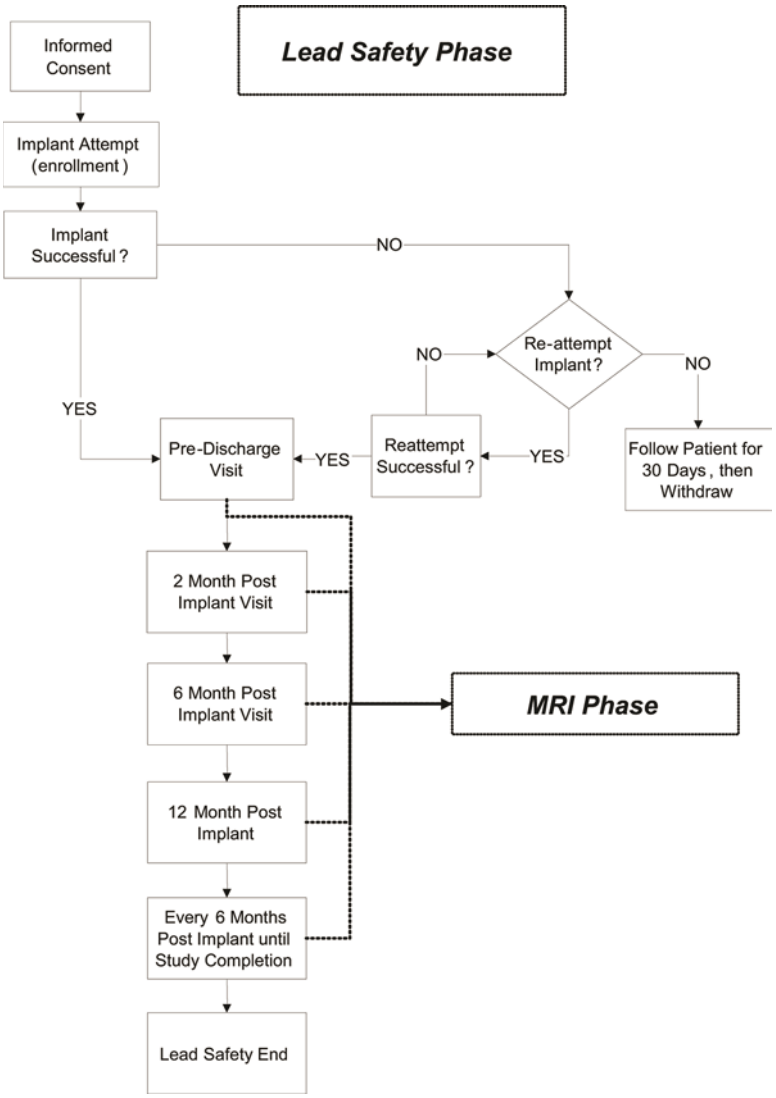
Study Design

The MRI study was a prospective multi-center clinical investigation, consisting of a Lead Safety Phase and an MRI Phase, designed to evaluate the safety and efficacy of the Accent MRI™ pacemaker system indicated for implant of a pacemaker within and outside of the MRI environment. The products being evaluated were the Accent MRI pacemaker, Tendril™ MRI lead and the SJM MRI Activator™ handheld device.

The Lead Safety Phase assessed the safety of the Tendril MRI lead and safety of the Accent MRI pacemaker system; the MRI Phase assessed the safety and efficacy of the Tendril MRI lead and the Accent MRI pacemaker system in an MRI environment.

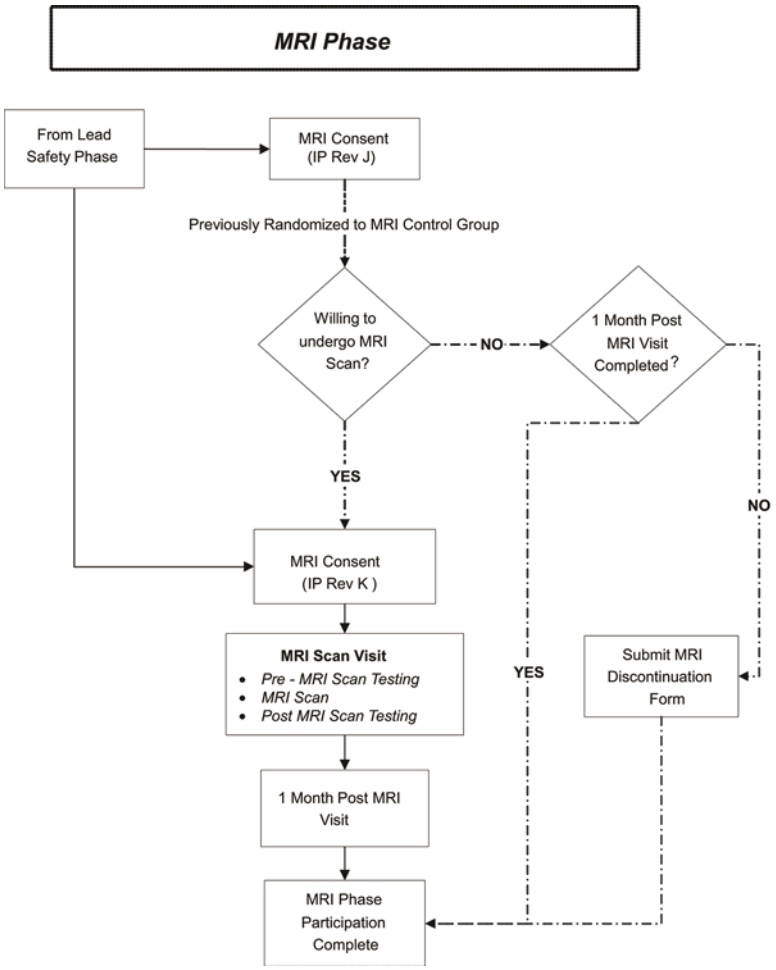
The figure below depicts the Lead Safety Phase of the MRI Study.

Figure 28. Lead Safety Phase



The figure below depicts the MRI Phase.

Figure 29. MRI Phase



Study Objectives

The objective of this clinical study was to verify the safety and efficacy of the Accent MRI™ pacemaker system indicated for implant of a pacemaker within and outside of the MRI environment.

Primary Objectives

The following are the primary safety and efficacy objectives defined for this study.

Lead Safety

Safety of the Tendril MRI™ lead was evaluated in terms of freedom from RA and RV lead-related complications for the acute (implant to two-month visit) and chronic (two-month visit through the 12 month visit) time frames.

MRI Safety

The safety of the Accent MRI system was evaluated in terms of freedom from MRI scan-related complications in the month following the MRI scan.

Lead Efficacy

Efficacy of the Tendril MRI™ lead in was evaluated in terms of the change in bipolar atrial and ventricular capture and sensing thresholds before and after the MRI scan.

Secondary Objectives

The secondary objectives are listed below.

Safety

Safety of the Accent MRI™ system was evaluated in terms of freedom from system-related complications through the 12 month visit.

Efficacy

Efficacy of the Tendril MRI™ lead was evaluated in terms of the bipolar atrial and ventricular capture thresholds at the MRI Visit.

Patient Selection Criteria

Inclusion Criteria

Eligible patients met all of the following:

1. Had an approved indication per ACC/AHA/HRS guidelines for implantation of a pacemaker.
2. Received a new pacemaker and lead.
3. Was willing to undergo an elective MRI scan without sedation.
4. Was able to provide informed consent for study participation (legal guardian is NOT acceptable).
5. Was willing and able to comply with the prescribed follow-up tests and schedule of evaluations.
6. Was not contraindicated for an MRI scan (per the pre-MRI safety screening form)[469].

Exclusion Criteria

Patients were excluded if they met any of the following:

1. Had an existing pacemaker or ICD. A new pacemaker and lead is required for enrollment.
2. Had an existing active implanted medical device, e.g., neurostimulator, infusion pump, etc.[470]
3. Had a non-MRI compatible device or material implanted (e.g., intracranial aneurysm clip, non-MRI compatible devices or material, metals or alloys, etc.).[471]
4. Had a lead extender or adaptor.
5. Was unable to fit in MRI bore; will come into contact with the magnet façade inside the MRI bore.
6. Had a prosthetic tricuspid heart valve.
7. Was currently participating in a clinical investigation that includes an active treatment arm.
8. Was allergic to dexamethasone sodium phosphate (DSP).
9. Was pregnant or planning to become pregnant during the duration of the study.
10. Had a life expectancy of less than 12 months due to any condition.
11. Had exclusion criteria required by local law (e.g., age).
12. Were unable to comply with the follow-up schedule.

Clinical Study Results

Patient Population

As of October 30, 2014, 920 patients were enrolled at 68 clinical sites in the Lead Safety Phase of the MRI Study. The first Accent MRI™ PM2218 pacemaker and Tendril MRI ™ LPA1200M leads were implanted on March 30, 2012.

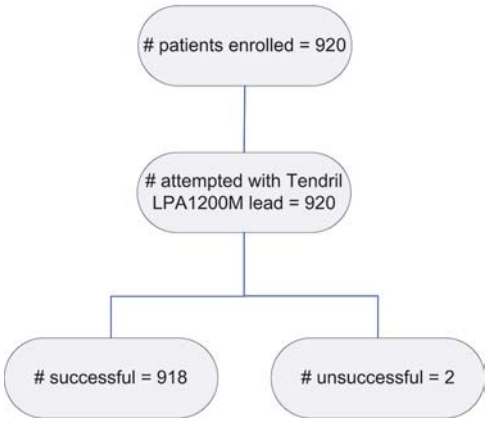
Of the 920 patients enrolled in the MRI Study, 918 were successfully implanted with an Accent MRI pacemaker system. Two implants were unsuccessful due to an inability to implant the Tendri MRI lead due to difficulty in obtaining access in one patient and a persistent left SVC in the other patient. Both patients received a market-released pacemaker system, followed for 30 days for safety after the study implant attempt, and then were withdrawn from the study per protocol.

Two hundred twenty-five (225) patients were enrolled in the MRI Phase of the MRI Study in the United States. An additional 30 supplemental scans were performed in Australia, for a total of 255 patients who contributed data to the MRI Phase. The first MRI scan was performed on April 2, 2014.

The figure below displays the number of successful and unsuccessful implants in the MRI Study.

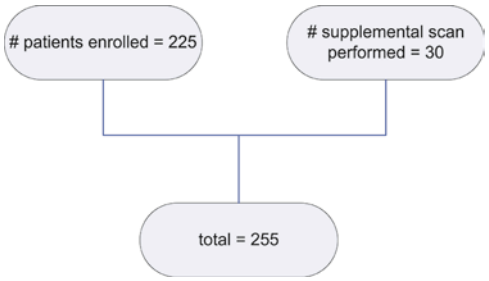
[469] Applies only to those patients who will participate in the MRI Phase of the study
[470] Applies only to those patients who will participate in the MRI Phase of the study
[471] Applies only to those patients who will participate in the MRI Phase of the study

Figure 30. Number of patients attempted and implanted with the Accent MRI pacemaker and Tendril MRI lead



The figure below displays the number of patients who contributed data to the MRI phase.

Figure 31. Number of patients participating in MRI phase/contributing scan data



As of October 30, 2014, the total time of follow-up from the time of successful implant was 18,425 patient-months. The average time of follow-up was 20.00 ± 4.66 (range 0.09 to 30.68) patient-months.

Demographic Data

As part of the Lead Safety Phase of the MRI Study, patients who were successfully implanted with the Accent MRI™ pacemaker system were seen at a pre-discharge visit during which the following tests/assessments were performed: electrical measurements on the RA and/or RV leads and identification of the radiopaque markers on the lead and pacemaker. Patients were again seen at two months post-implant, six months post-implant, 12 months post-implant, and every six months thereafter, during which the following tests/assessments were performed: electrical measurements on the RA and/or RV leads. Patients were also assessed for adverse events at all study visits.

For the MRI Phase of the study, patients completed an MRI Visit, and returned approximately thirty days later for a one-month post-MRI visit. At the MRI visit, for patients consenting to undergo an MRI scan, the following tests/assessments were performed: safety screening for the MRI scan, the study MRI scan, assessment for adverse events, including MRI scan-related adverse events, and electrical measurements on the RA and/or RV leads. At the one-month post-MRI visit, the following tests/assessments were performed: assessment for adverse events, including MRI scan-related adverse events, and electrical measurements on the RA and/or RV leads

The table below summarizes all the reported data on the 920 patients who completed the implant visit.

Table 235. Summary of demographic variables for all enrolled patients

Demographic Variable	All Enrolled Patients (N = 920)
Age	
Mean ± SD	73.0±10.8
Range (min, max)	(27,101)

Table 235. Summary of demographic variables for all enrolled patients

Demographic Variable	All Enrolled Patients (N = 920)
Gender, n (%)	
Female	421 (45.8%)
Male	499 (54.2%)
Cardiovascular History, n (%)	
Coronary Artery Disease	338 (36.7%)
Myocardial Infarction	119 (12.9%)
Unstable Angina	73 (7.9%)
Prior Cardiac Interventions, n (%)	
CABG	130 (14.1%)
PTCA/Stents/Atherectomy	152 (16.5%)
Ablation	100 (10.9%)
Non-Ventricular Arrhythmia History, n (%)	
None	370 (40.2%)
AF	481 (52.3%)
Paroxysmal	316 (65.7%)
Permanent	63 (13.1%)
Persistent	100 (20.8%)
AFL	123 (13.4%)
AT	41 (4.5%)
SVT	55 (6.0%)
Primary Indication for Device Implant, n (%)	
AV Block	244 (26.5%)
Pacemaker Generator Change	2 (0.2%)
Prevention/Termination of Tachyarrhythmias By Pacing	13 (1.4%)
Sinus Node Dysfunction	581 (63.2%)
Syncope	60 (6.5%)
Other	20 (2.2%)

The table below summarizes all the reported data on the 225 patients who were enrolled in the MRI Phase of the study, and the 30 patients who contributed supplemental MRI scan data.

Table 236. Summary of demographic variables for all patients contributing data to the MRI phase

Demographic Variable	Patients Enrolled in the MRI Study (N = 225)	Patients Contributing Supplemental MRI Scan Data (N = 30)	Total (N = 255)
Age			
Mean ± SD	69.8±11.6	73.0±5.9	70.2±11.1
Range (min, max)	(30.0,92.0)	(59.0,81.0)	(30.0,92.0)
Gender, n (%)			
Female	98 (43.6%)	16 (53.3%)	114 (44.7%)
Male	127 (56.4%)	14 (46.7%)	141 (55.3%)
Cardiovascular History, n (%)			
Coronary Artery Disease	26 (11.6%)	9 (30.0%)	35 (13.7%)
Myocardial Infarction	5 (2.2%)	0 (0.0%)	5 (2.0%)
Unstable Angina	6 (2.7%)	0 (0.0%)	6 (2.4%)
Prior Cardiac Interventions, n (%)			
CABG	1 (0.4%)	1 (3.3%)	2 (0.8%)
PTCA/Stents/Atherectomy	4 (1.8%)	4 (13.3%)	8 (3.1%)
Ablation	33 (14.7%)	5 (16.7%)	38 (14.9%)

Table 236. Summary of demographic variables for all patients contributing data to the MRI phase

Demographic Variable	Patients Enrolled in the MRI Study (N = 225)	Patients Contributing Supplemental MRI Scan Data (N = 30)	Total (N = 255)
Non-Ventricular Arrhythmia History, n (%)			
None	107 (47.6%)	4 (13.3%)	111 (43.5%)
AF	98 (43.6%)	20 (66.7%)	118 (46.3%)
Paroxysmal	62 (63.3%)	17 (85.0%)	79 (66.9%)
Permanent	15 (15.3%)	1 (5.0%)	16 (13.6%)
Persistent	21 (21.4%)	2 (10.0%)	23 (19.5%)
AFL	33 (14.7%)	6 (20.0%)	39 (15.3%)
AT	10 (4.4%)	6 (20.0%)	16 (6.3%)
SVT	10 (4.4%)	0 (0.0%)	10 (3.9%)
Primary Indication for Device Implant, n (%)			
AV Block	59 (26.2%)	6 (20.0%)	65 (25.5%)
Pacemaker Generator Change	1 (0.4%)	0 (0.0%)	1 (0.4%)
Prevention/Termination of Tachyarrhythmias By Pacing	5 (2.2%)	0 (0.0%)	5 (2.0%)
Sinus Node Dysfunction	141 (62.7%)	18 (60.0%)	159 (62.4%)
Syncope	15 (6.7%)	3 (10.0%)	18 (7.1%)
Other	4 (1.8%)	3 (10.0%)	7 (2.7%)

Primary Safety Endpoint Results

RA Lead-Related Complications (Implant through 2 month visit)

Eight hundred twenty-one (821) patients who had a Tendril MRI lead attempted or successfully implanted were analyzed for this endpoint. Twenty-three (23) RA lead-related complications were observed.

The probability of RA lead-related complication-free survival at the two-month follow-up visit was calculated as 97.20% with a 95% lower confidence bound of 95.81%, which is greater than the objective performance criterion of 92%.

RV Lead-Related Complications (Implant through 2 month visit)

Nine hundred nineteen (919) patients who had a Tendril MRI lead attempted or successfully implanted were analyzed for this endpoint. Ten RV lead-related complications were observed.

The probability of RV lead-related complication-free survival at the two-month follow-up visit was calculated as 98.45% with a 95% lower confidence bound of 96.81%, which is greater than the objective performance criterion of 92%.

RA Lead-Related Complications (2 month through 12 month visit)

Eight hundred and six (806) patients who had a Tendril MRI lead attempted or successfully implanted and who were not withdrawn before the two-month visit were analyzed for this endpoint. Six RA lead-related complications were observed.

The probability of RA lead-related complication-free survival at the 12-month follow-up visit was calculated as 98.82% with a 95% lower confidence bound of 97.04%, which is greater than the objective performance criterion of 95%.

RV Lead-Related Complications (2 month through 12 month visit)

Nine hundred two (902) patients who had a Tendril MRI lead attempted or successfully implanted and who were not withdrawn before the two-month visit were analyzed for this endpoint. No RV lead-related complications were observed.

The probability of RV lead-related complication-free survival at the 12-month follow-up visit was calculated as 100% with a 95% lower confidence bound of 100%, which is greater than the objective performance criterion of 95%.

MRI Scan-Related Complications

One hundred eight-one (181) patients who received a study scan were analyzed for this endpoint. No MRI scan-related complications were observed.

The proportion of patients free from MRI scan-related complications was calculated as 100% with a 95% lower confidence bound of 98.37%, which is greater than the objective performance criterion of 90%.

Primary Effectiveness Endpoints Results

MRI RA Lead Capture Threshold Efficacy

One hundred forty-four (144) patients who were implanted with an RA lead, received a study scan, and had capture threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a capture threshold increase of ≤0.5 V at 0.5 ms from before to the one-month post-MRI visit was calculated as 100% with a 95% lower confidence bound of 97.47%, which is greater than the objective performance criterion of 90%.

MRI RV Lead Capture Threshold Efficacy

One hundred sixty-seven (167) patients who were implanted with an RV lead, received a study scan, and had capture threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a capture threshold increase of ≤0.5 V at 0.5 ms from before to the one-month post-MRI visit was calculated as 100% with a 95% lower confidence bound of 97.82%, which is greater than the objective performance criterion of 90%.

MRI RA Lead Sensing Threshold Efficacy

One hundred twenty-one (121) patients who were implanted with an RA lead, received a study scan, and had sensing threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a sensing threshold decrease of ≤50% and atrial sensing amplitude at one-month post-MRI visit of ≥1.5 mV was calculated as 92.56% with a 95% lower confidence bound of 86.35%, which is greater than the objective performance criterion of 85%.

MRI RV Lead Sensing Threshold Efficacy

One hundred thirty-four (134) patients who were implanted with an RV lead, received a study scan, and had sensing threshold data pre- and one-month post-MRI scan were included in this analysis.

The proportion of patients who experienced a sensing threshold decrease of ≤50% and ventricular sensing amplitude at one-month post MRI visit of ≥5 mV was calculated as 97.76% with a 95% lower confidence bound of 93.60%, which is greater than the objective performance criterion of 87%.

Secondary Endpoint Results

System-Related Complications

Nine hundred twenty (920) patients who had an Accent MRI pacemaker system attempted or successfully implanted were analyzed for this endpoint. Forty-five (45) system-related complications (RA lead, RV lead, pacemaker- and system-related complications) were observed.

The probability of system-related, complication-free survival at the 12-month follow-up visit was calculated as 94.64% with a 95% lower confidence bound of 92.76%, which is greater than the objective performance criterion of 80%.

RA Lead Capture Threshold at the MRI Visit (pre-scan)

The proportion of patients who experienced a capture threshold of ≤2.0 V at 0.5 ms at the MRI visit (pre-scan) was calculated as 100% with a 95% lower confidence bound of 97.69%, which is greater than the objective performance criterion of 85%.

RV Lead Capture Threshold at the MRI Visit (pre-scan)

The proportion of patients who experienced a capture threshold of ≤2.0 V at 0.5 ms at the MRI visit (pre-scan) was calculated as 100% with a 95% lower confidence bound of 97.98%, which is greater than the objective performance criterion of 85%.

Additional Data

Patient Discontinuation/Withdrawals

A total of one hundred and five (105) patients participating in MRI Study were withdrawn from the study. Two (2) patients were withdrawn approximately one month after unsuccessful system implants in accordance with the protocol. Fifty-six (56) patients died and were also withdrawn from the study. In addition to these two unsuccessful implants and 56 deaths, 47 additional patients were withdrawn from the study. The table below summarizes the reason for all the patient withdrawals.

Table 237. Patient withdrawals, including deaths and unsuccessful implants

Reason for Withdrawal	# of Patients
Patient and/or Family Request	27
Patient Death	56
Patient Lost To Follow-Up	2
Patient Participation Terminated By Investigator	5
System Explanted Without A System Replacement	13
Unsuccessful Implant	2
Total	105

Conclusions Drawn from the Study

In patients indicated for implantation of a pacemaker, this study demonstrated that the Accent MRI™ pacemaker and Tendril MRI™ lead is effective and can be safely scanned in an MRI environment.

Adverse Events

The Reported Adverse Events (page 361) summarize the adverse events in the Accent MRI™ Pacemaker and Tendril MRI™ Lead Investigational Device Exemption Study (MRI Study). The MRI study was a prospective, multi-center clinical investigation designed to evaluate the safety and efficacy of the Accent MRI pacemaker system in a patient population indicated for implant of a pacemaker within and outside of an MRI environment.

Per the investigational plan, an adverse event was defined as any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a patient caused by or associated with a study device or intervention.

Adverse events were classified as complications or observations based on the following definitions:

- Complications are defined as adverse events that require invasive intervention (e.g. lead dislodgment requiring repositioning).
- Observations are defined as adverse events that can be managed without invasive intervention (e.g., oversensing or loss of pacing capture, which is remedied by reprogramming of the pacemaker).
- Other Reported Events are any other clinical event that is submitted by the investigator which is not caused by or associated with the study device and/or system component(s) and/or defined as an Adverse Event.

Reported Adverse Events

The table below lists the observations and complications reported from the MRI Study, see Summary Of Clinical Study (page 353). A total of 168 adverse events have been reported in 139 patients, of which 68 are complications and 100 are observations. None of the adverse events were related to or caused by the study MRI scans.

Table 238. MRI study adverse events

Event Description	# of Patients with AEs[472] (n=920)	% of Patients with AEs	#AEs	AE/pt-years (n=1,535.44 yrs)
Complications (total)	63	6.85%	68	0.044
Bleeding/Hematoma	2	0.22%	2	0.001
Cardiac Perforation	2	0.22%	2	0.001
Cardiac Tamponade	3	0.33%	3	0.002
Decompensated HF	1	0.11%	1	0.001
Device Connectivity Issue	1	0.11%	1	0.001
Device Migration	1	0.11%	1	0.001
Elevated Pacing Thresholds - RA Lead	2	0.22%	2	0.001
Elevated Pacing Thresholds - RV Lead	1	0.11%	1	0.001
Hemoptysis	1	0.11%	1	0.001
Hemothorax	1	0.11%	1	0.001
Infection	5	0.54%	5	0.003
Lead dislodgement or migration - RA Lead	24	2.61%	25	0.016
Lead dislodgement or migration - RV Lead	7	0.76%	7	0.005
Lead fracture	1	0.11%	1	0.001
Pacemaker Induced Cardiomyopathy	1	0.11%	1	0.001
Pericardial effusion	2	0.22%	2	0.001
Phrenic nerve/diaphragmatic stimulation	1	0.11%	1	0.001
Pneumothorax	4	0.43%	4	0.003
Pocket site/incision pain lasting greater than 72 hours post implant	2	0.22%	2	0.001
Stenosis of the left subclavian vein	1	0.11%	1	0.001
Thrombo-embolic event	1	0.11%	1	0.001
Twiddler's Syndrome	1	0.11%	1	0.001
Undersensing - RA Lead	1	0.11%	1	0.001
Wound dehiscence	1	0.11%	1	0.001
Observations (total)	**87**	**9.46%**	**100**	**0.065**
Atrial Arrhythmia	3	0.33%	3	0.002
Bleeding/Hematoma	9	0.98%	9	0.006

[472] Some patients experienced more than one event and therefore the number of patients is less than the number of events.

Table 238. MRI study adverse events

Event Description	# of Patients with AEs[472] (n=920)	% of Patients with AEs	#AEs	AE/pt-years (n=1,535.44 yrs)
Cellulitis/thrombophlebitis	1	0.11%	1	0.001
Cerebrovascular accident	1	0.11%	1	0.001
Decompensated HF	2	0.22%	2	0.001
Elevated pacing thresholds – RA Lead	3	0.33%	3	0.002
Elevated pacing thresholds – RV Lead	1	0.11%	1	0.001
Excessive rate responsive pacing	1	0.11%	1	0.001
Extracardiac stimulation	1	0.11%	1	0.001
Infection	4	0.43%	4	0.003
Lead dislodgement or migration - RA Lead	3	0.33%	3	0.002
Lead dislodgement or migration - RV Lead	1	0.11%	1	0.001
Loss of Capture - RA Lead	1	0.11%	1	0.001
Loss of Capture - RV Lead	1	0.11%	1	0.001
Mechanical abnormality of pacemaker pocket	1	0.11%	1	0.001
Noise reversion	2	0.22%	2	0.001
Oozing from implant site	1	0.11%	1	0.001
Oversensing - RA Lead	2	0.22%	2	0.001
Pacemaker mediated tachycardia (PMT)	20	2.17%	21	0.014
Pain at device site	1	0.11%	1	0.001
Pectoral stimulation	1	0.11%	1	0.001
Pericardial effusion	4	0.43%	4	0.003
Pericarditis	3	0.33%	3	0.002
Phrenic nerve/diaphragmatic stimulation	1	0.11%	1	0.001
Pleural effusion	1	0.11%	1	0.001
Pneumothorax	7	0.76%	7	0.005
Pocket site/incision pain lasting greater than 72 hours post implant	5	0.54%	5	0.003
Repetitive Nonreentrant Ventriculoatrial Synchrony	1	0.11%	2	0.001
Set screw damage	1	0.11%	1	0.001
Tachycardia	1	0.11%	1	0.001
Thrombo-embolic event	9	0.98%	9	0.006
Undersensing - RA Lead	2	0.22%	2	0.001
Undersensing - RV Lead	2	0.22%	2	0.001
Undersensing - PG	1	0.11%	1	0.001

Table 239. MRI study other reported events

ORE Description	# of Patients[473]	# of Events	Comments
Acute Encephalopathy	1	1	Hospitalized for general weakness, altered mental status and mild CHF.
Angina	6	7	Patients hospitalized for chest pain; angioplasty performed in one patient, angioplasty and stenting performed in one patient and stent placed in one patient. No action taken in one patient.
Aortic Valve Replacement	1	1	Patient had history of aortic stenosis; valve replaced with no sequelae.
Arrest – Cardiopulmonary	1	1	Patient brought to ER in full arrest; cardioverted and intubated. Patient ultimately expired.
Arrest – Respiratory	1	2	Patient aspirated on an ice chip and went into respiratory failure ultimately resulting in patient death.

[473] Some patients experienced more than one event and therefore the number of patients is less than the number of events.

Table 239. MRI study other reported events

ORE Description	# of Patients[473]	# of Events	Comments
Asystole	1	1	Patient suffered an acute MI at home and expired
Atrial Arrhythmia	24	26	Patients had chronic atrial arrhythmias prior to device implant or arrhythmias were not attributed to the study device/procedure.
Atrial Fibrillation	2	2	Medication adjusted in one patient; catheter ablation done in one patient.
Atrial Flutter	1	1	Medication adjusted
Cerebrovascular Accident	5	5	The CVA remained unresolved in four patients, two of whom died as a result of the CVA. One patient went through rehabilitation and recovered.
Chest Pain	5	5	Chest pain resolved with no action in three patients. Medication was adjusted on two patients one of which had cardiac catheterization.
Compression Fracture L2 Vertebral Body	1	1	Patient treated with Kyphoplasty
Decompensated Heart Failure	9	9	Medications added or adjusted. One patient died due to multiple comorbidities.
Device Upgraded to CRT	1	1	Tendril MRI RA lead retained. Patient remains active in study.
Electromagnetic Interference	1	1	Event unresolvable; no action was taken.
Elevated Pacing Thresholds	1	2	Events occurred during initial lead placement; resolved once final lead placement was obtained.
Episodic Dizziness	1	1	Event resolved with medications adjustment.
Fall	2	2	Falls unrelated to device or cardiac issues.
Gastroenteritis	1	1	Patient treated with medication; no additional sequelae.
Hypotension	2	2	Medications adjusted; no additional sequelae observed.
Left Arm Swelling	1	1	No DVT; no action required.
Left Shoulder Pain	1	1	Pain unrelated to device/implant; no action required.
Lumbar Spinal Stenosis	2	2	Patients surgically treated; unrelated to device/study procedures.
Mitral Stenosis	1	1	MVR with single vessel CABG.
Nausea & Generalized Weakness	1	1	Patient withdrew from study due to other underlying medical conditions unrelated to study device/procedures.
Perforated Appendix With Abscess	1	1	Patient had laparoscopic appendectomy.
Pericardial Effusion	1	1	Effusion occurred five months post system implant; determined to be unrelated to study system or procedure.
Pleural Effusion	1	1	Patient hospitalized prior to implant for bilateral effusions and heart block, and was implanted with study pacemaker system during the same admission. Effusion resolved with right thoracentesis one day before implant.
Pulmonary Edema	1	1	Noted on chest x-ray; no intervention required.
Shock/Hypotension	2	2	One patient treated with medication; one patient expired; death unrelated to device/study procedures.
Shortness of Breath	2	2	Device was reprogrammed in one patient. No action taken the other patient.
Syncope	2	2	Device reprogrammed
Thrombocytopenia	1	1	Unresolvable; multiple comorbidities
Thrombo-embolic Event	2	2	Patients treated with anticoagulants
Ventricular Arrhythmia	9	10	One patient died; the death was adjudicated as not related to study device/procedure.
Ventricular Tachycardia	1	1	No intervention required
Total	78	103	

Fifty-six (56) patients enrolled in the MRI study were withdrawn from the study due to death. Three (3) of the deaths were considered to be peri-operative mortalities (occurred ≤ 30 days post-implant). There were no deaths classified as related to the pacemaker or lead system.

A summary of the Events committee death classifications is shown in the table below.

Table 240. Events committee classification of patients deaths

Primary Cause	Number of Patients
Cardiac: Arrhythmic	4
Cardiac: Ischemic	1
Cardiac: Pump Failure	4
Cardiac: Unknown	1
Non-Cardiac	40
Unknown	6
TOTAL	**56**

Potential Adverse Events

Possible adverse events associated with the system, include, but are not limited to the following:

MRI system adverse events:

- Lead electrode heating and tissue damage resulting in loss of sensing or capture or both
- Lead heating resulting in thrombus formation or embolism
- Pulmonary embolism
- Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Induced currents on leads resulting in continuous capture, VT/VF, hemodynamic collapse, or all three
- Damage to the device or leads causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Movement or vibration of the device or leads
- Lead dislodgment
- Competitive pacing and potential for VT/VF induction if asynchronous pacing is programmed when MRI Settings are enabled
- Syncope due to loss of pacing if no pacing support is programmed with MRI settings
- Death due to untreated spontaneous arrhythmia because tachy therapy is disabled when MRI settings are programmed.

Potential pacing system adverse events:

- Air embolism
- Body rejection phenomena
- Cardiac tamponade or perforation
- Hematoma, bleeding hematoma, seroma
- Formation of fibrotic tissue; local tissue reaction
- Inability to interrogate or program due to programmer or device malfunction
- Infection/erosion
- Interruption of desired pulse generator function due to electrical interference either electromyogenic or electromagnetic
- Loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface
- Loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation)
- Lead malfunction due to conductor fracture or insulation degradation
- Loss of normal pacemaker function due to battery failure or component malfunction
- Pacemaker migration, pocket erosion
- Pectoral muscle stimulation
- Phrenic nerve or diaphragmatic stimulation
- Pneumothorax/hemothorax
- Endocarditis
- Excessive bleeding
- Induced atrial or ventricular arrhythmias
- Myocardial irritability
- Pericardial effusion
- Pericardial rub
- Pulmonary edema

- Rise in threshold and exit block
- Valve damage

Potential lead related adverse events:
- Cardiac tamponade
- Diaphragmatic/phrenic nerve stimulation
- Embolism
- Excessive bleeding
- Induced ventricular ectopy
- Infection
- Loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the pacing lead
- Thrombosis

Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and rarely, death.

Performance of Chamber Onset and Far Field Morphology SVT Discriminators

Testing and analysis was conducted to evaluate the performance impact from the Chamber Onset and Far Field Morphology SVT Discriminators.

Methodology

EGM Clip testing was performed to assess the diagnosis accuracy of the Chamber Onset and Far Field Morphology discriminators at nominal values, compared to their predecessor algorithms, Sudden Onset and Original Morphology Discrimination (MD). EGM clips adjudicated as SVT or VT by board certified EPs were played through Ellipse/Assura device firmware with the new algorithm enabled and again with the old algorithm enabled instead.

Four scenarios were assessed:
- Sensitivity and specificity of Sudden Onset vs Chamber Onset
- Sensitivity and specificity of Original Morphology Discriminator (MD) vs Far Field MD™ discriminator
- Sensitivity and specificity utilizing all discrimination features including rate branch at nominal settings for Unify/Fortify (devices without Chamber Onset or Far Field MD™ discriminator) vs Ellipse/Assura (devices with Chamber Onset and Far Field MD discriminator)
- Positive predictive value (PPV), negative predictive value (NPV), false positive rate (FPR), and false negative rate (FNR) for a population of 10,000 episodes using conditional probability analysis at nominal settings for Unify/Fortify (devices without Chamber Onset or Far Field MD discriminator) vs Ellipse/Assura (devices with Chamber Onset and Far Field MD discriminator)

Data

EGM clips were randomly sampled from multiple St. Jude Medical-sponsored clinical studies and registries. Clips used for Chamber Onset testing included an atrial and ventricular bipolar channel and were from tachycardias where the ventricular and atrial rates were approximately the same. Clips used for Far Field Morphology testing included a near field bipolar ventricular channel, a far field ventricular channel (RVtip-Can or RVcoil-Can), and morphology scores in order to assess performance of Original MD on the same clip. A second EGM that included a normal ventricular rate served as the source of the template used in morphology evaluation.

Results

Sudden Onset vs Chamber Onset

The table below shows the performance of the Chamber Onset algorithm vs. the Sudden Onset algorithm (with 95% confidence intervals calculated using the bootstrap method), for a total of 374 adjudicated patient clips and 778 simulated clips (Number of VT patient clips = 77, Number of SVT patient clips = 297, Number of VT simulated clips = 778)

Table 241. Chamber Onset vs. Sudden Onset

Arrhythmia Type (V=A)	Prevalence of arrhythmia type, in patients with device detected episodes, based on ACT (%)	Sudden Onset	Chamber Onset	Number of clips evaluated
	SVT	Specificity (%) [95% confidence interval][474]		
All SVT	8.0	23.9 [18.7, 29.1]	77.4 [72.8, 82.1]	297[475]
AT with 1:1 conduction	5.8	18.9 [13.6, 24.2]	76.5 [71.2, 81.8]	238

[474] Where specificity or sensitivity is equal to 100%, the confidence intervals could not be calculated.
[475] Note that the total includes one additional episode with far-R oversensing not associated with a clinical arrhythmia.

Table 241. Chamber Onset vs. Sudden Onset

Arrhythmia Type (V=A)	Prevalence of arrhythmia type, in patients with device detected episodes, based on ACT (%)	Sudden Onset	Chamber Onset	Number of clips evaluated
Sinus Tach	1.7	82.8 [69.1, 96.4]	100.0	29
AVNRT	0.5	3.4 [0, 10.2]	62.1 [44.9, 79.2]	29
VT		**Sensitivity (%) [95% confidence interval]**		
All VT/VF	**0.7**	**97.9 [96.9, 98.9]**	**84.4 [82.0, 86.9]**	**855**
Fast (> 170 bpm) VT with 1:1 Retrograde	0.5	97.6 [96.1, 99.3]	91.4 [88.4, 94.3]	347
Slow (< 170 bpm)VT with 1:1 retrograde conduction	0.3	97.1 [95.3, 98.8]	83.0 [79.1, 87.0]	342
Fast (> 170 bpm)VT with 1:1 retrograde and frequent PACs near initiation of arrhythmia	0.1	100.0	72.9 [66.1, 79.7]	166

As can be observed based on the results, it may be preferable to program Chamber Onset to Passive in those patients that are known to have slow VTs (< 170 bpm) or a history of 1:1 retrograde conduction along with frequent PACs. It is important to note that 1:1 arrhythmias are specifically challenging for physicians. A recent publication based on results from the OMNI study demonstrated that individual physician arrhythmia accuracy varies from 22% to 100% with a median of 87.7%[476]. The study also indicated that non-VT/VF arrhythmias with 1:1 AV conduction had significantly lower accuracy than other episodes (57.6% vs 93.2%). In contrast, the Chamber Onset algorithm had accuracy for non-VT/VF arrhythmias of 77.4%.

Original MD vs Far Field MD™ Discrimination

The table below shows the performance of the Far-Field Morphology vs. Original Morphology Discrimination setting (with 95% confidence intervals calculated using the bootstrap method), for a total of 206 adjudicated patient clips (Number of VT patient clips = 52, Number of SVT patient clips = 154).

Table 242. Far-Field Morphology vs. Original Morphology

Arrhythmia Type	Prevalence of arrhythmia type, in patients with device detected episodes, based on ACT (%)	Original MD	Far-Field MD	Number of clips evaluated
SVT		**Specificity (%) [95% confidence interval][477]**		
All SVT	**30.3**	**84.4 [72.8, 96.0]**	**94.8 [91.1, 98.5]**	**154**
AT/AF/AFl	24.6	79.3 [65.0, 93.7]	94.0 [89.2, 98.7]	116
AVNRT	0.9	100.0	91.7 [71.4, 100]	12
Sinus Tachycardia	2.8	100.0	100.0	20
Other	2.1	100.0	100.0	6
VT		**Sensitivity (%) [95% confidence interval]**		
All VT/VF	**16.9**	**65.4 [50.3, 80.5]**	**84.6 [73.0, 96.3]**	**52[478]**
VT + Simultaneous AT/AF/AF	1.1	25.0 [0.0, 55.7]	50.0 [0.7, 89.3]	4

[476] Fischer A, Patel A, et al., Wide variability in manual classification of arrhythmias in dual and triple chamber defibrillators during follow-up. Heart Rhythm, 2012; 9 (5S), S380.
[477] Where specificity or sensitivity is equal to 100%, the confidence intervals could not be calculated.
[478] Note that the total includes VT/VF episodes without AT/AF/AFl.

Overall Discrimination Performance

Total adjudicated clips = 206

Number of VT = 52

Number of SVT = 154

Table 243. Devices with Sudden Onset and Original MD vs Devices with Chamber Onset and Far Field MD Discrimination (at Nominal Settings)

	Devices Sudden Onset and Original MD	Devices with CO and FFMD
Sensitivity	78.8% [65.0%, 92.7%]	86.5% [75.7%, 97.4%]
Specificity	82.5% [75.4%, 89.5%]	95.5% [91.8%, 99.1%]

Table 244. Performance by Rate Branch (%)

		Devices Sudden Onset and Original MD	Devices with CO and FFMD
V>A	Sensitivity	100.0	100.0
	Specificity	na	na
V=A	Sensitivity	100.0	100.0
	Specificity	88.5	100.0
V<A	Sensitivity	0.0	0.0
	Specificity	95.0	97.5
Single Chamber	Sensitivity	75.7	86.5
	Specificity	71.7	90.0

Table 245. Estimated Overall Device Performance for 10,000 episodes at nominal 2 zone detection rates and discriminator settings (%)

	Devices Sudden Onset and Original MD	Devices with CO and FFMD
Positive predictive value	63.2	78.2
Negative predictive value	98.8	98.0
False positive rate	36.8	21.8
False negative rate	1.2	2.0

Table 246. Sensitivity of Sudden Onset and Chamber Onset, patient clip testing

	Sensitivity (%)	95% bootstrap confidence interval
Sudden Onset	96.1	91.8%, 100.0%
Chamber Onset	83.1	75.1%, 91.1%
Chamber Onset - Sudden Onset	-13.0	-20.2%, -5.8%

Table 247. Sensitivity of Sudden Onset and Chamber Onset, virtual patient clip testing

	Sensitivity (%)	95% bootstrap confidence interval
Sudden Onset	98.1	916.8%, 98.9%
Chamber Onset	84.6	81.8%, 87.0%
Chamber Onset - Sudden Onset	-13.5	-16.0%, -11.0%

Table 248. Specificity Sudden Onset and Chamber Onset

	Specificity (%)	95% bootstrap confidence interval

Table 248. Specificity Sudden Onset and Chamber Onset

	Specificity (%)	95% bootstrap confidence interval
Sudden Onset	23.9	18.7%, 29.1%
Chamber Onset	77.4	72.8%, 82.1%
Chamber Onset - Sudden Onset	53.5	47.6%, 59.5%

Table 249. Sensitivity of Original Morphology and Far Field Morphology

	Sensitivity (%)	95% bootstrap confidence interval
Original Morphology	65.4	50.3%, 80.5%
Far Field Morphology	84.6	73.0%, 96.3%
Far Field Morphology - Original Morphology	19.2	2.2%, 36.3%

Table 250. Specificity of Original Morphology and Far Field Morphology

	Specificity (%)	95% bootstrap confidence interval
Original Morphology	84.4	72.8%, 96.0%
Far Field Morphology	94.8	91.1%, 98.5%
Far Field Morphology - Original Morphology	10.4	-2.5%, 23.3%

Conclusions

The new Chamber Onset and Far Field Morphology discriminators reduce inappropriate therapy caused by false positive diagnoses. While each individual discriminator may not be appropriate for all patients, when used in combination, these features demonstrate an improved specificity while maintaining a low false negative rate.

Detect Fluid Early from IntrA-thoracic Impedance MoniToring (DEFEAT-PE STUDY)

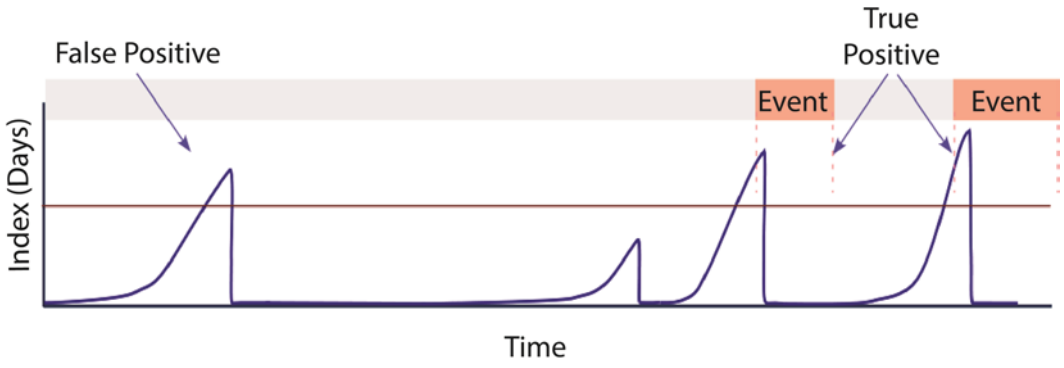
The purpose of this pivotal IDE study was to demonstrate the safety and effectiveness of the CorVue™ Thoracic Impedance Monitoring algorithm in the St. Jude Medical CRT-D devices and VR/DR devices.

Study Endpoints

The objective of this study was to demonstrate the safety and effectiveness of the CorVue™ Thoracic Impedance Monitoring algorithm.

- The primary efficacy endpoint was the false positive rate (FPR) per patient-year of follow up. The FPR is the number of times the fluid index exceeded the CorVue Threshold (and was unrelated to an event) divided by the number of patient-years of follow-up (see figure below (page 368)). The fluid index exceeding the CorVue Threshold is considered to be related to an impedance event if the rising occurs within 30 days prior to the event, or if the rising occurs when the event is ongoing. Otherwise, it is considered to be unrelated to an event.
- The secondary efficacy endpoint was sensitivity of the impedance monitoring feature to detect events. This was calculated as the proportion of heart failure (HF) events with a detected impedance event.

Figure 32. Impedance monitoring feature



Study Design

The study was a non-randomized, multi-center pivotal study that collected information on intrathoracic impedance measurements from St. Jude Medical CRT-D and ICD devices. The study was conducted at 34 investigational centers located in the U.S., and 162 patients (80 ICD and 82 CRT-D) were enrolled.

At enrollment, the CorVue™ Thoracic Impedance Monitoring algorithm was turned On. Following enrollment, patient follow-up visits were completed at Baseline, three months after baseline, and every three months thereafter until study completion.

Inclusion and Exclusion Criteria

Eligible patients met all of the following:

1. Implanted for at least 31 days with a St. Jude Medical CRT-D or ICD capable of enabling impedance data collection.
2. Implanted with a right atrial bipolar pacing lead (if applicable), a right ventricular true bipolar defibrillation lead, and a St. Jude Medical endocardial left ventricular bipolar pacing lead (if applicable).
3. Had at least one hospitalization or emergency room visit within the past six months for decompensated heart failure requiring medical treatment with at least one of the following pharmacological agents: intravenous diuretics, intravenous inotropes, intravenous nitrates, Natrecor therapy or ≥100% increase in oral diuretic therapy.
4. Had the ability to provide informed consent for study participation and was willing and able to comply with the prescribed follow-up tests and schedule of evaluation.

Patients were excluded if they met any of the following:

1. Were less than 18 years of age.
2. Implanted with an RV integrated pacing/defibrillator lead.
3. Implanted with a capped or inactive RA or RV pacing/defibrillator lead.
4. Implanted with a non-St. Jude Medical LV pacing lead.
5. Implanted with an epicardial lead.
6. Had end-stage renal disease requiring hemodialysis.
7. Received intermittent infusions of positive inotropic agents (at home, in an outpatient clinic, or in a short-stay unit) for refractory end-stage HF.
8. Were pregnant or planning a pregnancy in the next six months.
9. Were currently participating in a clinical investigation that included an active treatment arm.
10. Had a life expectancy of less than six months due to any condition.

Clinical Study Results

Patient enrollment in the DEFEAT-PE study began on June 9, 2009 and ended on June 30, 2010. A total of 162 patients were enrolled in the study. Eighteen patients were withdrawn prior to the baseline visit resulting in a total of 144 patients included in the analyses. The average duration of follow-up for the CRT-D cohort was 9.2 ± 5.4 (range 0 to 20.3) patient-months, and the ICD cohort had an average time of follow-up as 11.3 ± 3.9 (range 1.8 to 19.1) patient-months.

False Positive Rate

The primary efficacy endpoints for both cohorts (CRT-D and ICD) were demonstrated by the FPR per patient-year of follow-up.

The hypothesis is formally expressed as follows:

- H0: Expected FPR ≥1.5 per patient-year of follow-up
- •Ha: Expected FPR <1.5 per patient-year of follow-up

The desired outcome is to reject the null hypothesis. The null hypothesis is rejected at the 5% significance level if the 95% upper confidence limit (UCL) for expected FPR is less than 1.5 per patient-year of follow-up.

Analysis

Algorithm with Nominal Setting of 14 days

Based on the nominal threshold setting of 14 days, there were 112 departures above the CorVue Threshold that occurred in 144 patients between the Baseline visit and the data cutoff date.

Among these 112 departures, 18 were related to an event and 94 were unrelated. The total follow-up patient-years with available impedance measurements were 97.97 years. The FPR was 0.96 with a 95% UCL of 1.14. The 95% UCB was less than the objective performance criterion of 1.5 (see the table below. Therefore the null hypothesis was rejected at the 5% level of significance.

Table 251. FPR for algorithm with nominal setting in combined CRT-D and ICD cohorts

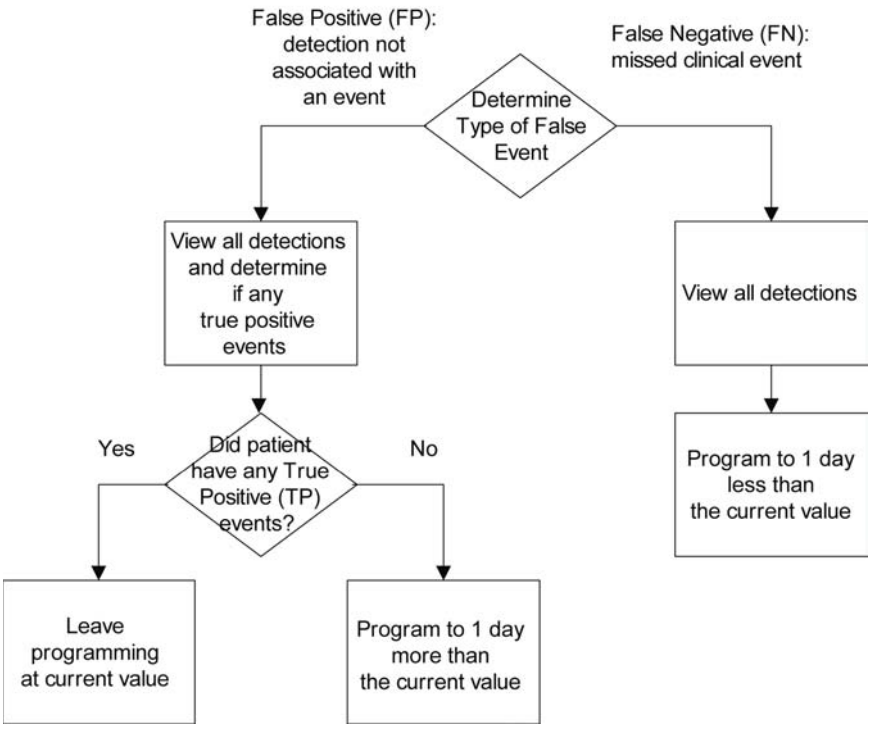
Algorithm Programming	Patient Cohort	N (Total Years of Follow Up)	Number of False Positives	FPR Per Patient Year of Follow Up	95% Upper Confidence Limit (UCL)	Objective Performance Criteria (OPC)
14 day nominal value	CRT-D +ICD	144 (97.97)	144 (97.97)	0.96	1.14	1.50

Algorithm with Nominal CorVue Threshold and Programmable CorVue Threshold

An additional analysis was carried out by using a programmable CorVue Threshold. In the additional analysis, the CorVue Threshold was set at 14 days and was then reprogrammed after the first false positive or false negative event. The method used for reprogramming the CorVue Threshold is described below:

- All events since the last visit were reviewed. If a false positive event was noted and the patient did not have any true positive events, the CorVue Threshold was adjusted to a higher threshold value (i.e., from 14 days to 15 days). If the patient had any true positive events prior to the device interrogation, the CorVue Threshold was unchanged.
- If the clinical event was a false negative, the CorVue Threshold was adjusted to a lower value (i.e., from 14 days to 13 days).

Figure 33. Diagram of CorVue Threshold reprogramming process



There were 79 patients who were reprogrammed after a first false positive or false negative event. The results of nominal settings with programmable CorVue Threshold were presented by combining both cohorts.

Based on the nominal CorVue Threshold of 14 days and using a programmable CorVue Threshold, there were 110 departures above the fluid index that occurred in 144 patients between the Baseline visit and the data cutoff date.

Among these 110 departures, 20 were related to an event and 90 were unrelated. The total follow-up with available impedance measurement was 97.97 patient-years. The FPR was 0.92 with a 95% UCL of 1.09. The 95% UCB was less than the objective performance criterion of 1.5 (see the table below). Therefore the null hypothesis was rejected at the 5% level of significance.

Table 252. FPR for algorithm with programmable CorVue Threshold in combined CRT-D and ICD cohorts

Algorithm Programming	Patient Cohort	N (Total Years of Follow Up)	Number of False Positives	FPR Per Patient Year of Follow Up	95% Upper Confidence Limit (UCL)	Objective Performance Criteria (OPC)
Nominal of 14 days + programmable threshold	CRT-D +ICD	144 (97.97)	90	0.92	1.09	1.50

Sensitivity

The secondary efficacy endpoints for both cohorts (CRT-D and ICD) were demonstrated by the sensitivity of the fluid index to detect events. This is calculated as the proportion of events with a related departure to the total number of events. A departure is considered to be related to an event if the event begins within 30 days of the index rising above the CorVue Threshold or if the rise occurs when the event is ongoing.

The hypothesis is formally expressed as follows:

- H0: Sensitivity ≤ 50%
- •Ha: Sensitivity > 50%

The desired outcome was to reject the null hypothesis at the 5% significance level. The null hypothesis will be rejected at the 5% significance level if the 95% lower confidence limit (LCL) for sensitivity is greater than 50%.

Algorithm with Nominal Setting of 14 days

There were a total of 79 events in ICD and CRT-D cohort combined: 21 were related to a fluid index greater than the CorVue Threshold and 58 were not. The sensitivity was 26.6% with a 95% LCL of 18.6%.

Table 253. Sensitivity of algorithm with nominal CorVue Threshold

Algorithm Programming	Patient Cohort	N	Number of True Positives	Number of False Positives	Sensitivity	95% Lower Confidence Limit (LCL)
ICD (new nominal of 14 days)	CRT-D +ICD	144	21	58	26.6%	18.6%

Algorithm with Nominal CorVue Threshold and Programmable CorVue Threshold

As described above for the false positive rate, an additional analysis was carried out with the nominal CorVue Threshold of 14 days and a programmable CorVue Threshold. The CorVue Threshold was initially set at 14 days and then reprogrammed after the first false positive or false negative event. (See the figure (page 370) above for the details of how the threshold was adjusted.)

There were 79 patients who were reprogrammed after a first false positive or false negative event. There were a total of 79 events in the ICD and CRT-D cohorts combined: 23 were related to a fluid index greater than the CorVue Threshold and 56 were not. The sensitivity was 29.1% with a 95% LCL of 20.8%.

Table 254. Sensitivity of algorithm with nominal CorVue Threshold and programmable CorVue Threshold

Algorithm Programming	Patient Cohort	N	Number of True Positives	Number of False Positives	Sensitivity	95% Lower Confidence Limit (LCL)
Nominal of 14 days + programmable threshold	CRT-D +ICD	144	23	56	29.1%	20.8%

Summary

In the DEFEAT PE study, the use of an impedance monitoring algorithm was tested rigorously in an IDE trial for the first time. As noted in the primary endpoint analysis above, the performance of the algorithm demonstrated a false positive rate of 0.96 (1.14 UCL) and a mean sensitivity of 26.6%. This FPR met the objective performance criteria of ≤1.5 and compares well to the published data.

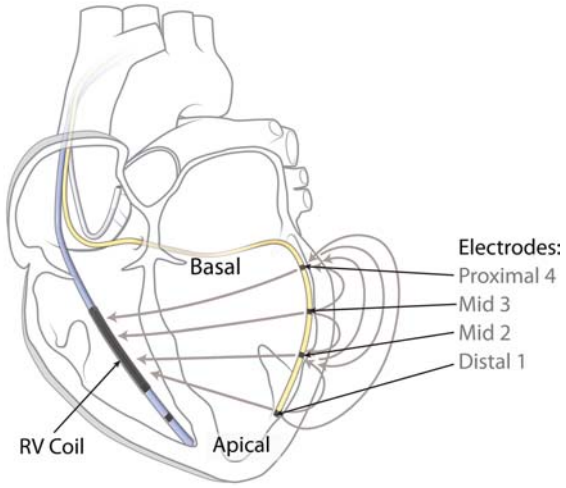
Promote™ Q CRT-D and Quartet™ Left Ventricular Heart Lead Study

The objective of this study was to assess the safety and efficacy of the Promote™ Q CRT-D and Quartet™ left ventricular heart lead (Promote™ Q device system) in a patient population indicated for cardiac resynchronization[479] therapy.

Primary Objectives

- Safety of the Promote Q device system was evaluated in terms of freedom from LV lead-related complications through three months.
- Safety of the Promote Q device system was evaluated in terms of freedom from system-related complications through three months.
- Efficacy of the system was evaluated in terms of the percentage of patients with an LV- pacing threshold of <2.5V at 0.5 ms in Vector 1 (D1-M2) and at least one other nonstandard programmable biventricular lead vector at three months. Standard vectors (i.e., vectors already available with a standard bipolar left ventricular lead) include Vector 1 (D1-M2), Vector 3 (D1-RV coil) and Vector 5 (M2-RV coil). Nonstandard vectors include Vector 2 (D1-P4), Vector 4 (M2-P4), Vector 6 (M3-M2), Vector 7 (M3-P4), Vector 8 (M3-RV coil), Vector 9 (P4-M2), and Vector 10 (P4-RV coil).

Figure 34. Image of Ten Quartet LV lead vectors on the heart and cathode to anode reference for each vector



Vector	Cathode to Anode
Vector 1	Distal 1 to Mid 2
Vector 2	Distal 1 to Proximal 4
Vector 3	Distal 1 to RV Coil
Vector 4	Mid 2 to Proximal 4
Vector 5	Mid 2 to RV Coil
Vector 6	Mid 3 to Mid 2
Vector 7	Mid 3 to Proximal 4
Vector 8	Mid 3 to RV Coil
Vector 9	Proximal 4 to Mid 2
Vector 10	Proximal 4 to RV Coil

Inclusion and Exclusion Criteria

Patients were included if they met all of the following:

[479] St. Jude Medical Promote Q CRT-D and Quartet Left Ventricular Heart Lead IDE Study included the Promote Q CRT-D Model CD3221-36 and Quartet Model 1458Q left ventricular heart lead. The data apply by similarity to the Promote Quadra™ and Unify Quadra™ devices.

1. Had an approved indication per ACC/AHA/HRS guidelines for implantation of a CRT-D system for treatment of heart failure or life-threatening ventricular tachyarrhythmia(s).
2. Were receiving a new implant or undergoing an upgrade from an existing ICD or pacemaker implant with no prior LV lead placement
3. Were able to provide informed consent for study participation and willing and to comply with the prescribed follow-up tests and schedule of evaluations.

Patients were excluded if they had any of the following:

1. A recent CVA or TIA within three months of enrollment
2. A contraindication for emergency thoracotomy
3. A hypersensitivity to a single 1.0 mg dose of dexamethosone sodium phosphate or short-term contact with heparin
4. A classification of Status 1 for cardiac transplantation or consideration for transplantation over the next three months
5. A cardiac transplantation within 40 days of enrollment
6. A recent myocardial infarction, unstable angina, or cardiac revascularization (PTCA, Stent, or CABG) within 40 days of enrollment
7. Participation in a clinical investigation that includes an active treatment arm
8. Pregnancy or plans to become pregnant during the duration of the study
9. A life expectancy of less than six months due to any condition
10. Age under 18 years
11. Inability to comply with the follow-up schedule.

Clinical Study Results

A total of 178 patients were enrolled at 24 clinical sites in the Promote Q CRT-D and Quartet left ventricular heart lead study. The first patient was enrolled on October 2, 2009. The total time of follow-up was 849.64 patient months. The average time of follow-up was 4.77 ± 1.94 (range 0.99 to 9.82) patient-months.

The table below contains a summary of the demographic information on all patients included in the Promote Q CRT-D and Quartet left ventricular heart lead study (178 patients).

Table 255. Promote Q CRT-D and Quartet left ventricular heart lead study demographics

Demographic Variable	All Enrolled Patients (N=178)
Age (years)	
Mean ± SD	68 ± 11
Range	(31, 87)
Gender, n (%)	
Female	56 (31.5%)
Male	122 (68.5%)
Ethnicity, n (%)	
Hispanic or Latino	11 (6.2%)
Not Hispanic or Latino	161 (90.4%)
Failed to Report	6 (3.4%)
Race, n (%)	
Asian	5 (2.8%)
Black or African American	29 (16.3%)
White	140 (78.7%)
Other	2 (1.1%)
Failed to Report	2 (1.1%)
NYHA Class, n (%)	
Class III	175 (98.3%)
Class IV	3 (1.7%)
LV Ejection Fraction (%	
Mean ± SD	25 ± 7
Range	(9, 50)

Table 255. Promote Q CRT-D and Quartet left ventricular heart lead study demographics

Demographic Variable	All Enrolled Patients (N=178)
Cardiomyopathy Etiology, n (%)	
Ischemic	103 (57.9%)
Non-Ischemic	75 (42.1%)
Alcoholic	3 (1.7%)
Hypertensive	24 (13.5%)
Idiopathic	27 (15.2%)
Valvular Disease	7 (3.9%)
Other	14 (7.9%)
Cardiovascular History, n (%)	
Coronary Artery Disease	122 (68.5%)
Myocardial Infarction	77 (43.3%)
Unstable Angina	23 (12.9%)
Prior Cardiac Interventions	98 (55.1%)
CABG	72 (40.4%)
PTCA/ Stents/Atherectomy	43 (24.2%)
Arrhythmia History, n (%)	
Atrial Arrhythmia	71 (39.9%)
Ventricular Arrhythmia	53 (29.8%)
Other Medical Conditions, n (%)	
No Other Medical Condition	19 (10.7%)
Diabetes	70 (39.3%)
COPD	36 (20.2%)
Renal Disease	33 (18.5%)
Hypertension	134 (75.3%)
Pacer Dependent	13 (7.3%)
Other (e.g., valve disease/replacement, hyperlipidemia, peripheral vascular disease)	78 (43.8%)
Primary CRT-D Indication for Implant, n (%)	
Upgrade from pacemaker	9 (5.1%)
HF with wide QRS, NYHA Class III or ambulatory Class IV, and EF <35% (ACC/AHA/HRS Class I Recommendation)	115 (64.6%)
HF with NYHA Class III or ambulatory Class IV, EF <35% and frequent dependence on ventricular pacing (ACC/AHA/HRS Class IIa Recommendation)	8 (4.5%)
HF with NYHA Class III or ambulatory Class IV, EF <35%, QRS > 120 ms, and AF (ACC/AHA/HRS Class IIa Recommendation)	14 (7.9%)
Upgrade from ICD	28 (15.7%)
PAVE (Patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class III or IV symptoms)	4 (2.2%)
Current Drug Therapy, n (%)	
ACE Inhibitors	114 (64.0%)
ARBs	37 (20.8%)
Beta Blockers	155 (87.1%)
Calcium Channel Blockers	18 (10.1%)
Cardiac Glycosides (Digitalis)	57 (32.0%)
Diuretics	143 (80.3%)
Inotropes	1 (0.6%)
Nitrates	24 (13.5%)
Antiarrhythmics (Class I)	2 (1.1%)
Antiarrhythmics (Class III)	31 (17.4%)

Table 255. Promote Q CRT-D and Quartet left ventricular heart lead study demographics

Demographic Variable	All Enrolled Patients (N=178)
Vasodilators	2 (1.1%)

Of the 178 patients enrolled in the Promote Q CRT-D and Quartet left ventricular heart lead study, 170 lead implants were successful (95.5% implant success rate). The reasons for an unsuccessful implant were: Inability to obtain stable lead position (n=4); poor venous anatomy or the inability to advance the lead into a small caliber coronary sinus vein (n=2); diaphragmatic/phrenic nerve stimulation (n=1); and cardiopulmonary arrest (n=1). All eight patients with unsuccessful implants were followed for a period of 30 days for adverse events and then were withdrawn from the study.

Primary Objective Results

1. Safety Objective 1: Freedom from left ventricular lead-related complications through three months > 85%

Freedom from LV lead-related complications through three months was estimated as 96% with a 97.5% lower confidence boundary (LCB) of 93%. The 97.5% LCB was greater than the objective performance criterion of 85%. **Hence, the objective was met.**

2. Safety Objective 2: Freedom from system-related complications through three months > 75%

The survival from system-related complications through three months was estimated as 92% with a 97.5% LCB of 88%. The 97.5% LCB was greater than the objective performance criterion of 75%. **Hence, the objective was met.**

3. Efficacy Objective: Responder rate of biventricular pacing at three months > 75%

The primary effectiveness endpoint for the Promote Q system was the responder rate to biventricular pacing at three months. A responder per protocol was defined as a patient with an LV-pacing threshold of <2.5V at 0.5 ms in the D1-M2 pacing configuration (Vector 1) **AND** at least one other nonstandard programmable biventricular lead vector. Nonstandard vectors included Vector 2 (D1-P4), Vector 4 (M2-P4), Vector 6 (M3-M2), Vector 7 (M3-P4), Vector 8 (M3-RV coil), Vector 9 (P4-M2), and Vector 10 (P4-RV coil).

Prespecified Analysis

Analysis per statistical plan: Per the statistical analysis plan, patients with unsuccessful implants (who therefore did not have three-month data) were treated as nonresponders. The responder rate at three months in this analysis was estimated as 79.7% with a 97.5% LCB of 73%. **Since the responder rate was < 75% at the three-month visit, the objective was not met.**

Alternate Analysis

Complete case analysis: In the complete case analysis, patients with successful implants who had evaluable pacing capture threshold measurements at the three-month visit were included. The responder rate at three months was estimated as 83.9% with a 97.5% LCB of 77.2%, which is greater than the objective performance criterion of 75%. **Hence, the objective was met.**

Additional Data

Below are histograms summarizing the study population's capture threshold measurements for each vector at the three-month visit.

Figure 35. Number of patients in each subset of capture threshold measurements using Vector 1 (D1-M2) at three months post-implant

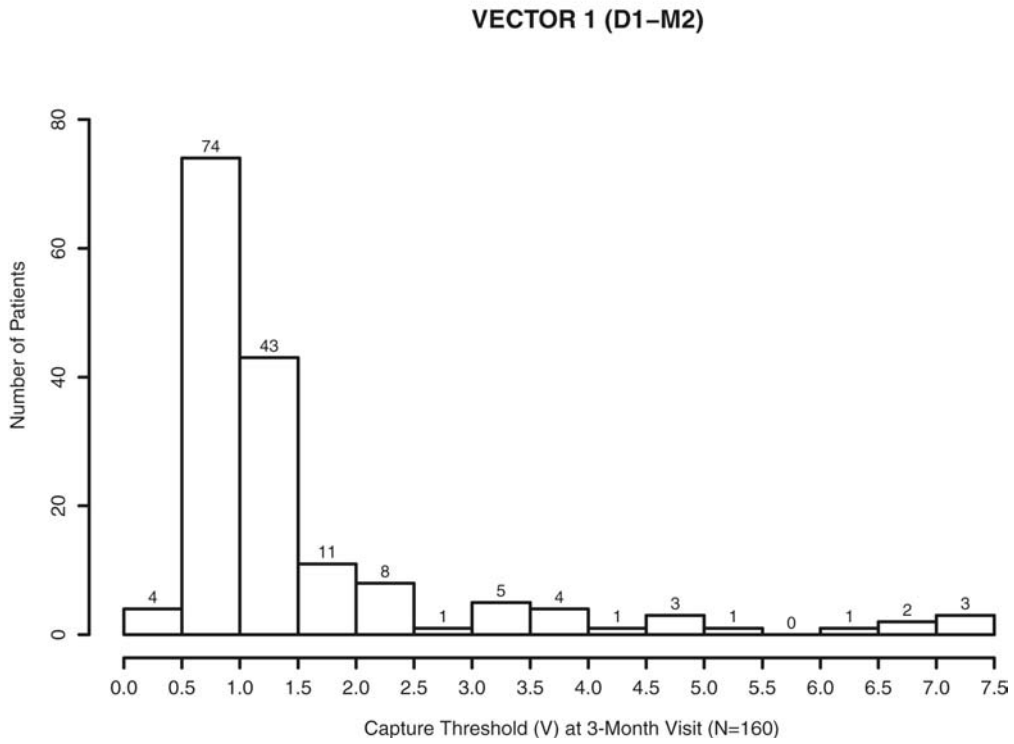


Figure 36. Number of patients in each subset of capture threshold measurements using Vector 2 (D1-P4) at three months post-implant

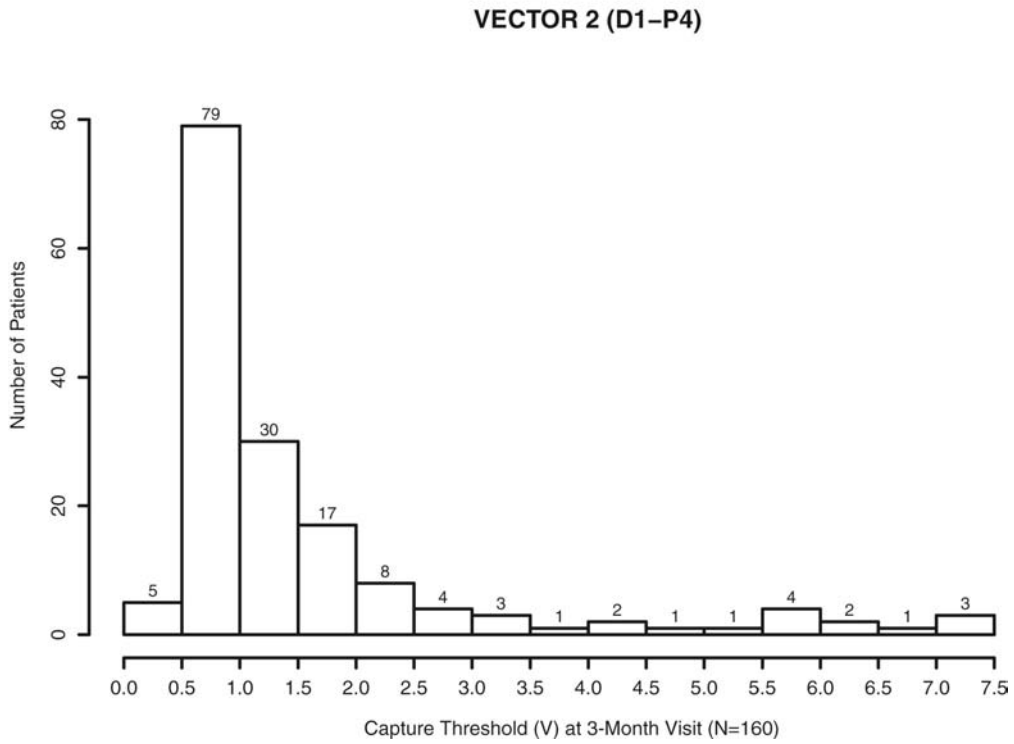


Figure 37. Number of patients in each subset of capture threshold measurements using Vector 3 (D1-RV Coil) at three months post-implant

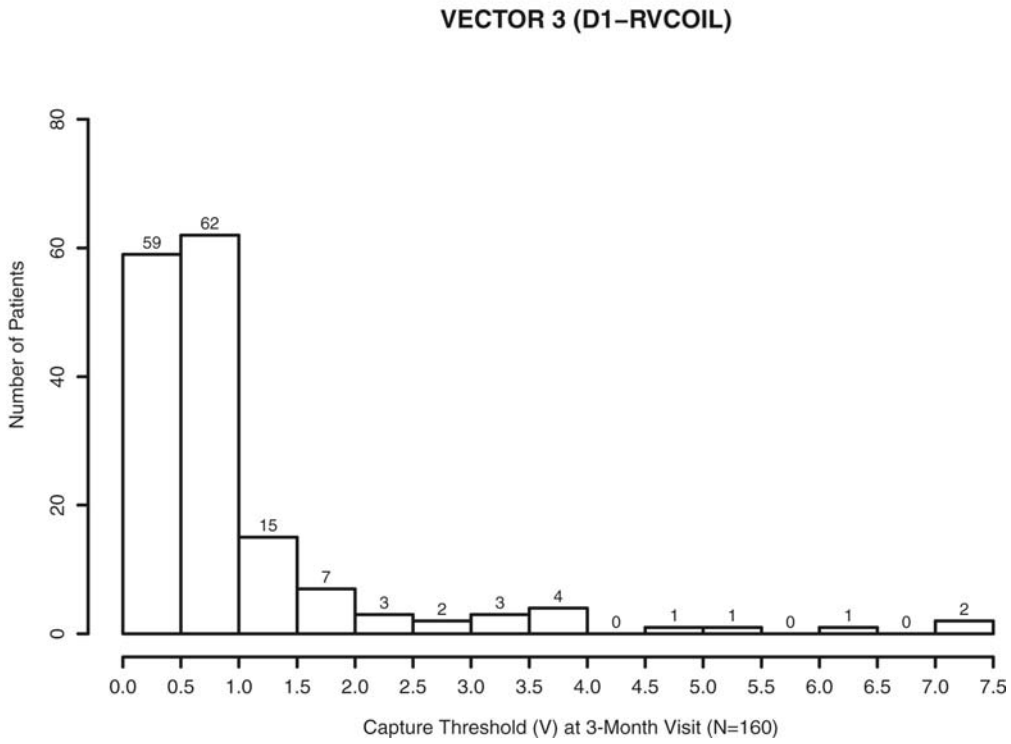


Figure 38. Number of patients in each subset of capture threshold measurements using Vector 4 (M2-P4) at three months post-implant

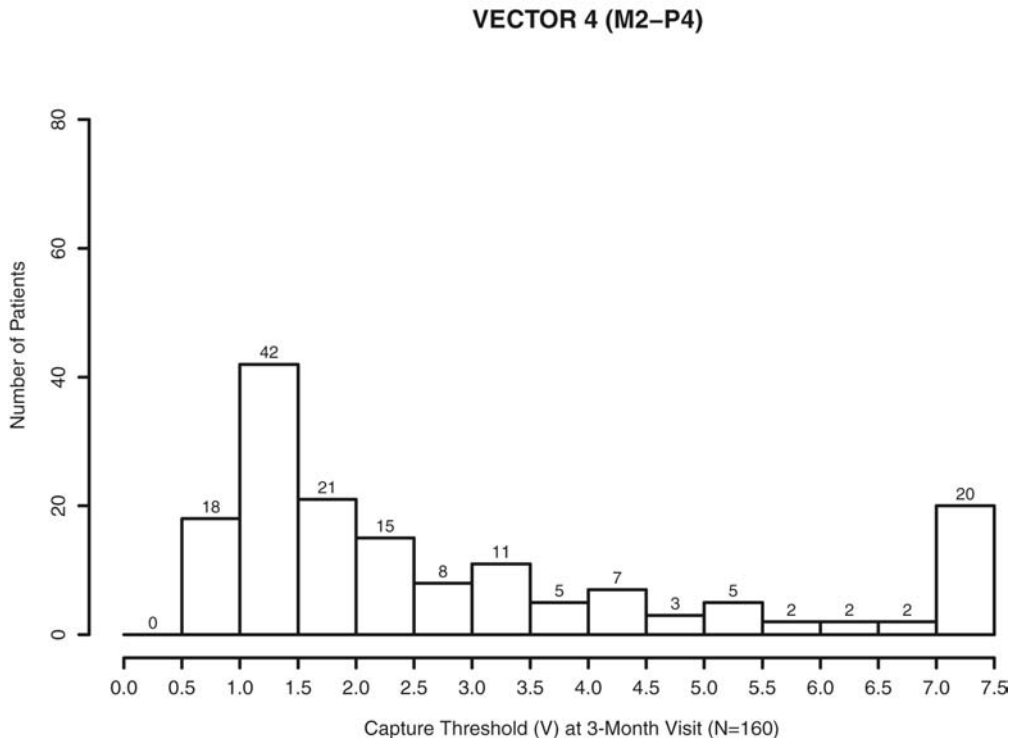


Figure 39. Number of patients in each subset of capture threshold measurements using Vector 5 (M2-RV Coil) at three months post-implant

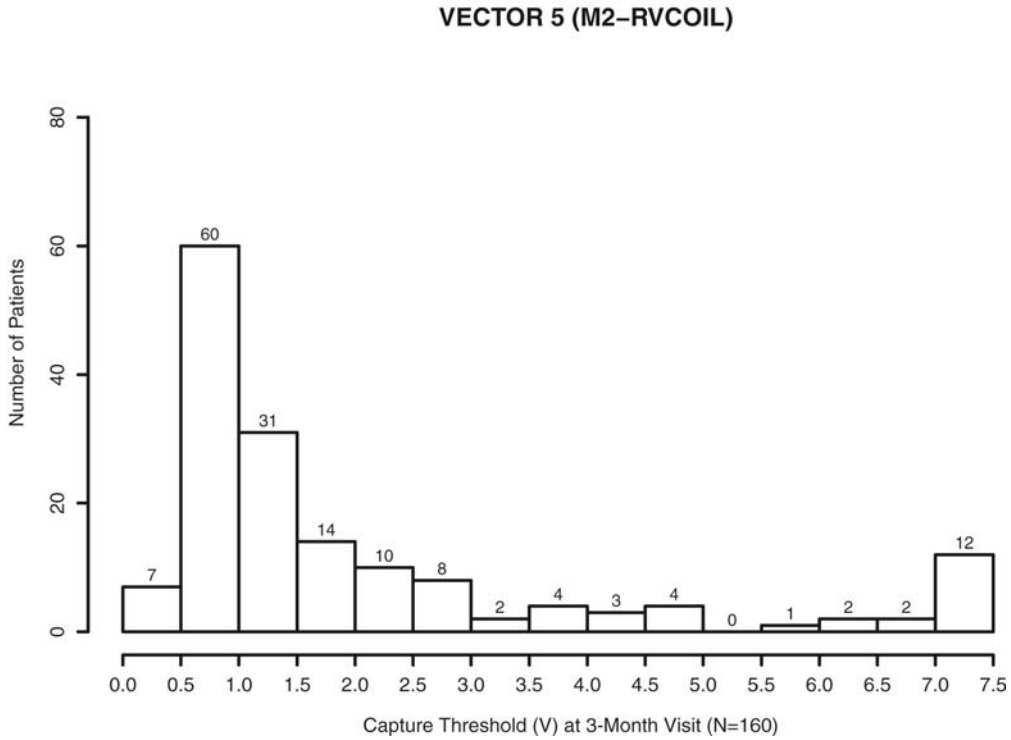


Figure 40. Number of patients in each subset of capture threshold measurements using Vector 6 (M3-M2) at three months post-implant

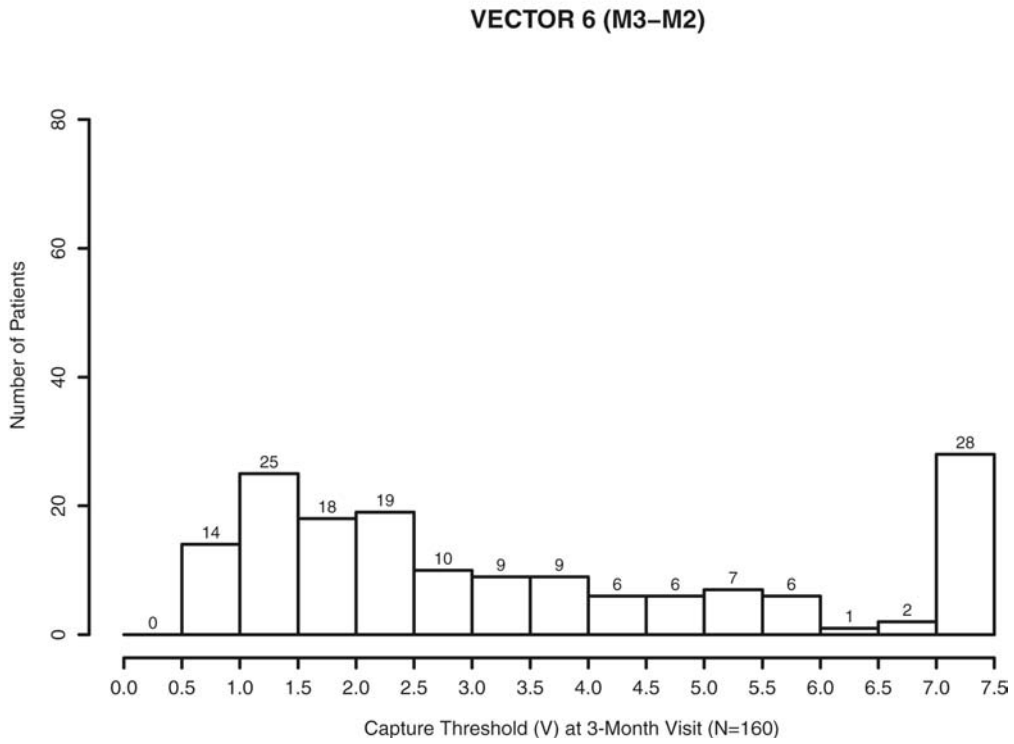


Figure 41. Number of patients in each subset of capture threshold measurements using Vector 7 (M3-P4) at three months post-implant

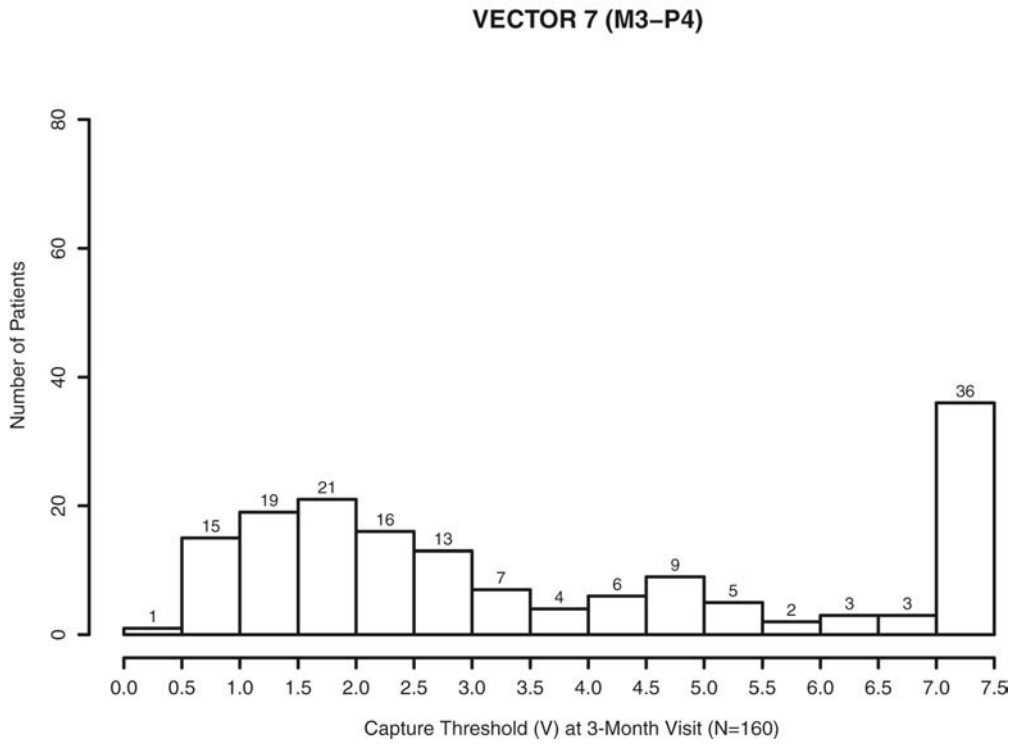


Figure 42. Number of patients in each subset of capture threshold measurements using Vector 8 (M3-RV Coil) at three months post-implant

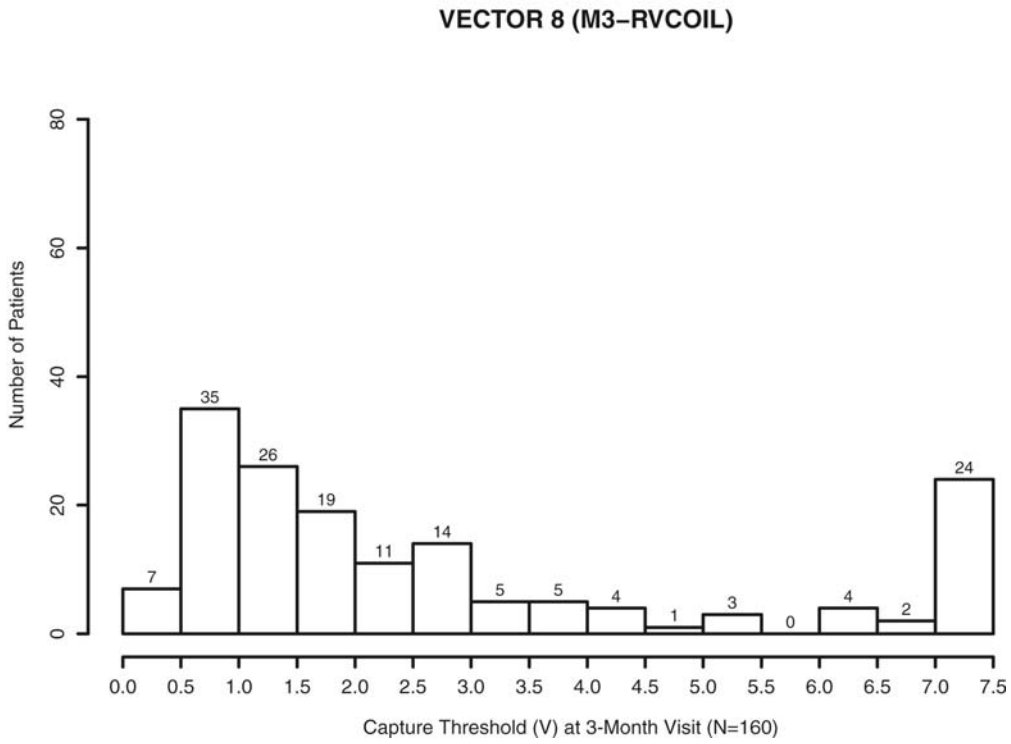


Figure 43. Number of patients in each subset of capture threshold measurements using Vector 9 (P4-M2) at three months post-implant

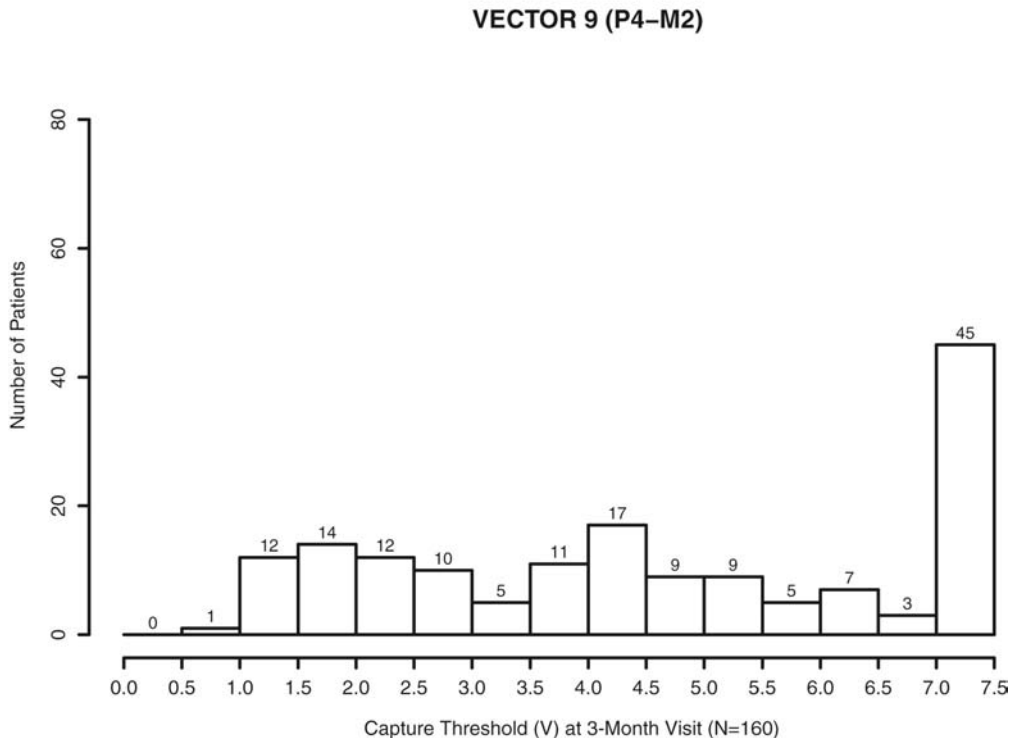
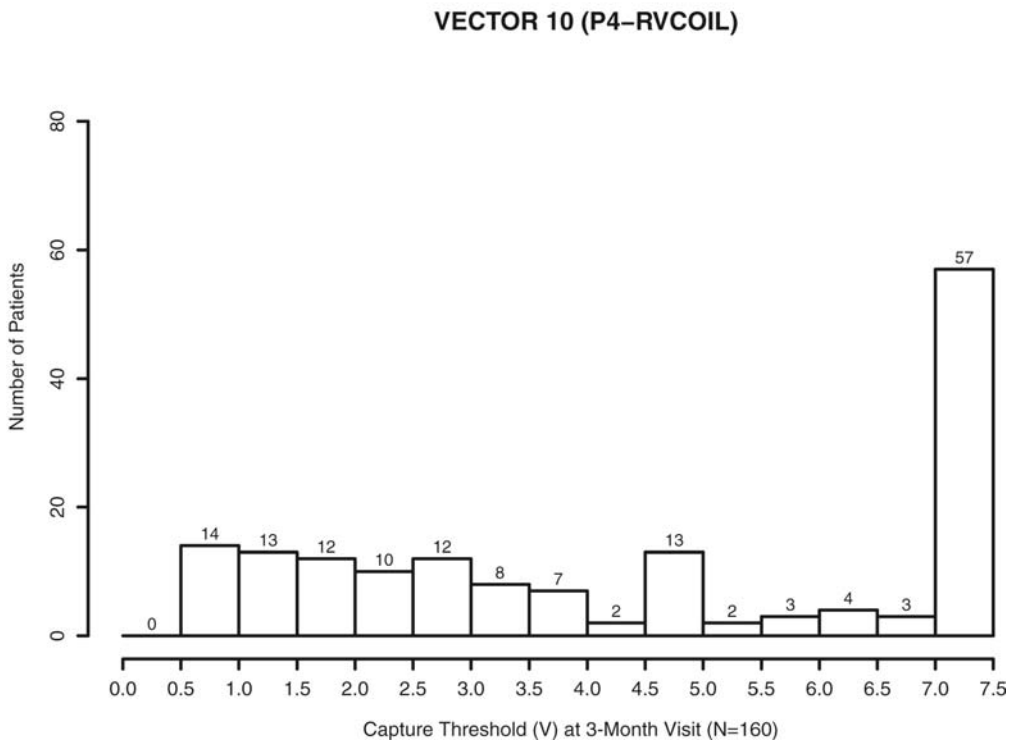


Figure 44. Number of patients in each subset of capture threshold measurements using Vector 10 (P4-RV Coil) at three months post-implant



Note

The histograms include measurements when LV-lead electrodes were positioned more proximally outside the coronary vein (e.g., in the coronary sinus).

The table below summarizes the number and percentage of patients who had capture thresholds < 2.5V in each vector during the three-month office visit. Outcomes at the pre-discharge and one-month visit were similar to the three-month visit. As observed in the table below, the Quartet lead enabled multiple vectors with capture thresholds of less than 2.5V.

Table 256. Patients with capture thresholds < 2.5V in each vector at three months

Vector		Capture Threshold < 2.5V @ Three Month Follow-Up	
		# of pts (N=161)	% of pts
1	D1 - M2	136	84
2	D1 - P4	137	85
3	D1 - RVCOIL	145	90
4	M2 - P4	90	56
5	M2 - RVCOIL	119	74
6	M3 - M2	68	42
7	M3 - P4	61	38
8	M3 - RVCOIL	93	58
9	P4 - M2	32	20
10	P4 - RVCOIL	40	25

The table below summarizes the utilization of individual electrodes (D1, M2, M3 and P4) as anode or cathode to form multiple vectors. It is important to understand how often each electrode is part of the vector configuration with a capture threshold of < 2.5V during the three-month visit. Each electrode is frequently associated (i.e., is part of the vector as a cathode or anode) with a vector configuration with capture threshold < 2.5V. Outcomes at the pre-discharge and one-month visit were similar to the three-month visit.

Table 257. Patients with capture thresholds < 2.5V using D1, M2, M3, and P4 electrodes at three months

	Capture threshold <2.5V @ 3 Months	
Electrodes	# of pts (N = 161)	% of pts
D1	145	90
M2	119	74
M3	93	85
P4	137	85

The table below displays the lead impedance performance at the three month visit. Outcomes at the pre-discharge and one-month visit were similar to the three-month visit. Impedance values are within normal limits for all ten vectors. The nonstandard vectors (vectors 8 and 10) provide two additional lower impedance options for the clinician to utilize.

Table 258. LV lead impedance (Ω) for the ten vectors at follow-up visits

Vector Type	Three Month Follow-Up (N=161) Mean ± SD (n)
Vector 1=D1-M2	1071.4 ± 277.1 (161)
Vector 2=D1-P4	1051.7 ± 256.4 (161)
Vector 3=D1-RVcoil	591.8 ± 159.1 (161)
Vector 4=M2-P4	1022.4 ± 290.3 (161)
Vector 5=M2-RVcoil	557.4 ± 154.0 (160)
Vector 6=M3-M2	1022.9 ± 305.5 (160)
Vector 7=M3-P4	1000.3 ± 298.7 (160)
Vector 8=M3-RVcoil	543.8 ± 156.0 (160)
Vector 9=P4-M2	1046.1 ± 303.1 (160)
Vector 10=P4-RVcoil	509.1 ± 144.5 (160)

Final Vector Programming

In the IDE study, the final vector selection was left to the physician's discretion. Physicians could program any of the available ten vectors. As shown in the data above, physicians had multiple vector options available to choose from. The data in the table below show that physicians initially chose to program the vectors they were most familiar with (i.e., standard vectors). As the follow-ups progressed from pre-discharge to one-month to three-month, it appeared that the physicians started to program nonstandard vectors (in the mid and basal region) more frequently.

Table 259. Final Programmed Vectors at Follow Up Visits

Vector		Programmed at Pre-discharge		Programmed at 1 month		Programmed at 3 months	
		# of pts (n = 170)	% of pts	# of pts (n = 168)	% of pts	# of pts (n = 164)	% of pts
1	D1 - M2	90	52.9	89	53.0	79	22.0
3	D1 - RVCOIL	34	20.0	38	22.6	36	22.0
5	M2 - RVCOIL	28	16.5	20	87.5	142	86.6
Total		152	89.4	147	87.5	142	86.6
2	D1 - P4	1	0.6	0	0.0	1	0.6
5	M2 - P4	2	1.2	3	1.8	1	0.6
6	M3 - M2	0	0.0	0	0.0	1	0.6
7	M3 - P4	1	0.6	56	34	61	38
8	M3 - RVCOIL	6	3.5	10	6.0	12	7.3
9	P4 - M2	0	0.0	0	0.0	0	0.0

Table 259. Final Programmed Vectors at Follow Up Visits

Vector		Programmed at Pre-discharge		Programmed at 1 month		Programmed at 3 months	
		# of pts (n = 170)	% of pts	# of pts (n = 168)	% of pts	# of pts (n = 164)	% of pts
10	P4 - RVCOIL	8	4.7	6	3.6	4	2.4
Total		18	10.6	21	12.5	22	13.4

Successful Reduction (%) of Capture Thresholds and Elimination (%) of Phrenic Nerve Stimulation by VectSelect Quartet™ LV pacing options

The ability to switch among the ten LV-lead vectors of the Quartet lead (VectSelect Quartet™ LV pacing options) was evaluated for successful reduction of capture threshold and elimination of phrenic nerve stimulation (PNS). High pacing thresholds and PNS are often observed in cardiac resynchronization therapy systems. Approaches to avoiding and managing these problems include device programming, reoperation, or abandonment of the left ventricular lead. Additional vectors reduce the need for invasive interventions by offering additional programming options. The VectSelect™ capability of the Quartet lead prevents the need for invasive interventions for LV lead-related issues. The successful reduction of capture thresholds and elimination of PNS by the VectSelect Quartet LV pacing options are presented below. The table below displays the incidence and resolution of PNS and elevated capture threshold in the Quartet and QuickFlex™ µ LV leads.

Table 260. Resolution of PNS and Elevated Capture Thresholds

	Patients in Promote Q/ Quartet IDE (N=178)	Patients in QuickFlex µ IDE(N=86)
Phrenic Nerve Stimulation (PNS) Comparison		
Patients (%) in whom PNS was clinically observed	23 (12.9%)	10 (11.6%)
Patients (%) in whom PNS was clinically observed and could not be resolved	0 (0%)	2 (20%)
Patients (%) in whom PNS was clinically observed and resolved by switching to a different pacing configuration	17 (74%)	4 (40%)
Patients (%) in whom PNS was clinically observed and resolved by changing pacing output	6 (26%)	4 (40%)
Elevated Capture Threshold Comparison		
Patients (%) in whom elevated capture thresholds were observed	1(0.6%)	1(1.2%)
Patients (%) in whom elevated capture threshold was clinically observed and resolved by switching to a different pacing configuration	1(0.6%)	1(1.2%)

In the Quartet LV lead, diaphragmatic/phrenic nerve stimulation was eliminated by changing the pacing vector in 17 out of 23 (74%) patients.

As shown in the table below, standard pacing vectors were associated more often with PNS adverse events than nonstandard pacing vectors.

Table 261. Vectors used to resolved PNS Adverse Events

Quartet Configuration	Resolution of PNS with VectSelect Quartet LV pacing options N=17(%)
Standard pacing vectors (N=10)	
Vector 1=D1-M2	5 (29.4%)
Vector 3=D1-RVcoil	3 (17.6%)
Vector 5=M2-RVcoil	2 (11.8%)
Nonstandard pacing vectors (N=7)	
Vector 2=D1-P4	0 (0%)

Table 261. Vectors used to resolved PNS Adverse Events

Quartet Configuration	Resolution of PNS with VectSelect Quartet LV pacing options N=17(%)
Vector 4=M2-P4	0 (0%)
Vector 6=M3-M2	0 (0%)
Vector 7=M3-P4	1 (5.9%)
Vector 8=M3-RVcoil	5 (29.4%)
Vector 9=P4-M2	0 (0%)
Vector 10=P4-RVcoil	1 (5.9%)

Summary of Conclusions from Promote Q/Quartet IDE study:

- The freedom from left ventricular lead-related complications through three months was estimated at 96% with a 97.5% LCB of 93%. This primary safety endpoint was met at the 2.5% significance level.
- The freedom from system-related complications through three months was estimated as 92% with a 97.5% LCB of 88%. This co-primary safety endpoint was met at the 2.5% significance level.
- Utilizing the complete case analysis, the primary effectiveness endpoint was estimated as 83.9% with a 97.5% LCB of 77.2%. This primary effectiveness endpoint was met at the 2.5% significance level.
- Out-of-clinic diaphragmatic/phrenic nerve stimulation was reported in 23 (14.3%) of patients with a successful implant and all of these events were resolved without invasive intervention. Diaphragmatic/phrenic nerve stimulation was eliminated by changing the pacing vector in 17 out of those 23 (73.9%) patients.
  - Standard pacing vectors were associated more often with PNS adverse events than nonstandard pacing vectors.
  - Both standard and nonstandard pacing vectors were used to resolve PNS. Out of the nonstandard vectors, vector 8 was a common vector that was used to resolve PNS.
- Multiple vector options with capture threshold < 2.5V were available for programming for patients at each visit and each programmable electrode was frequently utilized in a vector configuration with capture threshold < 2.5V across different follow-up visits.
- Impedance values are within normal limits for all ten vectors. The nonstandard vectors provide two additional lower impedance options for the clinician to utilize.

Summary of Published Literature

The Quartet™ LV lead can enable LV pacing at the preferred site without compromising lead stability for better management of heart failure patients. Multiple published studies have been conducted that demonstrate the clinical benefits of this system.

Intra-operative clinical benefits

Unpredictable patient anatomy and pacing complications such as PNS or high thresholds may decrease implant efficiency by requiring LV lead repositioning. However, the four electrodes of the Quartet lead provide more options to better manage implant challenges in CRT patients and to reduce the need for lead repositioning.

- Dänschel et al. reported that in 31% of patients (21/68), novel pacing vectors on the quadripolar electrode lead were utilized to avoid lead repositioning due to pacing complications such as PNS or high thresholds[480].
- In a separate 45 patient study by Forleo et al., lead repositioning was avoided in 6/7 patients in the quadripolar electrode lead group presenting with significant PNS while all 5 patients exhibiting PNS in the bipolar electrode lead group required lead repositioning to a different vein[481].
- In a study of 33 patients, Thibault et al. demonstrated that the Quartet lead allowed for resolution of PNS without the need to reposition the lead in 100% (9/9) of patients experiencing PNS during implant[482]. Repositioning can lead to implant times about 23 minutes longer than the average procedure[483].

Post-implant clinical benefits

After implant, the inability to resolve PNS or high thresholds may necessitate surgical LV lead revisions, which are often associated with pocket re-entry risks, such as infection.

- As observed in the Promote Q/Quartet IDE, PNS was resolved through programming in 100% (23/23) of cases post-operatively[484]. The need for surgical revision or reprogramming due to PNS, high thresholds, or lead dislodgement has been shown to be significantly less in patients with the Quartet lead than those with a conventional bipolar lead[485].

[480] Dänschel, W. et al. Initial clinical experience with a novel left ventricular quadripolar lead. Oral Session 183/5. Europace, 2010; 12 (suppl 1): i127. Abstract 183/5.
[481] Forleo, GB. et al. Left ventricular pacing with a new quadripolar transvenous lead for CRT: early results of a prospective comparison with conventional implant outcomes. Heart Rhythm. 2011 Jan;8(1):31-7.
[482] Thibault, B. et al. Electrode Selection to Avoid Phrenic Stimulation with a Quadripolar Left Heart Lead. Heart Rhythm 8: AB30-3 (2011).
[483] 1042 patients. Data on file at St. Jude Medical.
[484] Tomassoni G, et al. Post Operative Performance Of A Novel Left Ventricular Quadripolar Electrode Lead, Heart Rhythm 8: P01-43 (2011).
[485] Forleo, GB. et al. Left ventricular pacing with a new quadripolar transvenous lead for CRT: early results of a prospective comparison with conventional implant outcomes. Heart Rhythm. 2011 Jan;8(1):31-7.

- Sperzel et al. noted a 1.4% (1/70) surgical revision rate for the Quartet lead at one month post-implant[486] which is lower than LV lead surgical revision rates reported in the literature (4%)[487].
- Additionally, Sperzel et al. demonstrated that at one month post implant, the additional proximal electrodes available on the Quartet lead were used in 24% (16/67) of cases to optimize pacing parameters and prevent cases of PNS[488].

As is shown in these study results, the Quartet LV lead offers noninvasive lead repositioning options that may reduce the need for surgical revisions and improve post-operative efficiency.

The additional electrode choices available with the Quartet LV lead make it possible to advance the distal tip close to the apex of the heart where the lead is often more stable while retaining the ability to pace in a more basal region by using the proximal electrodes (See figure above (page 372)). Recent analysis of the MADIT-CRT data has shown that LV pacing in an apical position could double the propensity for heart failure hospitalization or death when compared to pacing in a more basal location[489]. Merchant et al. also found that patients with apical LV pacing showed less improvement in NYHA class and less LV reverse remodeling compared to those with mid-ventricle or basal pacing[490]. The Quartet lead uniquely enables LV pacing in a more basal region without compromising a stable lead position.

DecisionTx™ Programming

Performance Analysis of DecisionTx™ Programming in Combination with Low Frequency Attenuation and ATP

Analysis was performed to evaluate the effect of the following St. Jude Medical™ (SJM) features in decreasing the number of inappropriate and unnecessary shocks.

- DecisionTx™ Programming, a group of parameter settings designed to optimize SVT Discrimination (see SVT Discrimination Criteria Programming Guidelines)
- Antitachycardia pacing (ATP)
- Low Frequency Attenuation, a filtering algorithm designed to improve sensing

The analysis was performed using data from the Advancements in ICD Therapy (ACT) registry, an SJM sponsored data collection effort that followed over 5,000 ICD and CRT-D patients for a two-year period. No specific programming guidelines were provided at implant or during follow-up in the ACT registry.

Patients selected for this performance analysis were required to have:

- One or more VT/VF Detections (appropriate or inappropriate) at some time during the two-year follow-up period
- A stored EGM associated with at least one of the VT/VF Detections
- Morphology scores available in the stored EGMs (Morphology Discrimination did not have to be enabled)

A total of 824 patients met these qualifications, comprising 3,805 VT/VF Detections. One episode/EGM documenting VT/VF Detection was randomly selected from each of the 824 patients and used for the analysis. Eleven EGMs were found not analyzable, leaving a total of 813 episodes for the analysis.

Impact of DecisionTx™ Programming

The analysis compared the diagnosis of each episode to the predicted outcome had the DecisionTx™ Programming settings been programmed at the time of the episode. Fifty-eight SVT episodes occurring during the two-year follow-up period were diagnosed as VT and treated with unnecessary HV therapy. Analysis of these episodes found that 47 episodes (80.3%) would have been correctly diagnosed as SVT with DecisionTx Programming and would have not been treated with HV therapy. Thus, using the DecisionTx Programming settings would have resulted in an 80.3% decrease in the number of SVTs inappropriately treated with HV Therapy.

Impact of ATP Usage

An analysis by Sweeney et al.[491] of four prospective trials found that ATP as the first therapy converted an average of 92.4% of VTs occurring at rates < 188 bpm and 82.5% of VTs occurring at rates between 188 bpm and 250 bpm. DecisionTx™ Programming includes ATP as the initial therapy in all rate zones. The analysis found that using programming guided by DecisionTx Programming parameters would result in a 40.7% reduction in the delivery of HV Therapy. There were a small number of episodes (1.7%) that were unsuccessfully treated with ATP and required HV therapy to terminate the VT/VF Episode. As ATP was initially attempted for these episodes, DecisionTx Programming did not impact their outcome.

Low Frequency Attenuation Enabled

Bench-testing has demonstrated that the enhanced Low Frequency Attenuation filter eliminates oversensing of the T-wave in 95% of tested QRS-complexes[492]. Analysis of these episodes found that 100% of episodes incorrectly diagnosed as VT/VF due to T-wave oversensing would have been eliminated. Thus, none of these episodes that received HV therapy would have resulted in shock had the filter been applied.

---

[486] Sperzel JK, et al. Initial clinical experience with a novel left ventricular quadripolar lead [abstract]. HRS 2010 Poster Session 5 Friday, May 14, 2010, 2:00 PM-5:00 PM, [PO5-151].
[487] Moss AJ, et al. Cardiac-Resynchronization Therapy for the Prevention of Heart-Failure Events. N Engl J Med 2009;361:1329-1338.
[488] Sperzel JK, et al. Initial clinical experience with a novel left ventricular quadripolar lead [abstract]. HRS 2010 Poster Session 5 Friday, May 14, 2010, 2:00 PM-5:00 PM, [PO5-151].
[489] Singh, JP. et al. Left ventricular lead position and clinical outcome in the Multicenter Automatic Defibrillator Implantation Trial Cardiac Resynchronization Therapy (MADIT-CRT) trial. Circulation. 2011 Mar 22;123(11):1159-66.
[490] Merchant, FM. et al. Impact of segmental left ventricle lead position on cardiac resynchronization therapy outcomes. Heart Rhythm 2010;7:639 - 644.
[491] Sweeney et al. Differences in effects of electrical therapy type for ventricular arrhythmia on mortality in implantable cardioverter-defibrillator patients. Heart Rhythm. 2010; 7(3); 353-360.
[492] Report on file, St. Jude Medical, Sylmar, California.

Summary

The analysis found that 18.2% of episodes detected as VT/VF in the ACT registry were treated with HV therapy. However, had the patients been able to benefit from the use of DecisionTx™ Programming, in combination with improved sensing with the Low Frequency Attenuation Filter and use of ATP as the initial therapy, only 7.8% of episodes detected as VT/VF would have been treated with a shock (see the table below)). For VT/VF episodes <250 bpm, the percentage receiving HV therapy would decrease from 5.1% to 0.84%. Furthermore, 98.5% of VT/VF Detections would have been managed without inappropriate delivery of HV therapy.

Table 262. Summary of results of the impact of DecisionTx™ Programming on VT/VF episodes from the ACT Registry

Cause of Shock	Baseline	DecisionTx™ Programming	
	% of VT/VF Detections treated with HV Therapy	Projected % of VT/VF Detections treated with HV Therapy	Projected % Reduction
VT/VF	10.6%	6.3%	40.7%
VT (<188 bpm)	0.5%	0.04%	
VT (188-250 bpm)	4.6%	0.8%	
VT (>250 bpm) & VF	3.8%	3.8%	
Unsuccessful ATP	1.7%	1.7%	
Non-VT/VF	7.6%	1.5%	80.3%
SVT	7.1%	1.4%	
Oversensing	0.4%	0.0%	
Other (bigeminy, noise, etc)	0.1%	0.1%	
Total	**18.2%**	**7.8%**	**57.1%**
	Baseline	**DecisionTx™ Programming**	
% of VT/VF detections not treated with HV therapy	81.8%	92.2%	
% of VT/VF detections without inappropriate HV therapy	92.4%	98.5%	

Acute IEGM Studies

Description of the Acute IEGM Studies

The Acute Evaluation of Programmer Guided PV and AV Delays Using IEGM Method and Echocardiogram for Optimization Study, (Acute IEGM PV and AV Study) and the Acute Evaluation of Programmer Guided VV Delay Using IEGM Method and Echocardiogram for Optimization in Cardiac Resynchronization Therapy (Acute IEGM-CRT VV Study) were acute, multi-center clinical trials designed to determine if the IEGM method of optimizing PV and AV delays and VV delay, respectively, was comparable to standard echo determinations.

This was assessed using the Concordance Correlation Coefficient (CCC) for the paired aortic velocity time integral (AVTI) values on each patient.

Inclusion/Exclusion Criteria

Table 263. Inclusion and exclusion criteria

	Acute IEGM PV and AV Study	Acute IEGM-CRT VV Study
Inclusion Criteria	Patient has been implanted with a St. Jude Medical™ Dual-Chamber ICD[493] or CRT-D[494].	Patient has been implanted with a St. Jude Medical CRT-D[495].
	Patient can provide informed consent for study participation and be willing and able to comply with the prescribed tests.	
Exclusion Criteria	No intrinsic atrial activity (atrial rate ≤ 40 bpm).	AV block or no intrinsic atrial activity (atrial rate ≤ 40 bpm).
		Have RV ring anodal stimulation during LV pacing at

[493] PhotonDR, PhotonμDR, EpicDR, Epic+DR, AtlasDR, or Atlas+DR device.
[494] EpicHF or Atlas+HF device.
[495] EpicHF or Atlas+HF device.

Table 263. Inclusion and exclusion criteria

	Acute IEGM PV and AV Study	Acute IEGM-CRT VV Study
		two times the voltage of the LV capture threshold.
	Have Atrial Fibrillation at the time of the study testing and evaluation.	
	Unable to provide analyzable echocardiographic images. (For example, due to an inadequate acoustic window).	
	Have undergone an echocardiographic assessment within the previous two hours.	
	Under the age of 18 years.	
	Pregnant at the time of testing.	

Patient Population

A summary of the enrollment assessment information on all patients included in the Acute IEGM PV and AV Study and the Acute IEGM-CRT VV Study is shown in the following table.

Table 264. Enrollment assessment information

Demographic Variable	Acute IEGM PV and AV Study Overall Group (N = 58)	Acute IEGM-CRT VV Study Overall Group (N = 57)
Age (years):		
Mean ± SD	68 ± 11	71 ± 10
Range	41-89	42-89
Gender, n (%):		
Male	47 (81%)	42 (74%)
Female	11 (19%)	15 (26%)
NYHA Class, n (%):		
I	3 (5%)	0
II	20 (34%)	10 (18%)
III	30 (52%)	43 (75%)
IV	4 (7%)	4 (7%)
No Heart Failure	1 (2%)	0
LV Ejection Fraction (%):		
Mean ± SD	26 ± 10[496]	24 ± 9
Range	10-60	10-49
QRS Duration (ms):		
Mean ± SD	134 ± 32	148 ± 24
Range	80-200	100-206
Cardiomyopathy Classification:		
Ischemic, n (%):		
Non-Ischemic, n (%):	43 (74%)	35 (61%)
None	14 (24%)	22 (39%)
	1 (2%)	0

Patient Cohort for the Acute IEGM PV and AV Study

Fifty-eight patients were enrolled in the Acute IEGM PV and AV Study. For the PV delay determination, two patients could not have AVTI measurements performed at the PV delays determined by the IEGM method due to the presence of intrinsic conduction. Therefore, a total of 56 patients with paired AVTI measurements for the PV delay determinations were used for this analysis. For the AV delay determination, two patients could not have AVTI measurements performed at the AV delays determined by the IEGM method due to the presence of intrinsic conduction. Therefore, a total of 56 patients with paired AVTI measurements for the AV delay determinations were used for this analysis.

[496] Two patients did not have LVEF available.

Patient Cohort for the Acute IEGM-CRT VV Study

Fifty-seven patients were enrolled in the Acute IEGM-CRT VV Study. The IEGM method test was unable to be conducted on one patient due to their programmed sensitivity settings. The IEGM AVTI image was inadvertently not saved on the site's original echo tape for a second patient. And a third patient's data was not able to be analyzed due to a protocol deviation whereby the AVTI measurement using the IEGM-derived VV delay value was not performed (the site mistakenly repeated the AVTI measurement using the Echo-optimal VV delay and, as a result, no paired data was available). Therefore, analyzable data was available for a total of 54 patients and was used to evaluate the primary endpoint for the VV delay determination.

Of the 54 analyzable patients, the AVTI values for the IEGM VV delays were not measured at the Echo-derived optimal PV delays as specified in the protocol for two patients. For one patient, the PV delay was programmed to 120 ms instead of the optimal PV delay of 100 ms and for the other patient the PV delay was programmed to 120 ms instead of the optimal PV delay of 160 ms. Although the AVTI measurements at these suboptimal VV delays do not correlate as well with the maximum AVTI measured with the optimal PV delay and therefore, reduce the likelihood of proving the effectiveness of the IEGM algorithm, both of these patients are included in the primary analysis in order to avoid bias.

Primary Objectives

The Acute IEGM PV and AV Study

The study endpoints were the CCC between the maximum echo aortic VTI (Max Echo AVTI) and AVTI at the PV and AV delays determined by the IEGM AVTI. Per the protocol, the Max Echo AVTI values for PV delay and AV delay were determined as the maximum AVTI value of a total of seven selected PV and AV delays including the IEGM-predicted PV and AV delays. The primary hypothesis was assessed based on the first 52 analyzable patients for each with a two-sided p-value together with a two-sided 95% confidence interval (CI) of the CCC. Analyses based on all analyzable patients are also presented.

The specific objectives were:

- The CCC between the Max Echo AVTI and AVTI at the PV delay determined by the IEGM method will not be less than 0.90.
- The CCC between the Max Echo AVTI and AVTI at the AV delay determined by the IEGM method will not be less than 0.90.

The Acute IEGM-CRT VV Study

The study endpoint was the CCC between the Max Echo AVTI and AVTI at the VV delay determined by the IEGM method. Per the protocol, the Max Echo AVTI value was determined as the maximum AVTI value of a total of ten (10) selected VV delays including the IEGM-predicted VV delay. The primary hypothesis was assessed based on the minimum required sample size of 52 analyzable patients with a two-sided p-value together with a two-sided 95% confidence interval of the CCC. Analyses based on all analyzable patients are also presented.

The specific objective was:

- The CCC between the Max Echo AVTI and AVTI at the VV delay determined by the IEGM method will not be less than 0.90.

Study Results

Minimum Sample Size Cohort Analysis

Table 265. Minimum sample size cohort analysis

	Evaluation Method	Median AVTI (cm)	Mean AVTI ± SD (cm)	Median Optimized Delay (ms)	Mean Optimized Delay ± SD (ms)
PV Delay (n = 52)	Max Echo	26.1	27.9 ± 10.1	130	124 ± 32
	IEGM	24.5	26.3 ± 9.3	130	128 ± 16
	The CCC between Max Echo AVTI and IEGM AVTI values was 96.7% with the 95% CI of (94.6% 98.0%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore, the objective was met and the IEGM method was in agreement with the Echo optimization for determining the PV delay.				
AV Delay (n = 52)	Max Echo	25.8	25.7 ± 9.0	170	167 ± 28
	IEGM	24.1	24.5 ± 8.5	180	178 ± 16
	The CCC between Max Echo and IEGM AVTI values was 97.7% with a 95% CI of (96.2%, 98.6%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore the objective was met and the IEGM method was in agreement with the Echo optimization for determining the AV delay.				
VV Delay (n = 52)	Max Echo	26.8	27.9 ± 8.9	15 (LV First)	14 ± 45 (LV First)
	IEGM	25.8	26.3 ± 8.6	10 (LV First)	13 ± 21 (LV First)
	The CCC between Max Echo and IEGM AVTI values was 96.6% with a 95% CI of (94.4%, 98.0%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore the objective was met and the IEGM method was in agreement with the Echo optimization for determining the VV delay.				

All-Patient Analysis

Table 266. All-patient analysis

	Evaluation Method	Median AVTI (cm)	Mean AVTI ± SD (cm)	Median Optimized Delay (ms)	Mean Optimized Delay ± SD (ms)
PV Delay (n = 56)	Max Echo	26.1	27.7 ± 9.9	125	123 ± 32
	IEGM	24.6	26.1 ± 9.1	130	128 ± 16
	The CCC between Max Echo AVTI and IEGM AVTI values was 96.1% with the 95% CI of (93.7% 97.6%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore, the objective was met and the IEGM method was in agreement with the Echo optimization for determining the PV delay.				
AV Delay (n = 56)	Max Echo	24.7	25.5 ± 8.8	170	165 ± 28
	IEGM	23.6	24.2 ± 8.4	180	178 ± 16
	The CCC between Max Echo and IEGM AVTI values was 97.5% with a 95% CI of (96.0%, 98.5%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore the objective was met and the IEGM method was in agreement with the Echo optimization for determining the AV delay.				
VV Delay (n = 54)	Max Echo	26.5	27.7 ± 8.8	15 (LV First)	15 ± 44 (LV First)
	IEGM	25.1	26.2 ± 8.5	10 (LV First)	13 ± 20 (LV First)
	The CCC between Max Echo and IEGM AVTI values was 96.6% with a 95% CI of (94.4%, 97.9%), exceeding the objective performance criteria of 90%. The two-sided p-value assessing the primary hypothesis was <0.01. Therefore the objective was met and the IEGM method was in agreement with the Echo optimization for determining the VV delay.				

Summary

In summary, the primary study objectives were met for the PV delay, AV delay, and VV delay determinations. Thus, the IEGM method is effective in deriving the optimized PV, AV, and VV delays in comparison to the standard Echo optimization method.

ADOPT-A Study

Summary of the ADOPT-A Clinical Study

The purpose of the ADOPT-A clinical study was to evaluate the safety and efficacy of the AF Suppression™ pacing feature (formerly called Dynamic Atrial Overdrive or DAO). Since the AF Suppression pacing feature included in the Current™ and Promote™ devices is functionally identically to the feature in the pacemakers implanted in the ADOPT-A study, no additional clinical evaluation was performed. 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 three 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, eight Canadian Centers, and three 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. The patient characteristics are shown in the following table. 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. The additional reported indications for implant are shown in the following table.

Table 267. Patient characteristics

	DAO OFF (n=196)	DAO ON (n=203)
Mean Age	71.22 ± 9.81	71.31 ± 9.97
Male	50%	51%

Table 267. Patient characteristics

	DAO OFF (n=196)	DAO ON (n=203)
Female	50%	49%
Mean Left Ventricular Ejection Fraction	57% ± 12	56% ±13
Mean Symptomatic Atrial Fibrillation Episodes Prior to Implant (six months)	7.89 ± 4.24	8.14 ± 4.19

Table 268. Additional indications for pacemaker implant

	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%)

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 six-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.

The distribution of AF Burden over time is shown in the following figure. The AF Burden Reduction is shown in the following table. 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.

A statistically significant and consistently decreasing AF burden observed over time between DAO ON vs. DAO OFF group ($p<0.05$) is shown in the following figure and table.

Figure 45. Distribution of AF burden

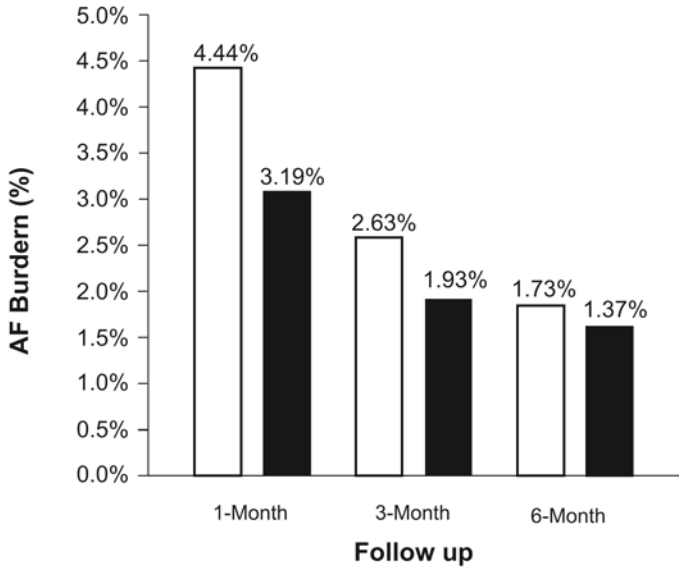


Table 269. AF burden reduction

	DAO OFF	DAO ON
Total Patients	158	73
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%

Secondary objective results are further described below:

- **Symptomatic AF Episodes.** There is a statistically significant reduction in the number of symptomatic AF episodes six months post implant compared to six 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.

Adverse Events

None of the deaths or complications that occurred during the clinical study was related to the DAO algorithm. The only DAO-related observation was intolerance to high rate pacing reported in five patients, two of which were resolved by either medication or programmed parameter adjustment.

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.

AF Suppression™/CRT-D Study

Summary of the AF Suppression™/CRT-D Study

The Atrial Fibrillation Suppression Pacing in Cardiac Resynchronization Therapy Devices (AF Suppression™/CRT-D) study was a prospective, randomized study designed to demonstrate that AF Suppression pacing does not negatively affect CRT effectiveness in patients receiving CRT-D therapy.

The clinical study was conducted using the Epic+™ HF V-352 and Atlas™+ HF V-344 devices. However, the data collected also applies to the Promote™ devices. Since the Promote devices are functionally equivalent to the Epic+/Atlas+ devices with respect to the AF Suppression Pacing feature, no additional clinical evaluation was required to support the safety and effectiveness of the Promote CRT-Ds.

The objective of this clinical study was to demonstrate that AF Suppression pacing does not negatively affect CRT effectiveness in patients currently receiving CRT therapy. Since the AF Suppression feature would not typically be turned on immediately after device implantation, and since the primary objective was to demonstrate that the addition of AF Suppression pacing does not negatively impact the known efficacy of CRT in patients currently receiving CRT, the study enrolled patients who were already receiving CRT therapy with stable heart failure symptoms.

The study was a multi-center, randomized, blinded, controlled clinical study. Patients enrolled in this study were randomized in a 1:1 ratio to one of two groups: CRT with AF Suppression ON and CRT with AF Suppression OFF. The primary endpoint of the study was comparison of the mean change in Six-Minute Hall Walk distance at three months.

Study Inclusion and Exclusion criteria are listed below:

Inclusion Criteria

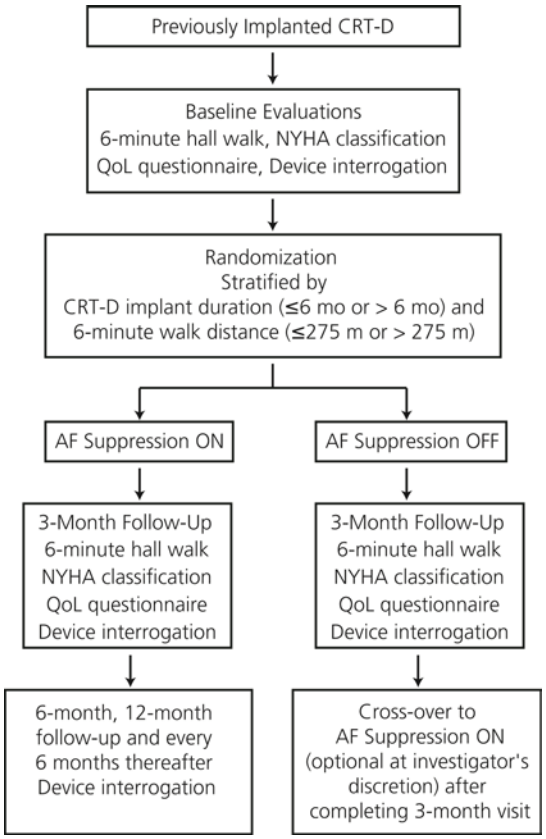
- Previously implanted SJM CRT-D pulse generator capable of AF Suppression pacing for a minimum of three months.
- Stable HF symptoms (i.e., no heart failure hospitalizations or need for intravenous inotropes or diuretics within 30 days of enrollment) while receiving cardiac resynchronization therapy.
- Ability to complete the Six-Minute Hall Walk Test with the only limiting factor(s) being related to their cardiac fitness.
- Ability to independently comprehend and complete a quality of life questionnaire.
- Ability to provide informed consent for study participation. Willingness and ability to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria

- Continuous atrial fibrillation (continuous is defined as AF lasting > One Month) within one-year prior to enrollment
- Classification of Status 1 for cardiac transplantation or consideration for transplantation over the next three months.
- Recent myocardial infarction, unstable angina or cardiac revascularization (PTCA, stent or CABG) within 40 days of enrollment.
- Recent CVA or TIA within three months of enrollment.
- Participating in a clinical investigation that includes an active treatment arm.
- Pregnant or a planning for pregnancy in the next six months.
- Life expectancy of less than six months.
- Less than 18 years of age.

The study design for the trial is shown in the following figure. The total time of follow-up from the time of randomization as of June 28, 2006 was 948.6 patient-months. The average time of follow-up was 5.0 ± 2.4 (range < 1 to 9.3) patient months.

Figure 46. Study overview



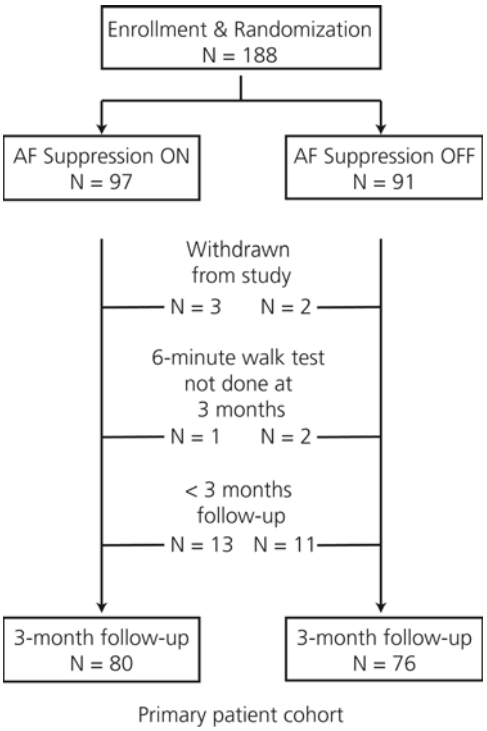
Patient Population

Patient Population

A total of 188 patients were enrolled in the AF Suppression/CRT-D study. All patients were randomized at the end of the baseline visit. Randomization was blocked by investigational site. Of the 188 patients, 97 were randomized to the AF Suppression ON group and 91 were randomized to the AF Suppression OFF group.

The analyzable patient group for the study is shown in the following.

Figure 47. Analyzable patient group



A summary of baseline information for the 156 patients who completed a six-minute walk test at three months is shown in the following table. This patient group will be included in the primary analysis of the primary endpoint. The baseline information is also broken down by randomization group. The table shows that the two groups are comparable in all variables presented.

Table 270. Comparison of baseline variables between the treatment and control groups for the primary patient cohort (N = 156)

Variable	Overall Group (N=156)	AF Suppression ON (N = 80)	AF Suppression OFF (N = 76)	p-value ON vs. OFF
Age				0.35
Mean ± SD	68.6 ± 10.2	69.4 ± 10.8	67.8 ± 9.5	
Range	(38,88)	(38,88)	(47,87)	
Gender				0.35
Male	118 (76%)	63 (79%)	55 (72%)	
Female	38 (24%)	17 (21%)	21 (28%)	
NYHA Class, n (%)				0.66[497]
I	12 (8%)	5 (6%)	7 (9%)	
II	83 (53%)	45 (56%)	38 (50%)	
III	57 (37%)	28 (35%)	29 (38%)	
IV	2 (1%)	1 (1%)	1 (1%)	
Not reported	2 (1%)	1 (1%)	1 (1%)	
LV Ejection Fraction (%)				0.55
Mean ± SD	28.2 ± 11.3	27.6 ± 9.8	28.7 ± 12.7	
Range	(8,70)	(9,61)	(8,70)	
Cardiomyopathy Classification, n (%)				0.95
Ischemic[498]	129 (83%)	66 (83%)	63 (83%)	
CAD	125 (97%)	64 (97%)	61 (97%)	
Myocardial Infarction	101 (78%)	55 (83%)	46 (73%)	
	78 (60%)	39 (59%)	39 (62%)	

[497] This p-value was calculated by combining Class III and IV as one category.
[498] Individual patients may be included in more than one subcategory.

Table 270. Comparison of baseline variables between the treatment and control groups for the primary patient cohort (N = 156)

Variable	Overall Group (N=156)	AF Suppression ON (N = 80)	AF Suppression OFF (N = 76)	p-value ON vs. OFF
CABG	51 (40%)	27 (41%)	24 (38%)	
PTCA	21 (16%)	11 (17%)	10 (16%)	
Unstable Angina	27 (17%)	14 (18%)	13 (17%)	
Non-Ischemic	7 (26%)	3 (21%)	4 (31%)	
Hypertensive	9 (33%)	4 (29%)	5 (38%)	
Idiopathic	4 (15%)	3 (21%)	1 (8%)	
Valvular	7 (26%)	4 (29%)	3 (23%)	
Other				
Atrial Arrhythmia History, n (%)	66 (42%)	37 (46%)	29 (38%)	0.31
Other Medical History[499], n (%)				
Hypertension	120 (77%)	62 (78%)	58 (76%)	0.86
Diabetes	65 (42%)	32 (40%)	33 (43%)	0.66
COPD	31 (20%)	13 (16%)	18 (24%)	0.24
Other	83 (53%)	43 (54%)	40 (53%)	0.89
None	8 (5%)	4 (5%)	4 (5%)	0.94
Baseline Medications, n (%)				
ACE	100 (64%)	49 (61%)	51 (67%)	0.45
ARB	33 (21%)	18 (23%)	15 (20%)	0.67
Beta Blockers	148 (95%)	78 (98%)	70 (92%)	0.13
Diuretics	125 (80%)	59 (74%)	66 (87%)	0.04
Positive Inotropes	57 (37%)	25 (31%)	32 (42%)	0.16
Nitrates	41 (26%)	19 (24%)	22 (29%)	0.46
Anti-Coagulants/Anti-Platelets	117 (75%)	54 (68%)	63 (83%)	0.03
Calcium Channel Blockers	13 (8%)	7 (9%)	6 (8%)	0.85
Antiarrhythmics	42 (27%)	23 (29%)	19 (25%)	0.60
Anti-Hypertensives	62 (40%)	30 (38%)	32 (42%)	0.56
Quality of Life (total):	34.4 ± 26.2	32.7± 25.7	36.2 ± 26.9	0.41
Mean ± SD	(0,98)	(0,93)	(0,98)	
Range				
6-Minute Hall Walk Distance (m):	315 ± 115	313 ± 127	318 ± 100	0.82
Mean ± SD	(37,641)	(37,641)	(37,579)	
Range				

Primary Objective and Results

The data was cut off when a total of 156 patients completed a six-minute walk test at three months.

The primary endpoint is based on the mean change in six-minute walk distance from baseline to three months in the ON and OFF groups. Patients were analyzed in their randomized group according to intention-to-treat.

The walk distance at Baseline and three months, as well as the difference between Baseline and three months in each of the ON and OFF groups is shown in the following table. The 95% lower confidence bound on the difference between the mean change in the ON group and OFF group, based on a two-sample t-distribution is -9.3 m, which is greater than the pre-specified objective criterion of -20 m. Hence, the null hypothesis is rejected, and therefore the mean change in the AF Suppression ON group is not inferior to the mean change in the AF Suppression OFF group.

Table 271. Baseline and three-month six-minute walk distance

	AF Suppression ON Mean ± SD (m) (N = 80)	AF Suppression OFF Mean ± SD (m) (N = 76)
Baseline	313 ± 127	317 ± 100
3-months	315 ± 128	314 ± 107
Change	2 ± 55	-3 ± 52

[499] Individual patients may be included in more than one subcategory.

Secondary Objectives and Results

Six-Minute Hall Walk Distance: Comparison of Standard Deviation of Change at Three Months

The standard deviations for the change in six-minute walk distance between three months and baseline is compared between the ON and OFF groups. The p-value for the F test is 0.70, demonstrating that there is no evidence for a difference in standard deviations between the ON and OFF groups.

Additionally, the distribution-free Ranklike test for dispersion was used to test the equality of the standard deviations in the two groups. This is a non-parametric test and does not depend on the normality of the change in walk distance distributions. A subgroup size of six was used to perform this test. The p-value for this test is 0.81, once again demonstrating that there is no evidence for a difference in standard deviations between the ON and OFF groups.

Six-Minute Walk Distance: Comparison of Proportion Increased, No Change, and Decreased

In addition to the primary analysis of the six-minute walk distance, as stated in the protocol, an analysis was carried out on the number of patients who had an increase in walk distance (by more than 10 m), had no change (i.e. change from Baseline was between -10 and 10 m), and decreased (by more than 10 m). This analysis was carried out for the same patient cohort as in the primary analysis of the primary endpoint.

Table 272. Change in walk distance

Change in Walk Distance	AF Suppression ON (N = 80)	AF Suppression OFF (N = 76)
Increased by ≥10 m, n (%)	34 (43%)	30 (39%)
No Change, between -10 m and 10 m, n (%)	14 (18%)	16 (21%)
Decreased by ≤–10 m, n (%)	32 (40%)	30 (39%)
p-value	0.84	

A chi-square test was carried out to compare the proportions between the two groups. As expected, the two groups showed no statistically significant difference (p = 0.84) at the 5% significance level. Hence, once again it is concluded that the change in walk distance is comparable between the ON and OFF groups.

Patient Discontinuation/Withdrawals

A total of seven patients participating in the AF Suppression/CRT-D Study were withdrawn from the study. One patient died and was withdrawn from the study. Of the remaining six patients, four were withdrawn prior to completion of the three-month visit.

A summary of patients who were withdrawn from the study is shown in the following table.

Table 273. Patient discontinuations/withdrawals (excludes withdrawals for deaths)

Reason for Withdrawal	Treatment Group	Days after Enrollment
Participation terminated by investigator	ON	3
Participation terminated by investigator	ON	188
Participation terminated by investigator	ON	9
Patient request	OFF	3
Patient request	ON	86
Patient request	OFF	1

Conclusions Drawn from the Clinical Study

The clinical study results show that there was no statistically significant difference in the mean change in Six-Minute Hall Walk distance at three months between the AF Suppression ON and AF Suppression OFF groups. The secondary endpoints (comparison of the standard deviation of change in Six-Minute Hall Walk distance at three months and the comparison of the proportion increased/unchanged/decreased in the Six-Minute Hall Walk distance at three months) also showed no statistically significant difference between the two groups.

The clinical data demonstrates that AF Suppression pacing does not negatively affect CRT effectiveness in patients receiving CRT-D therapy.

Automaticity Clinical Investigation

Summary of Clinical Investigation

The Automaticity Clinical Investigation was conducted to show that the St. Jude Medical™ Current Accel™ ICD Models CD2215-36 and CD1215-36 and Promote Accel™ CRT-D Model CD3215-36 are safe and effective.

This study was a prospective, non-randomized, multi-center clinical trial. Patients were enrolled at 15 investigational centers located in the US. A total of 128 patients were enrolled in the study. Data are presented on the first 19, 38, and 45 patients available to complete the primary endpoint analysis for the ACap™ Confirm, Ventricular AutoCapture™ (VAC), and LVCap™/RVCap™ Confirm features, respectively, as defined in the protocol. The total time of follow-up was 747.6 patient months. The average time of follow-up was 5.84 ± 1.96 (range 1.38 to 9.00) patient months.

The number of patients implanted with each device model is shown in the following table.

Table 274. Number of Patients with Each Device Model

Device Model	Number of Patients
CD1215-36	14
CD2215-36	33
CD3215-36	81
Total	**128**

Inclusion Criteria:

Eligible patients met all of the following:

- Have an approved indication, as outlined by AHA/HRS guidelines, for implantation of an ICD or a CRT-D for the treatment of life-threatening ventricular tachyarrhythmia(s) or heart failure, or undergo revision of an existing ICD or CRT-D system to replace the pulse generator.
- Have the ability to provide informed consent for study participation and be willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria:

Patients were excluded if they met any of the following:

- Have a classification of Status 1 for cardiac transplantation or consideration for transplantation over the next 3 months.
- •Have had a recent myocardial infarction, unstable angina or cardiac revascularization (PTCA, Stent or CABG) within 40 days of enrollment.
- •Have had a recent CVA or TIA within 3 months of enrollment.
- •Are allergic to dexamethasone sodium phosphate (DSP).
- •Currently participating in a clinical investigation that includes an active treatment arm.
- •Pregnant or are planning for pregnancy within 6 months following enrollment.
- •Have a life expectancy of less than 6 months.
- •Less than 18 years of age.

A summary of the demographic information for all enrolled patients is shown in the following table.

Table 275. Demographic Information for All Enrolled Patients

Demographic	All Patients (N=128)
Age (years)	
Mean ± SD	67 ± 12
Range	39-88
Gender, N (%)	
Male	96 (75%)
Female	32 (25%)
Ventricular Arrhythmia History, N (%)	58 (45%)
Atrial Arrhythmia History, N (%)	46 (36%)
Cardiomyopathy Etiology, N (%)	
Ischemic	87 (68%)
Non-Ischemic	37 (29%)
None	4 (3%)

Table 275. Demographic Information for All Enrolled Patients

Demographic	All Patients (N=128)
Cardiovascular History, N (%)	
Prior Myocardial Infarction	70 (55%)
Prior Unstable Angina	20 (16%)
Prior CABG	50 (39%)
Prior PTCA	46 (36%)
Primary Indication for CRT-D Implant, N (%)	
HF with wide QRS	61 (48%)
HF – no sinus rhythm (ACC/HRS/HFSA Class IIa indication: NYHA Class III or ambulatory Class IV heart failure symptoms, LVEF ≤ 35%, QRS ≥ 120 ms, atrial fibrillation, optimal recommended medical therapy)	3 (2%)
HF – no sinus rhythm and no QRS (ACC/HRS/HFSA Class IIa indication: NYHA Class III or ambulatory Class IV heart failure symptoms, LVEF ≤ 35%, optimal recommended medical therapy, frequent dependence on ventricular pacing.)	4 (3%)
CRT-D Replacement (CRT-D or CRT-D system change-out)	9 (7%)
PAVE + ICD Indication	4 (3%)
ICD Replacement (ICD or ICD system change-out)	18 (14%)
Familial Condition	1 (1%)
MADIT II	8 (6%)
SCD-HeFT	15 (12%)
Syncope	1 (1%)
VT	3 (2%)
VF	1 (1%)
Baseline Medications[500], N (%)	
ACE	78 (61%)
ARB	26 (20%)
Beta Blockers	105 (82%)
Calcium Channel Blockers	17 (13%)
Cardiac Glycosides	34 (27%)
Diuretics	96 (75%)
Nitrates	33 (26%)
Antiarrhythmics (Class I)	2 (2%)
Antiarrhythmics (Class III)	17 (13%)

Primary Objective and Results

The data was cut off when data on the first 19, 38, and 45 patients available to complete the primary endpoint analysis for the ACap™ Confirm, VAC, and LVCap™/RVCap™ Confirm features, respectively, was available.

Primary Safety Endpoint

The primary safety endpoint for this study is freedom from system related complications through 3 months.

H_0: Freedom from system related complications through 3 months ≤ 85%

H_1: Freedom from system related complications through 3 months > 85%

All 128 enrolled patients were included in this analysis. The survival time for patients who experienced a system related complication was calculated as the number of days from the date of successful implant to the date the complication was first identified. For patients who did not experience a system related complication and withdrew from the study before the time of analysis, the survival time was censored on the date of their withdrawal. For patients who did not experience a system related complication by the time of analysis, the survival time was censored on the date of data cut-off. The Kaplan-Meier estimate of freedom from system related complications at 3 months was 93.6% and its standard error using Greenwood's formula was 0.022. The 95% lower confidence bound was 89.9%, which was greater than the objective performance criteria of 85%. The null hypothesis was rejected at the 5% significance level.

Primary Effectiveness Endpoints

[500] Individual patients may be included in more than one subcategory.

ACap™ Confirm Effectiveness Endpoint

The effectiveness endpoint for the ACap™ Confirm feature is the difference in bipolar atrial capture thresholds determined by ACap Confirm and by a manual test at 3 months.

$H_0: |\Delta\mu \geq 0.25$
$H_1: |\Delta\mu| < 0.25$

where

$|\Delta\mu|$

represents the absolute mean difference in bipolar atrial capture thresholds at 3 months.

A total of 76 patients had paired bipolar atrial capture threshold measurements from ACap Confirm and a manual test at 3 months. As specified in the statistical analysis plan, the primary analysis was performed on the first 19 patients who had paired bipolar atrial capture threshold measurements at 3 months. The data are summarized in the following table.

Table 276. ACap Confirm Effectiveness Endpoint – Primary Analysis (N = 19)

	ACap Confirm (V)	Manual Test (V)	Difference ACap Confirm and Manual Test
Range	(0.375, 2.000)	(0.500, 1.000)	(-0.125, 1.250)
Mean ± SD	0.743 ± 0.357	0.737 ± 0.195	0.0066 ± 0.3103
Median	0.750	0.750	-0.1250

The p-values from the two one-sided tests were both < 0.001. Therefore, the p-value for testing the null hypothesis, which was calculated as the larger p-value from the two one-sided tests, was < 0.001. The null hypothesis was rejected at the 1.67% significance level.

VAC Effectiveness Endpoint

The effectiveness endpoint for VAC is the difference in bipolar ventricular capture thresholds determined by VAC and by a manual test at 3 months.

$H_0: |\Delta\mu \geq 0.25$
$H_1: |\Delta\mu| < 0.25$

where

$|\Delta\mu|$

represents the absolute mean difference in bipolar ventricular capture thresholds at 3 months.

A total of 43 patients had paired bipolar ventricular capture threshold measurements from VAC and a manual test at 3 months. As specified in the statistical analysis plan, the primary analysis was performed on the first 38 patients who had paired bipolar ventricular capture threshold measurements at 3 months. The data are summarized in the following table.

Table 277. VAC Effectiveness Endpoint – Primary Analysis (N = 38)

	VAC (V)	Manual Test (V)	Difference VAC – Manual Test
Range	(0.375, 2.750)	(0.500, 3.000)	(-0.250, 0.250)
Mean ± SD	0.809 ± 0.405	0.862 ± 0.442	-0.0526 ± 0.0948
Median	0.750	0.750	-0.0625

The p-values from the two one-sided tests were both < 0.0001. Therefore, the p-value for testing the null hypothesis, which was calculated as the larger p-value from the two one-sided tests, was < 0.0001. The null hypothesis was rejected at the 1.67% significance level.

LVCap™ Confirm/RVCap™ Confirm Effectiveness Endpoints

The effectiveness endpoints for the LVCap™ Confirm/RVCap™ Confirm features are the difference in bipolar LV capture thresholds determined by LVCap Confirm and by a manual test at 3 months and the difference in bipolar RV capture thresholds determined by RVCap Confirm and by a manual test at 3 months. LVCap Confirm/RVCap Confirm will be met at a significance level of α if and only if both LVCap Confirm and RVCap Confirm are met at a significance level of α.

$H_0: |\Delta\mu \geq 0.25$
$H_1: |\Delta\mu| < 0.25$

where

$|\Delta\mu|$

represents the absolute mean difference in bipolar LV (for LVCap Confirm) or RV (for RVCap Confirm) capture thresholds at 3 months.

A total of 45 patients had both paired bipolar LV capture threshold measurements from LVCap Confirm and a manual test and paired bipolar RV capture threshold measurements from RVCap Confirm and a manual test at 3 months. As specified in the statistical analysis plan, the primary analysis was performed on the first 45 patients who had both paired bipolar LV capture threshold measurements from LVCap Confirm and a manual test and paired bipolar RV capture threshold measurements from RVCap Confirm and a manual test at 3 months. The data are summarized in the following tables.

Table 278. LVCap Confirm Effectiveness Endpoint – Primary Analysis (N = 45)

	LVCap Confirm (V)	Manual Test (V)	Difference LVCap Confirm – Manual Test
Range	(0.625, 2.875)	(0.750, 3.000)	(-0.375, 1.625)
Mean ± SD	1.458 ± 0.631	1.456 ± 0.618	0.0028 ± 0.2852
Median	1.250	1.250	0.000

Table 279. RVCap Confirm Effectiveness Endpoint – Primary Analysis (N = 45)

	RVCap Confirm (V)	Manual Test (V)	Difference RVCap Confirm – Manual Test
Range	(0.375, 2.250)	(0.500, 2.250)	(-0.250, 0.125)
Mean ± SD	0.739 ± 0.279	0.794 ± 0.278	-0.0556 ± 0.0824
Median	0.750	0.750	0.000

The p-values from the two one-sided tests for LVCap Confirm were both < 0.0001. Therefore, the p-value for testing the null hypothesis for LVCap Confirm was < 0.0001. The p-values from the two one-sided tests for RVCap Confirm were both < 0.0001. Therefore, the p-value for testing the null hypothesis for RVCap Confirm was < 0.0001. Both null hypotheses were rejected at the 1.67% significance level.

Discussion of Primary Endpoints

The primary safety endpoint of system related complications was met at the 5% significance level. The ACap™ Confirm effectiveness endpoint, VAC effectiveness endpoint, and the LVCap™ Confirm/RVCap™ Confirm effectiveness endpoint were all met at the 1.67% significance level. The pre-specified criteria for study success, as specified in the statistical analysis plan, were met.

DEFINITE Trial

Summary of the DEFINITE Trial

The purpose of the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial was to evaluate the hypothesis that an implantable cardioverter defibrillator (ICD) will reduce the risk of death in patients with non-ischemic cardiomyopathy and moderate-to-severe left ventricular dysfunction. Patients enrolled in the DEFINITE trial were randomly assigned to receive either standard oral medical therapy for heart failure (HF) or standard oral medical therapy for HF and a single-chamber ICD. A total of 229 patients were randomized to each study group. The DEFINITE trial was a prospective, randomized, investigator-initiated study based on previously reported observational data[501]. Standard oral medical therapy included angiotensin converting enzyme inhibitors (ACE) or ACE substitute (hydralazine and nitrates or angiotensin receptor II blockers [ARBs]) as well as beta blocker therapy unless the beta blocker therapy was

[501] Levine JH, Waller T, Hoch D, Greenberg S, Goldberger J, Kadish A. Implantable cardioverter defibrillator: use in patients with no symptoms and at high risk. Am Heart J 1996;131:59-65.

contraindicated (beta blocker therapy used in the trial "carvedilol or metoprolol"). Digoxin and diuretic therapy were utilized to manage clinical symptoms. Antiarrhythmics such as amiodarone were discouraged, but were used if necessary to manage supraventricular tachyarrhythmias and/or atrial fibrillation.

Patient Population

The patient cohort for the DEFINITE trial included a non-ischemic cardiomyopathy population with a history of symptomatic heart failure, moderate to severe LV dysfunction (LVEF ≤ 35%) and the presence of ambient arrhythmias. Ambient arrhythmias were defined by an episode of non-sustained ventricular tachycardia on Holter or telemetric monitoring (three to 15 beats at a rate of more than 120 bpm or an average of at least 10 premature ventricular complexes per hour on 24-hour Holter monitoring. It was required that the absence of clinically significant coronary artery disease (CAD) as the cause of the cardiomyopathy be confirmed by coronary angiography or by a negative stress imaging study. The definitions for the presence of CAD are as follows: a) coronary angiography demonstrating ≥ 50% proximal or 75% distal luminal stenosis in one or more of the main coronary arteries; b) stress testing with nuclear perfusion imaging or dobutamine echocardiography demonstrating any evidence of ischemia; or c) history of documented Q-wave myocardial infarction. Patients eligible for participation were also required to be 18-80 years of age.

Patients were excluded if they had coronary artery disease, unexplained syncope within the past six months, prior cardiac arrest, VT of more than 15 beats at a rate of 120 bpm, NYHA Class IV heart failure at the time of enrollment, familial cardiomyopathy with history of sudden cardiac death, existing permanent pacemaker, EP study within the past three months or amiodarone therapy for ventricular arrhythmias

Methods/Results

Patients were randomly assigned to one of the two treatment groups: standard oral medical therapy for HF and oral medical therapy for HF along with a single-chamber ICD. Randomization was stratified by center and also by the use or non-use of amiodarone to treat supraventricular tachyarrhythmias or atrial fibrillation. For the patients receiving an ICD implantation, the ICDs were programmed with a VVI pacing rate of 40 beats per minute and ventricular fibrillation (VF) detection rate of 180 beats per minute. Patients were followed as per their randomization assignment at three-month intervals. All patients assigned to the control group underwent ICD implantation if they experienced an arrhythmic event. If patients experienced a cardiac arrest or an unexplained syncope, these were said to be consistent with an arrhythmic event. All patient deaths were reviewed by an independent events committee using the Epstein[502] classification system.

The baseline characteristics of the two groups were compared with the use of two-sample t-tests for continuous variables and chi-square tests for categorical variables. Baseline characteristics were similar for both treatment groups with the exception of duration of heart failure: 3.27 years in the standard-therapy group and 2.39 years in the ICD group, (p = 0.04) (see the following table).

Table 280. Baseline characteristics

Characteristic	All Patients (n = 458)	Standard Therapy Group (n = 229)	ICD Group (n = 229)
Age (yrs) average (range)	58.4 (20-84)	58.1 (22-79)	58.4 (20-84)
Gender: Male *(%)*	326 (71)	160 (70)	166 (72)
Race *(%)*			
White	308 (67)	154 (67)	155 (68)
African-American	118 (26)	59 (26)	59 (26)
Hispanic	26 (6)	13 (6)	13 (6)
Other	5 (1)	3 (1)	2 (1)
Hx of Diabetes *(%)*	105 (23)	53 (23)	52 (23)
Hx of A-Fib *(%)*	112 (24)	60 (26)	52 (23)
CDM Years[503] average (range)	2.83 (0-39)	3.27 (0-39)	2.39 (0-21)
NYHA Class *(%)*			
I	99 (22)	41 (18)	58 (25)
II	263 (57)	139 (61)	124 (54)
III	96 (21)	49 (21)	47 (21)
QRS (ms) average (range)	115 (78-196)	116 (79-192)	115 (78-196)
LBBB *(%)*	90 (20)	45 (20)	45(20)
RBBB *(%)*	15 (3)	7 (3)	8 (4)

[502] Epstein AE, Carlson MD, Fogoros RN, Higgins SL, Venditti FJ Jr. Classification of death in antiarrhythmia trials. J Am Coll Cardiol 1996;27:433-42.
[503] P < 0.05 vs. standard therapy.

Table 280. Baseline characteristics

Characteristic	All Patients (n = 458)	Standard Therapy Group (n = 229)	ICD Group (n = 229)
Qualifying Arrhythmia *(%)*			
NSVT Only	103 (22)	52 (23)	51 (22)
PVC Only	43 (9)	22 (10)	21 (9)
NVST and PVC	312 (68)	155 (68)	157 (69)
LVEF % average (range)	21 (7-35)	22 (10-35)	21 (7-35)
Walk Distance (m) average (range)	319 (18-1316)	328 (18-1316)	311 (29-1143)

The log-rank test was used to compare Kaplan–Meier survival curves in the two groups, and the Cox proportional-hazards model was used to adjust for covariates and to estimate the hazard ratio for death and corresponding 95% confidence interval in the ICD group as compared with the standard-therapy group[504].All analyses were conducted according to the intention to treat. Follow-up lasted for a mean (±SD) 29.0 ± 14.4 months.

Overall Mortality

The DEFINITE study was designed to have a statistical power of 85% based on a one-sided test, assuming two-year mortality rates of 15% in the standard-therapy group and 7.5% in the ICD group and the enrollment of 458 patients, with the pre-defined stopping point for analysis at the time of the 56th death. A two-sided test was performed to improve robustness of the analysis and in order to retain 85% statistical power, the results were analyzed at the 68th death. The results of the two-sided analyses are presented below.

Results – 68 Deaths

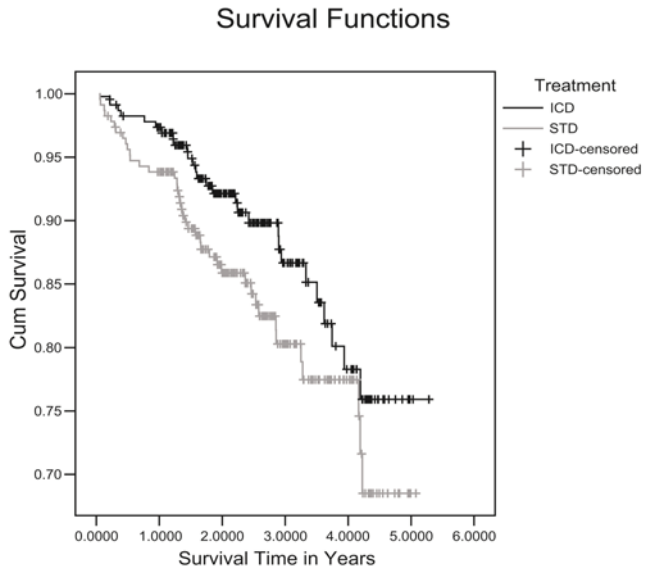
Using the revised analysis stopping point of 68 deaths[505] for the two-sided survival analysis, 40 deaths occurred in the Standard therapy group and 28 deaths occurred in the ICD group. Total mortality rates (all cause) for each group at one year was 6.2% for the Standard therapy group and 2.6% for the ICD group and at two years was 14.1% and 7.9% for the two groups, respectively (see the following table). While there were fewer deaths in the ICD group than in the standard therapy group (28 vs. 40), the difference in overall survival was not statistically significant (p = 0.08; hazard ratio 0.65, 95% confidence interval 0.40 to 1.06; see the following figure).

Table 281. Mortality

Patient Group	Number of Patient Deaths	One-Year Mortality (%)	Two-Year Mortality (%)
Standard Therapy Group	40	6.2	14.1
ICD Group	28	2.6	7.9

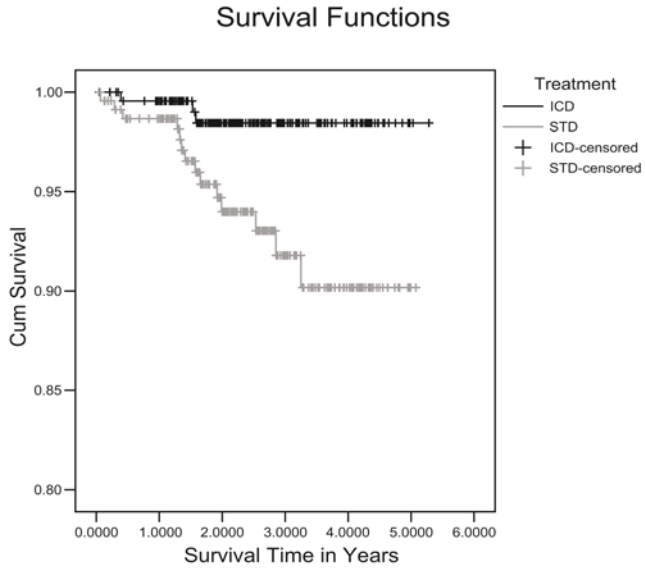
[504] Kalbfleish JD, Prentice RL. The statistical analysis of failure time data. New York: John Wiley, 1980:321.
[505] Kadish A, Dyer A, Daubert JP, et.al., Prophylactic Defibrillator Implantation in Patients with Nonischemic Dilated Cardiomyopathy. N Engl J Med 2004;350:2151-8.

Figure 48. Kaplan-Meier survival curve, total mortality



A pre-specified secondary endpoint of the study was Arrhythmic Sudden Death. A total of 17 sudden deaths were reported as part of the 68-death analyses. There were fewer sudden cardiac deaths in the ICD group (3) than the Standard therapy group (14) (see the following figure).

Figure 49. Kaplan-Meier survival curve, arrhythmic sudden deaths



Device related complications and observations were reported and an overview of the observations and complications that occurred during the trial are detailed in the following table. There were no unanticipated adverse effects reported during the DEFINITE trial. A total of 48 complications were reported during the study. There were three complications that occurred during implantation of the ICDs. All complications associated with implantation were resolved and there were no procedure-related deaths. During follow-up 45 complications were reported.

Table 282. Observed adverse events (n = 227)

	# Pts AEs[506] (n = 227)	% of Pts with AEs	# of AEs	AE/pt-years (n = 672.3 yrs)
Complications (total)	44	19.4%	48	0.071
Hemothorax	1	< 1%	1	0.001
Pneumothorax	1	< 1%	1	0.001
Bleeding	2	< 1%	2	0.003
High Defibrillation/Cardioversion Requirements > 650 V	1	< 1%	1	0.001
Detection Difficulties	1	< 1%	1	0.001
Lead Dislodgment or Migration	4	1.8%	4	0.006
Lead System Fracture	2	< 1%	2	0.003
Lead System Insulation Damage	2	< 1%	2	0.003
Infection Requiring Explant	1	< 1%	1	0.001
Erosion	1	< 1%	1	0.001
Venous Thrombosis	1	< 1%	1	0.001
Suspected Device Malfunction	5	2.2%	5	0.007
Battery Depletion	25	11.0%	25	0.037
Device Recall	1	< 1%	1	0.001
Observations (total)	58	25.6%	105	0.156
Prolonged Procedure (> 180 min)	2	< 1%	2	0.003
Bleeding	1	< 1%	1	0.001
Cardiac Perforation	1	< 1%	1	0.001
High Defibrillation/Cardioversion Requirements > 650 V	4	1.8%	4	0.006
High Defibrillation/Cardioversion Requirements > 750 V	1	< 1%	1	0.001
Detection Difficulties	1	< 1%	1	0.001
High Pacing Thresholds (> 2 V @ 0.5 ms)	1	< 1%	1	0.001
Low R-wave Amplitude (< 3 mV)	2	< 1%	2	0.003
Infection Not Requiring Explant	1	< 1%	1	0.001
Venous Thrombosis	3	1.3%	3	0.004
Inappropriate Shock Therapies	46	20.3%	88	0.131

Summary

There were fewer deaths in the ICD group than in the standard therapy group (hazard ratio 0.65). Total mortality rates (all cause) for each group at one year was 6.2% for the Standard therapy group and 2.6% for the ICD group and at two years was 14.1% and 7.9% for the two groups, respectively. The difference in all cause mortality using a two-sided test was not statistically significant (p = 0.08). A pre-specified secondary endpoint of the study was Arrhythmic Sudden Death. There were fewer sudden cardiac deaths in the ICD group (3) than in the Standard therapy group (14).

Frontier II: Summary of Clinical Investigations

- VecToR Study (page 406)
- RHYTHM Study (page 408)

See also the PAVE Study (page 411) below.

VecToR Study

The VecToR CRT-P study was designed to pursue approval for cardiac resynchronization therapy for a Heart Failure (HF) patient population, which, in the investigators' opinion, does not need the additional benefit of back up defibrillation. An identical system (i.e., Frontier biventricular pacing system) as used in the PAVE population was used in the VecToR CRT-P population. The safety data presented shows that the system is safe for its intended use and demonstrates the safety of the Frontier CRT-P system.

[506] Some patients experience more than one adverse event.

The VecToR (CRT-P) study did not enroll sufficient numbers of randomized patients to meet its effectiveness objectives. Although the VecToR (CRT-P) study and the RHYTHM (CRT-D) study used different pulse generators (Frontier and Epic HF, respectively), both used the same biventricular pacing function which is delivered through the legally marketed SJM Aescula lead to provide cardiac resynchronization therapy. Data from the RHYTHM Study is used to demonstrate CRT effectiveness, as the patient populations in RHYTHM and VecToR are comparable.

The VecToR study was a prospective, double-blind, randomized, controlled, multi-center clinical trial of patients with New York Heart Association Class III/IV congestive heart failure, and was conducted at 41 participating sites (39 in the US, 2 in Canada). The study compared the safety and effectiveness of cardiac resynchronization pacing therapy (CRT-P), using the Frontier Model 5508 pulse generator and the Aescula 1055K Left Heart Lead to no CRT-P therapy.

Study Inclusion and Exclusion criteria are listed below:

Inclusion Criteria

1. Symptomatic ischemic or nonischemic dilated cardiomyopathy, which is not due to reversible causes.
2. Left ventricular end-diastolic diameter >54mm as measured by echocardiography.
3. Left ventricular ejection fraction ≤ 35% as measured by echocardiography.
4. QRS duration of ≥140 ms.
5. Stable but advanced heart failure due to left ventricular dysfunction (diagnosed for at least 6 months) despite stable conventional medical therapy.
6. Completed the 6-minute walk test as outlined in the protocol with the only limiting factor(s) being fatigue and/or shortness of breath.
7. Adequate cardiographic acoustic windows.
8. Provided informed consent for study participation and, are willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria

1. Can walk >450 meters during the 6-minute walk test.
2. Have standard bradycardia indications or likely to need pacing within the next 6-months.
3. Are classified as NYHA Class I or II.
4. Have a history of persistent or chronic atrial fibrillation or a history of atrial fibrillation which required intervention to revert to normal sinus rhythm.
5. Have an implanted cardioverter defibrillator (ICD) or, are being considered for implantation of an ICD.
6. Are contraindicated for an emergency thoracotomy.
7. Are considered status 1 for cardiac transplantation and are likely to receive transplantation within 1 year
8. Are being treated with parenteral inotropic agents (e.g., dobutamine) or have been treated with such agents within the past 30 days.
9. Have prosthetic valve replacement(s).
10. Have severe musculoskeletal disorder(s).
11. Are under the age of 18 years.
12. Are pregnant or plan a pregnancy in the next 6 months.
13. Are currently participating or participated within the past 30 days in any clinical investigation.
14. Have a life expectancy of less than 6 months.
15. Cannot independently comprehend and complete the Minnesota Living With Heart Failure questionnaire.
16. Are allergic to dexamethasone sodium phosphate (DSP).

To gain initial experience, investigators were given the option of prospectively determining that the first two patients implanted would not be randomized and would not count toward the implant success rate. However, these "Roll-In" patients met all inclusion criteria, were blinded to their treatment arm, and were followed per protocol. As such and as defined in the protocol, this "Roll-In" group is included in the safety analysis. All patients received the pacing system comprised of the investigational Frontier pulse generator and Aescula left heart lead, and a legally marketed right atrial and right ventricular lead. Patients were followed every 3 months for the first twelve months, and every six months thereafter. Patients in the CRT OFF group were allowed to cross over after completing the requirements of the 6-month visit.

As of September 7, 2004, the total time of follow-up from the time of successful implant in 120 patients was 2383 patient months. The average time of follow-up was 19.9 ± 8.9 (range 0.8 to 35.4) patient months.

Patient Population

The overall VecToR study population included 144 patients. Fifty-nine (59) patients were randomized to ON, and 47 patients were randomized to OFF. Revision C of the VecToR protocol excluded NYHA Class II patients. Thirty-eight (38) were "roll-in" patients (non-randomized) and received the cardiac resynchronization pacing therapy system (Frontier pulse generator and Aescula lead system). Safety analyses include all patients with the Frontier pulse generator and the Aescula left heart lead, including ON, OFF, and roll-in. The mean age was 67.1 ± 9.7 years and there were 62.5% male and 37.5% female. Twenty-nine percent (29%) of the patients were NYHA Class II, 65% were NYHA Class III, and 6% were NYHA Class IV prior to implant.

Primary Safety Objectives and Results

The primary safety objectives for the VecToR study are presented below.

Freedom from System-Related Complications Through Six Months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from system-related complications will not be less than 70%. A system-related complication was defined as a complication that is caused by a failed pacing system. A pacing system refers to all implanted components, including the pulse generator, leads, and the interaction of these components.

Results: There were 12 system-related complications in 11 patients within six-months follow-up. The freedom from system-related complications is 90.7% with a lower bound of 86.4%. Objective met.

Freedom from Pulse Generator-Related Complications Through Six Months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from pulse generator-related complications for the combined group through six months will not be less than 90%.

Results: There were no pulse generator-related complications through six months. The survival rate is 100% with a lower bound of 97.1%. Objective met.

Freedom from Aescula™ Lead-Related Complications Through Six Months

Objective: The lower bound of the one-sided 95% confidence interval of the freedom from Aescula™ lead-related complication through six months will not be less than 75%.

Results: There were 8 Aescula lead-related complications in 8 patients through six-months follow-up. All patients from the VecToR study who were successfully implanted are included in this analysis. The freedom from Aescula lead-related complications is 93.3% with a lower bound of 89.5%. Objective met.

Rate of Successful Implantation of the Aescula™ Lead

Objective: The lower bound of the one-sided 95% confidence interval of the successful implantation rate of the Aescula lead will not be less than 80%. The success rate was defined as the proportion of patients who received the complete pacing system.

Results: A total of 144 patients who were randomized to CRT ON or OFF in the VecToR study and underwent attempted BV implants. One hundred and twenty (120) were successfully implanted. The rate of successful implant of the Aescula lead is 84% with a lower bound of 78% which does not meet the protocol defined objective for this endpoint (lower 95% confidence bound of 80%).

Aescula™ Lead Pacing Threshold at Six Months

Objective: The upper bound of the one-sided 95% confidence interval of mean capture threshold will not be greater than 3.0 V for the combined group at six months.

Results: The electrical performance data of the LV lead were available on a total of 110 patients at six months. The pacing threshold at six months for the LV lead is 2.10 V with an upper bound 95% confidence interval of 2.34 V. Objective met.

RHYTHM Study

The RHYTHM ICD Study demonstrated that the SJM CRT-D system (Epic HF and Aescula lead) was safe and effective in NYHA Class III and IV heart failure patients with prolonged QRS duration and served as the basis for the recent PMA approved (PMA # P030054). The RHYTHM ICD study enrolled patients who also had a current ICD indication, which at the time the study was initiated included patients who were indicated for an ICD solely for primary prevention or prophylaxis (i.e., the patients were at risk of ventricular tachyarrhythmias and sudden death due to other clinical characteristics, but had not experienced a spontaneous or induced tachycardia).

The RHYTHM ICD study was a prospective, multicenter, randomized, double-blind, controlled clinical investigation designed to assess the safety and effectiveness of the Epic HF ICD system in patients who were indicated for implantable cardioverter defibrillation therapy with New York Heart Association Classification of III or IV and a prolonged QRS duration. The objective of this clinical study was to verify the safety and effectiveness of the Epic HF ICD (Model V-338) system in an ICD indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration.

Study Inclusion and Exclusion criteria are listed below:

Inclusion Criteria

1. Approved indication for implantation of an ICD for treatment of a life-threatening ventricular tachyarrhythmia(s).
2. Symptomatic, advanced heart failure (ischemic or non-ischemic) not due to reversible causes, diagnosed for at least 6-months.

3. New York Heart Association (NYHA) Classification of III or IV, despite receiving a minimum of 90 days of appropriate pharmacological therapy.
4. Receive optimal pharmacological therapy for CHF (including angiotensin converting enzyme inhibitor and beta blocker, as tolerated) which has been stable during the 30 days prior to enrollment.
5. Left ventricular ejection fraction (LVEF) ≤ 35%.
6. Ventricular conduction delay manifested as a QRS duration ≥150 msec.
7. Ability to complete cardiopulmonary exercise stress testing and 6-Minute hall walk test, with the only limiting factor(s) being fatigue and/or shortness of breath.
8. Ability to independently comprehend and complete a quality of life questionnaire (Minnesota Living with Heart Failure).
9. Ability to provide informed consent for study participation and be willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria

1. Standard bradycardic indication for pacing.
2. History of chronic atrial fibrillation (continuous AF lasting > 1 Month) within 1 year prior to enrollment or have undergone cardioversion for AF in the past month.
3. Ability to walk > 450 meters during the 6-Minute walk test.
4. NYHA Classification of I or II.
5. Contraindication for an emergency thoracotomy.
6. Classification of Status 1 for cardiac transplantation or consideration for transplantation over the next 6-months.
7. Recent myocardial infarction, unstable angina or cardiac revascularization (PTCA or CABG) within 1 month of enrollment.
8. Recent CVA or TIA - within 3 months of enrollment.
9. Severe musculoskeletal disorder(s).
10. Pregnant or a planning for pregnancy in next 6-months.
11. Currently participating in, or has participated in any clinical investigation within the last 30 days. (the only exception being that of a registry trial)
12. Life expectancy of less than 6-months.
13. Less than 18 years of age.

All patients who met enrollment criteria underwent implantation of the Epic HF ICD system and a St. Jude Medical left ventricular pacing lead. ICD therapy was activated at the time of implant for all patients. Patients underwent Baseline evaluation between two weeks and 30 days following successful device implantation. Baseline was considered time zero for the purposes of evaluation of resynchronization study endpoints.

Patients were randomized following completion of Baseline testing and were assigned to either the treatment group (CRT ON) or the control group (CRT OFF) at a 2:1 ration. Patients who underwent unsuccessful implantation of the Epic HF ICD system were followed for a period of 30 days prior to withdrawal from the study. All patients who were successfully implanted were followed at 1, 3, 6 and every 3 months thereafter until the study was completed. Cross-over from the control group was allowed after completing the 6-month visit.

As of March 17, 2004, the total time of follow-up from the time of successful implant was 2205 patient months. The average time of follow-up was 12.1 ± 3.4 (range 0.3 to 20.3) patient months.

Patient Population

Of the 205 patients enrolled in the RHYTHM ICD study, one hundred and eighty-three (183) lead implant attempts were successful (180 successful on the first attempt and 3 successful on the second attempt). One additional patient had a successful left ventricular lead implant, but had high defibrillation thresholds. This patient was withdrawn from the study and received a heart transplant, leaving a total of 182 successful system implants.

Patients who were successfully implanted with the Epic HF ICD system had a Baseline visit approximately two weeks after implant, during which the following tests/assessments were performed: Electrical measurements on RA, RV and LV leads, cardiopulmonary exercise (CPET) test, echocardiogram, NYHA class assessment, 6 minute walk test, and Minnesota Living with Heart Failure questionnaire. Of the 182 patients with successful implants, two patients expired and one patient withdrew from the study before the Baseline visit and therefore, 179 patients had a Baseline visit. One additional patient who had a Baseline follow-up visit refused randomization and all the Baseline evaluations except device interrogation and electrical measurements, but remained in the study. Therefore, a total of 178 patients completed the requirements of the Baseline visit.

Primary Effectiveness Objective and Results

Cardiac Resynchronization Therapy Effectiveness (Peak VO2)

Objective: To determine if the treatment group (CRT ON) shows a statistically significant improvement over the control group (CRT OFF) at six months.

Results: In the intention-to-treat analysis, patients who crossed over from the CRT OFF group to the CRT ON group during the study were analyzed according to the original treatment group they belonged to. A summary of the improvement in peak VO2 values in the two treatment groups for this analysis is shown in the following table. The average improvement in the CRT ON group over the CRT OFF group was approximately 1.9 ml/kg/min. The p-value was 0.001. Objective met.

Table 283. Improvement in Peak VO2 Values (ml/kg/min) Intention-to-Treat Analysis (N=126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	12.8 ± 3.7	11.2 ± 3.0
6-months	11.4 ± 5.6	11.7 ± 3.2
Change	-1.41 ± 4.6	0.52 ± 2.5
Overall improvement in CRT ON vs. CRT OFF = 1.9 ml/Kg/min		

Secondary Objective and Results

Improvement in NYHA Class at Six Months Over Baseline

Objective: To determine if the treatment group (CRT ON) shows an improvement over the control group (CRT OFF) at six months.

Results: The average change in NYHA Class from Baseline to 6-months for each group is shown in the following table. Objective met.

Table 284. Baseline and Six Month NYHA Class (N=126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	2.86 ± 0.52	3.01 ± 0.33
6-months	2.58 ± 0.73	2.53 ± 0.69
Change	-0.28 ± 0.63	-0.48 ± 0.65

Improvement in Quality of Life at Six Months Over Baseline

Objective: To determine if the treatment group (CRT ON) shows an improvement over the control group (CRT OFF) at six months.

Results: Patient quality of life (QOL) was assessed with the Minnesota Living with Heart Failure questionnaire. A lower score indicates an improvement in quality of life. A summary of the improvement in Quality of Life in the two groups from baseline to 6 months is shown in the following table.

Table 285. Improvement in Quality of Life Score (N=126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	42.0 ± 23	48.3 ± 24
6-months	45.4 ± 31	40.4 ± 22
Change	3.4 ± 31	-7.8 ± 22

The average improvement in the CRT ON group over the CRT OFF group was approximately 11 points. Objective met.

Improvement in Six-Minute Hall Walk at Six Months Over Baseline

Objective: To determine if the treatment group (CRT ON) shows an improvement over the control group (CRT OFF) at six months.

Results: A summary of the improvement in 6-minute walk distance between baseline and 6 months is shown in the following table.

Table 286. Improvement in Six Minute Walk Distance (meters) (N=126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	298 ± 94	284 ± 105
6-months	283 ± 150	297 ± 122
Change	-15 ± 142	13 ± 74

The average improvement in the CRT ON group over the CRT OFF group was approximately 28 meters.

Additional Data

Biventricular Pacing at Six Months

The average percentage of biventricular pacing at the 6-month visit in the 83 patients who were in the CRT ON group among the 126 patients in the primary resynchronization cohort was 95% ± 6%, with a range of 70% to 100%.

ECHO Data

Echocardiographic analysis was performed at the baseline and 6-month follow-up visits. The following parameters were evaluated from the echocardiographic analysis: LVEDD, LVESD, LVEF, MR, E/A Wave Point Ratio, and Sphericity Index. Cardiac dyssynchrony (including Pre-Ejection Delay Time and Intraventricular Mechanical Delay) was also evaluated at baseline and 6-Months. A summary of the improvement in these parameters between baseline and 6-months is shown in the following table.

Table 287. Improvement in Echocardiography Parameters

Parameter	CRT OFF (N = 40) Mean ± SD	CRT ON (N = 82) Mean ± SD
LVEDD (mm)	-2.4 ± 6.5	-4.3 ± 5.4
LVESD (mm)	-3.0 ± 6.4	-4.6 ± 7.0
LVEDV (ml)	-37 ± 53	-43 ± 69
LVESV (ml)	-36 ± 47	-43 ± 58
LVEF (%)	2.9 ± 6.2	4.3 ± 9.9
MR (grade)	0.10 ± 0.50	-0.06 ± 0.74
E/A Wave Point Ratio	-0.02 ± 1.2	-0.08 ± 0.8
Sphericity Index	0.02 ± 0.1	-0.02 ± 0.1
Pre-Ejection time (ms)	7.3 ± 33	-1.5 ± 52
IVMD (ms)	-6.4 ± 48	-14.5 ± 52
Tei Index	-0.05 ± 0.5	-0.4 ± 0.8
Contraction Interval (ms)	-55 ± 103	-94 ± 124

PAVE Study

Summary of the PAVE Study

The Post-AV Node Ablation Evaluation (PAVE) study was a prospective, randomized, controlled, multi-center clinical trial conducted at 49 participating sites (44 in the US, five in Canada) comparing the safety and effectiveness results for patients receiving the Frontier™ Model 5508 CRT-P and the Aescula™ 1055K left heart lead to those receiving legally marketed right ventricular pulse generators and standard leads following an AV nodal ablation for chronic atrial fibrillation. Chronic AF is defined as persisting without interruption for at least one month.

Patients with chronic (permanent) atrial fibrillation may also be indicated for and receive an ICD under FDA approved standard ICD indication language. The standard ICD indication includes patients who have experienced an episode of ventricular tachycardia or ventricular fibrillation (secondary prevention) or meet the criteria for prophylactic ICD therapy (primary prevention). Likewise, patients who have atrial fibrillation may receive a biventricular pacemaker if they have undergone AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure. The prospective, randomized, controlled PAVE study was completed and successfully demonstrated that biventricular pacing is safe and effective in post-AV nodal ablation patients with NYHA Class II or III heart failure. The addition of ICD back-up therapy will not affect the biventricular pacing performance of the device and ICD therapy is the

standard of care in patients with an ICD indication and chronic (permanent) atrial fibrillation. In addition, St. Jude Medical CRT-D devices have previously been proven to be safe and effective (RHYTHM ICD Study) in patients with an ICD indication and NYHA Class III or IV heart failure with prolonged QRS durations and LVEF ≤ 35%. Since the Promote™ CRT-D provides biventricular pacing similar to the Frontier II CRT-P[507], no additional clinical evaluation was performed.

The study's cumulative implant duration for all enrolled patients was 8,979 months with a mean of 24.33 ± 15.22 months (range of 0.13 to 55.95 months). Two hundred and ten patients underwent successful LV lead placement. The cumulative duration for all investigational patients (BV, LV and Roll-in groups only) was 5,928 months.

For this randomized study, the key inclusion criteria were:

- Patients who will undergo complete AV nodal ablation for chronic atrial fibrillation (defined as persisting without interruption for at least one month) resulting in complete AV block
- Patients who are on a stable medical therapy regimen, and
- Patients who are able to complete the six-minute walk with the only limiting factor(s) being fatigue and/or shortness of breath.

Key study exclusion criteria were:

- Patients who are classified as NYHA Class IV
- •Patients who can walk > 450 m in six-minute walk test
- •Patients who have an implanted ICD or being considered for implant of an ICD
- •Patients with prosthetic valve replacements
- •Patients with severe musculoskeletal disorder(s). and
- •Patients who cannot independently comprehend and complete the quality of life questionnaire.

The overall study population included 369 patients. One hundred and fifty-one were randomized to BV, and 109 were randomized to RV. In addition, 53 were randomized to LV pacing under a previous revision of the investigational plan. Fifty-six were "Roll-in" patients (nonrandomized) and received the biventricular pacing system (Frontier CRT-P and Aescula lead system). All patients had permanent pacemaker implant indication following an elective AV nodal ablation for chronic atrial fibrillation. The mean age was 69.3 ± 9.93 years; 34.4% were female and 65.6% were male. Fourteen percent of the patients had no diagnosis of heart failure or were NYHA Class I, 49% were NYHA Class II, and 37% were NYHA Class III prior to implant.

Primary Effectiveness Objective and Result

Exercise Capacity as Measured by Distanced Walked in Six-Minute Walk Test

Objective: To determine if the treatment group (BV) shows a statistically significant improvement over the control group (RV) at the six months follow-up time.

Results: The treatment group (BV) showed statistically significant improvement over the control group (RV) in distance walked from pre-implant to six months (p = 0.03). The BV group also had a greater percentage of patients showing improvements than the RV group (p = 0.035). The improvement in the six-minute walk between BV and RV groups is shown in the following figure. The improvement distribution in the six-minute walk between BV and RV groups is shown in the following table.

Figure 50. Improvements in six-minute walk distance in BV and RV groups (p = 0.03)

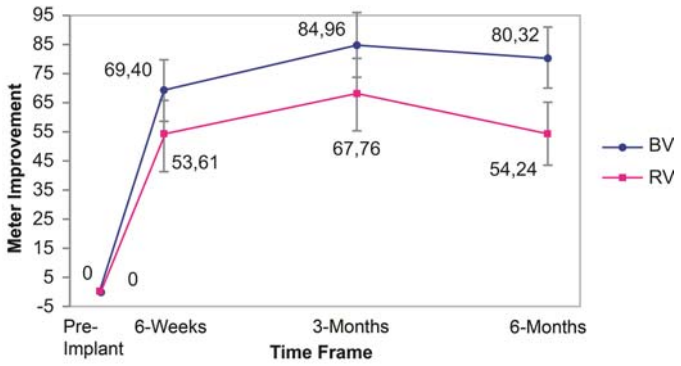


Table 288. Distribution of improvement in BV and RV Group in six-minute walk (p = 0.035)

	RV (N = 66)	BV (N = 84)
Improved (> 5 m)	46 (69.70%)	69 (82.14%)

[507] The Frontier II CRT-P has the same functionality as the Frontier CRT-P with the addition of independently programmable ventricular outputs.

Table 288. Distribution of improvement in BV and RV Group in six-minute walk (p = 0.035)

	RV (N = 66)	BV (N = 84)
No Change (–5 to 5 m)	4 (6.06%)	4 (4.76%)
Worsened (< –5 m)	16 (24.24%)	11 (13.10%)

Secondary Effectiveness Objectives and Results

Quality of Life as Measured by SF-36 Score

Objective: To determine if the BV group shows improvement over the RV group at the six-month follow-up in the health-related quality of life as measured by the SF-36 score.

Results: Using the SF-36 Quality-of-Life questionnaire, a standardized measurement of quality of life, the study found that for the six-week to six-month visit time period, the improvement in SF-36 scales was not different between groups.

Functional Capacity as Measured by Peak VO2

Objective: To determine if the BV group shows improvement in functional capacity, as measured by peak VO2, from the six-week follow-up to the six-month follow-up.

Results: The BV group showed an improvement of 0.86 ml/kg/min in peak VO2 from six weeks to six months measured during CPX testing. The BV group also had a greater percentage of patients showing improvement in peak VO2. The improvement in peak VO2 in BV and RV groups is shown in the following figure. The distribution of improvement in peak VO2 between BV and RV groups is shown in the following table.

Figure 51. Figure 1-2. Improvements in peak VO2 in BV and RV groups

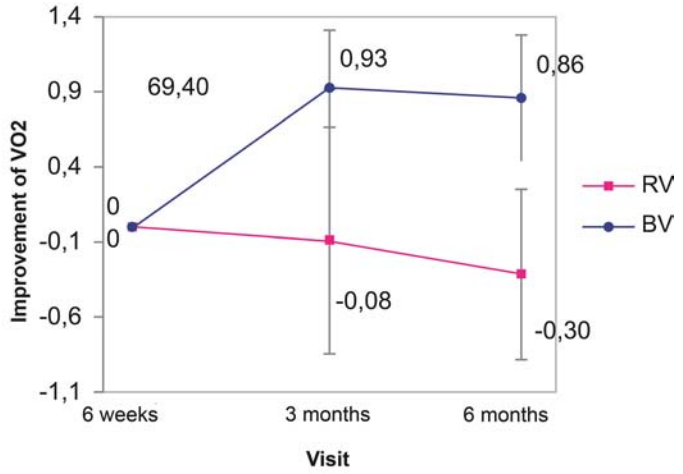


Table 289. Distribution of improvements in VO2 in BV and RV groups

Change in Peak VO2 (ml/kg/min)	RV (N = 10)	BV (N = 35)
Improved (> 0.5)	4 (40%)	21 (60.0%)
No Change (–0.5 to 0.5)	0 (0%)	4 (11.4%)
Worsened (< –0.5)	6 (60%)	10 (28.6%)

RHYTHM ICD Study

Summary of the RHYTHM ICD Study

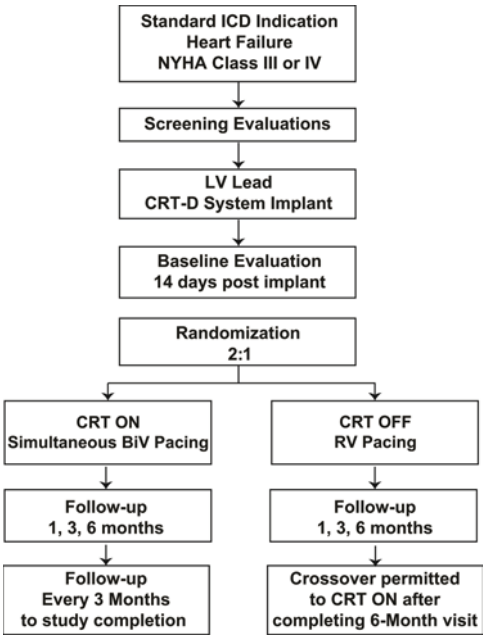
The St. Jude Medical, Inc. **R**esynchronization for **H**emod**Y**namic **T**reatment for **H**eart Failure **M**anagement (RHYTHM) ICD study was conducted under an IDE (investigational device exemption).

The purpose of the clinical study was to assess the safety and effectiveness of the Epic HF CRT-D system in patients who were indicated for standard implantable cardioverter defibrillation therapy with New York Heart Association Classification of III or IV and a prolonged QRS duration. Since the Promote device is functionally equivalent to the Epic HF device with respect to the biventricular pacing therapies, no additional clinical evaluation was performed.

The RHYTHM ICD study was a prospective, multicenter, randomized, double-blind, controlled clinical investigation designed to assess the safety and effectiveness of the Epic HF CRT-D system in patients who were indicated for standard implantable cardioverter defibrillation therapy with New York Heart Association Classification of III or IV and a prolonged QRS duration. The products being evaluated were the Epic HF V-338[508] CRT-D and the Aescula™ and QuickSite™ LV leads.

The RHYTHM ICD study design is shown in the following figure.

Figure 52. Figure 1-1. RHYTHM ICD study design



Study Objectives

The objective of this clinical study was to verify the safety and effectiveness of the Epic HF CRT-D (Model V-338) system in a standard ICD indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration.

Primary Objectives

The following are the primary safety and effectiveness objectives defined for this study.

- Safety of the Epic HF CRT-D system evaluated in terms of survival from LV lead and system-related complications.
- Defibrillation system effectiveness determined in terms of detection/redetection times and compared to those observed in the St. Jude Medical Photon™ DR device clinical investigation.
- Resynchronization effectiveness evaluated in terms of exercise capacity, as measured by cardiopulmonary exercise testing.

Secondary Objectives

The secondary objectives are listed below.

- NYHA Classification

[508] The EpicHF ModelV338 devices included in the RHYTHM ICD study did not include the AutoIntrinsic Conduction Search or the Rate-Responsive PVARP programmable parameters, or devicebased battery management. For information on these features, refer to the reference manual.

- Quality of Life Questionnaire
- Six-Minute Hall Walk Test
- Implant success rate for the Aescula Model 1055K LV pacing lead
- Aescula Model 1055K LV lead electrical performance

Patient Selection Criteria

Inclusion Criteria

Patients eligible for enrollment had:

- An approved indication for implantation of a standard ICD for treatment of a life-threatening ventricular tachy\-arrhythmia(s).
- Symptomatic, advanced heart failure (ischemic or non-ischemic) not due to reversible causes, diagnosed for at least six months.
- A New York Heart Association (NYHA) Classification of III or IV, despite receiving a minimum of 90 days of appropriate pharmacological therapy.
- Received optimal pharmacological therapy for CHF (including angiotensin converting enzyme inhibitor and beta blocker, as tolerated) which has been stable during the 30 days prior to enrollment.
- A left ventricular ejection fraction (LVEF) ≤ 35%.
- A ventricular conduction delay manifested as a QRS duration ≥ 150 ms.
- The ability to complete cardiopulmonary exercise stress testing and six-minute hall walk test, with the only limiting factor(s) being fatigue and/or shortness of breath.
- •The ability to independently comprehend and complete a quality of life questionnaire.
- •The ability to provide informed consent for study participation and be willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Exclusion Criteria

Eligible patients did not/were not:

- Have a standard bradycardic indication for pacing.
- Have a history of chronic atrial fibrillation (continuous AF lasting > one month) within one year prior to enrollment or have undergone cardioversion for AF in the past month.
- Have the ability to walk > 450 m during the six-minute walk test.
- Have a NYHA Classification of I or II.
- Have a contraindication for an emergency thoracotomy.
- Have a classification of Status 1 for cardiac transplantation or consideration for transplantation over the next six months.
- Have a recent myocardial infarction, unstable angina or cardiac revascularization (PTCA or CABG) within one month of enrollment.
- Have a recent CVA or TIA - within three months of enrollment.
- Have severe musculoskeletal disorder(s).
- Pregnant or a planning for pregnancy in the next six months.
- Currently participating in, or had participated in any clinical investigation within the last 30 days. (The only exception being that of a registry trial.)
- Have a life expectancy of less than six months.
- Less than 18 years of age.

Clinical Study Results

Patient Population

Two hundred and five patients were enrolled at 50 clinical sites in the RHYTHM ICD clinical investigation. The first Epic HF V-338 and Aescula 1055K left ventricular lead system was implanted on July 8, 2002. The first QuickSite 1056K lead was implanted on March 26, 2003.

Of the 205 patients enrolled in the RHYTHM ICD study, 183 lead implant attempts were successful (180 successful on the first attempt and three successful on the second attempt). One additional patient had a successful left ventricular lead implant, but had high defibrillation thresholds. This patient was withdrawn from the study and received a heart transplant, leaving a total of 182 successful system implants. A breakdown of the reasons for the 23 unsuccessful implants is shown in the following figure.

Table 290. Unsuccessful implants (N = 23)

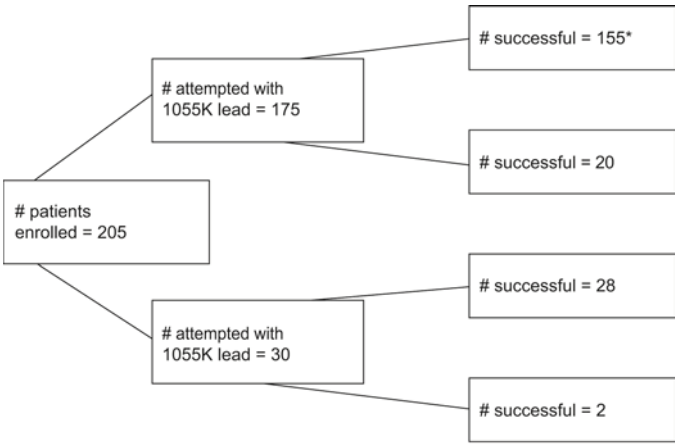
Reason	# Patients
LV Lead-Related:	
Unable to Cannulate the CS	7
Unable to Obtain Distal Placement	6
Unable to Obtain Stable Lead Position	3
High Pacing Thresholds	3

Table 290. Unsuccessful implants (N = 23)

Reason	# Patients
CS Dissection	3
Other:	
High Defibrillation Threshold	1
TOTAL	23

The leads used and the number of successful system implants for each category of leads are shown in the following figure.

Figure 53. Figure 1-2. Number of patients attempted and implanted with Model 1055K and 1056K leads



* Includes one patient with a successful lead implant, but an unsuccessful system implant due to high defibrillation thresholds.

The total time of follow-up from the time of successful implant was 2,755 patient-months. The average time of follow-up was 15.1 ± 4.1 (range 0.3 to 23.8) patient-months.

Baseline Demographic Data

Patients who were successfully implanted with the Epic HF CRT-D system had a Baseline visit approximately two weeks after implant, during which the following tests/assessments were performed: Electrical measurements on RA, RV and LV leads, cardiopulmonary exercise (CPET) test, echocardiogram, NYHA class assessment, six-minute walk test, and Minnesota Living with Heart Failure (MLWHF) questionnaire. Of the182 patients with successful implants, two patients expired and one patient withdrew from the study before the Baseline visit and therefore, 179 patients had a Baseline visit. One additional patient who had a Baseline follow-up visit refused randomization and all the Baseline evaluations except device interrogation and electrical measurements, but remained in the study. Therefore, a total of 178 patients completed the requirements of the Baseline visit.

The summarized reported data on the 178 patients available for analysis at the Baseline visit, as well as broken down by randomization group is shown in the following table.

Table 291. Summary of baseline variables and comparisons between CRT OFF and CRT ON groups

Demographic variable	Overall Group (n = 178)[509]	CRT OFF (N = 59)	CRT ON (N = 119)	p-value (CRT ON vs. CRT OFF)
NYHA Class, n (%):				0.61
I	3 (1.7%)	2 (3.4%)	1 (0.8%)	
II	10 (5.6%)	4 (6.8%)	6 (5.0%)	
III	154 (86.5%)	50 (84.7%)	104 (87.4%)	

[509] Of the 182patients that had successful system implants, two patients expired and one patient withdrew from the study before their Baseline visit; one additional patient refused randomization and all Baseline evaluations, except device interrogation and electrical measurements, and therefore, is not included.

Table 291. Summary of baseline variables and comparisons between CRT OFF and CRT ON groups

Demographic variable	Overall Group (n = 178)[509]	CRT OFF (N = 59)	CRT ON (N = 119)	p-value (CRT ON vs. CRT OFF)
IV	11 (6.2%)	3 (5.1%)	8 (6.7%)	
LV Ejection Fraction (%) - ECHO:				
Mean ± SD Range	24.8 ± 7.7 (9, 48)	23.3 ± 6.4 (11, 43)	25.6 ± 8.3 (9, 48)	0.07
QRS Duration (ms):				
Mean ± SD Range	168 ± 15 (120, 210)	167 ± 15 (130, 200)	169 ± 16 (120, 210)	0.40
LVEDD (mm):				
Mean ± SD Range	66.2 ± 8.8 (47.7, 85.9)	66.0 ± 9.4 (50.1, 84.2)	66.2 ± 8.5 (47.7, 85.9)	0.88
LVESD (mm):				
Mean ± SD Range	57.0 ± 9.87 (37.1, 78.2)	56.9 ± 10.5 (37.9, 78.2)	57.1 ± 9.4 (37.1, 76.2)	0.93
Quality of Life Score:				
Mean ± SD Range	48 ± 24 (0, 103)	46 ± 24 (4, 100)	48 ± 24 (0, 103)	0.53
Six-Minute Walk (m):				
Mean ± SD Range	280 ± 99 (31, 561)	291 ± 89 (31, 480)	275 ± 103 (37, 561)	0.30
CPET Test:				
Peak VO_2 (ml/kg/min): Mean ± SD Range	11.3 ± 3.3 (4.3, 26.9)	12.3 ± 3.5 (6.0, 23.1)	10.8 ± 3.0 (4.3, 26.9)	0.006
Exercise Time (minutes): Mean ± SD Range	8.3 ± 3.3 (0.7, 19.8)	8.9 ± 3.6 (2.3, 19.8)	8.0 ± 3.2 (0.7, 16.5)	0.08
Baseline Medications, n (%):				
ACE Inhibitors/Substitutes	129 (72.5%)	44 (74.6%)	85 (71.4%)	0.79
Beta Blockers	147 (82.6%)	52 (88.1%)	95 (79.8%)	0.24
Angiotensin Receptor Blockers	34 (19.1%)	10 (16.9%)	24 (20.2%)	0.76
Diuretics	157 (88.2%)	54 (91.5%)	103 (86.6%)	0.47
Positive Inotropics/Glycoside	112 (62.9%)	39 (66.1%)	73 (61.3%)	0.65
Nitrates	62 (34.8%)	23 (39.0%)	39 (32.8%)	0.51
Anti-Coagulants & Anti-Platelets	150 (84.3%)	48 (81.4%)	102 (85.7%)	0.59
Calcium Channel Blockers	20 (11.2%)	9 (15.3%)	11 (9.2%)	0.35
Anti-Arrhythmics	42 (23.6%)	13 (22.0%)	29 (24.4%)	0.87

Primary Safety Endpoint Results

LV Lead-Related Complications (at Six Months)

The following table summarizes the LV lead-related complications at six months. One hundred and fifty-five patients who had a successful 1055K LV lead implant were analyzed for this endpoint. A total of 11 patients experienced 13 1055K LV lead-related complications.

The survival from 1055K lead-related complications at six-months was calculated as 92.8% with a 95% lower confidence bound of 89.4%, which is greater than the objective performance criteria of 75%.

Table 292. Aescula 1055K LV lead-related complications

Description of Complication	Number of Events	Number of Patients
Diaphragmatic Stimulation	3	3
Lead Dislodgment/Migration	9	8
Elevated Pacing Threshold	1	1

Table 292. Aescula 1055K LV lead-related complications

Description of Complication	Number of Events	Number of Patients
TOTAL	13	11[510]

Epic HF System-Related Complications (at Six Months)

The System Related Complications at six months are shown in the following table. One hundred and eighty-two patients who had a successful Epic HF system implant with either the Aescula or QuickSite LV lead were analyzed for this endpoint. A total of 14 patients experienced 18 Epic HF system-related complications.

The survival from system-related complications at six months was calculated as 92.8% with a 95% lower confidence bound of 89.7%, which is greater than the objective performance criteria of 70%.

Table 293. Epic HF system-related complications

Description of Complication	Number of Events	Number of Patients
Diaphragmatic Stimulation	3	3
High Defibrillation/Cardioversion Requirements	2	2
Infection	2	2
Lead Dislodgment/Migration	9	8
Elevated Pacing Threshold	2	2
TOTAL	18	14[511]

Survival from All Complications (at Six Months)

In addition to the protocol-specified LV lead-related and system-related complication endpoints, survival from all complications at six months, including procedural complications and patients with unsuccessful implants, was analyzed following a review of the clinical results.

Two hundred and five patients who were attempted with the Epic HF system were included in this analysis. All complications experienced by each patient are shown in the following table. A total of 22 patients experienced 31 complications.

The survival from all complications at six months was calculated as 89.6% with a 95% lower confidence bound of 85.9%.

Table 294. All complications

Description of Complication	Number of Events	Number of Patients
Bleeding/Hematoma	6	6
Blood Clot/Thrombosis	1	1
CS Dissection	2	2
Diaphragmatic/Phrenic Nerve Stimulation	3	3
High Defibrillation/Cardioversion Requirements	2	2
Infection	2	2
Noise on EGM Post-Shock (non-SJM RV lead)	1	1
Lead Dislodgment/Migration	9	8
Retained Foreign Body	1	1
Pneumothorax	2	2
Elevated Pacing Threshold	2	2
TOTAL	31	22[512]

Primary Effectiveness Endpoint Results

Defibrillation System Effectiveness: VF Detection/Redetection Times

[510] One patient experienced both a lead dislodgment/migration and diaphragmatic stimulation, and one patient experienced two lead dislodgments/migrations.
[511] One patient experienced both a lead dislodgment/migration and diaphragmatic stimulation, one patient experienced two lead dislodgments/migrations, one patient had high defibrillation threshold and lead dislodgment/migration, and one patient had an elevated pacing threshold and an infection.
[512] Five patients each experienced two complications and one patient experienced four complications.

The defibrillation system effectiveness of the Epic HF CRT-D system was evaluated by comparing the time to detect or redetect an episode of ventricular fibrillation to performance criteria established in the protocol based on historical data from the Photon DR device study (P910023/S47). A total of 440 episodes in 172 patients were analyzed for detection times, and 90 episodes in 55 patients were analyzed for redetection times.

A summary of the detection and redetection times for VF episodes is shown in the following table. The mean detection and redetection times were within the objective performance criteria of 3.4 seconds and 1.9 seconds, respectively. The p-values for the detection and redetection time hypotheses were less than 0.0004. The 95% upper confidence bound was 3.11 seconds for the mean detection time and 1.61 seconds for the redetection time.

Table 295. Summary of VF detection and redetection times

Summary	Detection Time	Redetection Time
n (episodes)	440	90
N (patients)	172	55
Mean ± SD	3.1 ± 0.66	1.6 ± 0.35
Range	(1.5, 6.8)	(0.8, 2.8)

Primary Cardiac Resynchronization Therapy Effectiveness Endpoint

The resynchronization effectiveness of the Epic HF CRT-D system was evaluated by comparing the CRT ON group to the CRT OFF group for peak VO_2, an indicator of a patient's maximal exercise capacity. Patients completed a CPET at the baseline visit approximately two weeks after their CRT-D implant, and again at the six-month visit. The sample size required to satisfy this endpoint was 126 patients.

In the intention-to-treat analysis, patients who crossed over from the CRT OFF group to the CRT ON group during the study were analyzed according to the original treatment group they belonged to.

A summary of the improvement in peak VO2 values in the two treatment groups for this analysis is shown in the following table. The average improvement in the CRT ON group over the CRT OFF group was approximately 1.9 ml/kg/min. The p-value was 0.001.

Table 296. Improvement in peak VO2 values (ml/kg/min) intention-to-treat analysis (N = 126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	12.8 ± 3.7	11.2 ± 3.0
Six-months	11.4 ± 5.6	11.7 ± 3.2
Change	-1.41 ± 4.6	0.52 ± 2.5
Overall improvement in CRT ON vs. CRT OFF = 1.9 ml/kg/min		

Analysis of Exercise Time

The improvement in exercise time between the Baseline and six-month visits was analyzed. Patients who were not able to perform the CPET at six-months due to documented heart failure were assigned exercise times of 0. The following table shows that the CRT ON group had an improvement in exercise time over the CRT OFF group of approximately 109 seconds. The p-value was 0.002.

Table 297. Change in exercise time (seconds) (N = 126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	558 ± 216	498 ± 192
Six-months	510 ± 270	558 ± 210
Change	-50.4 ± 252	58.2 ± 132
Overall improvement in CRT ON vs. CRT OFF = 109 seconds		

Secondary Endpoint Results

Resynchronization Effectiveness

Secondary endpoints for resynchronization effectiveness were NYHA class, Quality of Life, and the Six-Minute Hall Walk Test. These endpoints were evaluated on the same patient group that was analyzed for the Peak VO2 endpoint.

New York Heart Association Classification

The average change in NYHA Class from Baseline to six months for each group is shown in the following table. Overall the improvement in the CRT ON group was greater than the improvement in the CRT OFF group by approximately 0.2 functional classes.

Table 298. Average improvement in NYHA class (N = 126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	2.86 ± 0.52	3.01 ± 0.33
Six-months	2.58 ± 0.73	2.53 ± 0.69
Change	-0.28 ± 0.63	-0.48 ± 0.65
Overall change in CRT ON vs. CRT OFF = 0.2 functional classes		

Quality of Life

Patient quality of life was assessed with the MLWHF questionnaire. A lower score indicates an improvement in quality of life.

A summary of the improvement in quality of life in the two treatment groups is shown in the following table. The average improvement in the CRT ON group over the CRT OFF group was approximately 11 points.

Table 299. Improvement in quality of life score (N = 126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	42.0 ± 23	48.3 ± 24
Six-months	45.4 ± 31	40.4 ± 22
Change	3.4 ± 31	-7.8 ± 22
Overall improvement in CRT ON vs. CRT OFF = 11 points		

6-Minute Hall Walk Test

A summary of the improvement in six-minute walk distance in the two treatment groups for this analysis is shown in the following table. The average improvement in the CRT ON group over the CRT OFF group was approximately 28 m.

Table 300. Improvement in six-minute walk distance (m) (N = 126)

	CRT OFF Mean ± SD (N = 43)	CRT ON Mean ± SD (N = 83)
Baseline	298 ± 94	284 ± 105
Six-months	283 ± 150	297 ± 122
Change	-15 ± 142	13 ± 74
Overall improvement in CRT ON vs. CRT OFF = 28 m		

Additional Data

Echocardiographic Data

Echocardiographic analysis was performed at the Baseline and six-month follow-up visits. The following parameters were evaluated from the echocardiographic analysis: LVEDD, LVESD, LVEF, MR, E/A Wave Point Ratio, and Sphericity Index. Cardiac dyssynchrony (including Pre-Ejection Delay Time and Intraventricular Mechanical Delay) was also evaluated at Baseline and six months. A summary of the improvement in these parameters between Baseline and six months is shown in the following table.

Table 301. Improvement in echocardiography parameters

Parameter	CRT OFF Mean ± SD (N = 40)	CRT ON Mean ± SD (N = 82)
LVEDD (mm)	-2.4 ± 6.5	-4.3 ± 5.4
LVESD (mm)	-3.0 ± 6.4	-4.6 ± 7.0
LVEDV (ml)	-37 ± 53	-43 ± 69
LVESV (ml)	-36 ± 47	-43 ± 58
LVEF (%)	2.9 ± 6.2	4.3 ± 9.9
MR (grade)	0.10 ± 0.50	-0.06 ± 0.74
E/A Wave Point Ratio	-0.02 ± 1.2	-0.08 ± 0.8
Sphericity Index	0.02 ± 0.1	-0.02 ± 0.1
Pre-Ejection time (ms)	7.3 ± 33	-1.5 ± 52
IVMD (ms)	-6.4 ± 48	-14.5 ± 52
Tei Index	-0.05 ± 0.5	-0.4 ± 0.8
Contraction Interval (ms)	-55 ± 103	-94 ± 124

Biventricular Pacing at Six Months

The average percentage of biventricular pacing at the six-month visit in the 83 patients who were in the CRT ON group among the 126 patients in the primary resynchronization cohort was 95% ± 6%, with a range of 70 to 100%.

Patient Discontinuation/Withdrawals

A total of 47 patients participating in the RHYTHM ICD study were withdrawn from the study. Twenty patients (including the 19 patients with unsuccessful LV lead implants and the one patient with an unsuccessful system implant due to high defibrillation thresholds) were withdrawn approximately one month after unsuccessful system implants in accordance with the protocol. Twenty-two patients died and were also withdrawn from the study. Three of the 22 deaths occurred in patients who had previously unsuccessful implants. In addition to these 20 unsuccessful implants and 22 deaths, five additional patients were withdrawn from the study. A summary of the reason for these five patient withdrawals is shown in the following table.

Table 302. Patient discontinuations/withdrawals (excludes withdrawals for deaths and after unsuccessful implants)

Reason for Withdrawal	CRT Group	Days after Implant
System Explant	N/A[513]	1
Heart Transplant	ON	75
Patient Request	ON	28
Patient Request	ON	397
Patient's Family Request	ON	293

Conclusions Drawn From The RHYTHM ICD Study

In NYHA Class III and IV heart failure patients with LV dyssynchrony and a standard ICD indication, this study demonstrated that cardiac resynchronization is safe and improves functional status.

RHYTHM ICD Study: V-V Optimization Phase

Summary of the V-V Optimization Phase of the RHYTHM ICD Study

The objective of the V-V Optimization Phase of the RHYTHM ICD study was to demonstrate that optimizing the interventricular timing of biventricular pacing therapy yields an improvement in exercise capacity (Peak VO_2) or in left ventricular performance as measured by echocardiography using the left ventricular end systolic diameter (LVESD), that is similar to simultaneous biventricular pacing in a standard ICD indicated patient population with advanced heart failure (NYHA Classification III or IV) and prolonged QRS duration. Included in the study were the Epic HF Models V-337 and V-338[514] devices and the Atlas+ HF Model V-343 device.

[513] Patient was withdrawn before the Baseline visit and randomization.
[514] The EpicHF ModelV338 device had the Interventricular Pace Delay enabled by the programmer.

The primary endpoint was stated as follows (where p is defined as the percentage of patients improved):

H_0:p (Optimized V-V) ≤ p (Simultaneous) - 0,25
H_1:p (Optimized V-V) > p (Simultaneous) - 0,25

Patients completed a cardiopulmonary exercise test (CPET) and an echocardiography test at the Baseline and six-month visits. The sample size required to satisfy the endpoint was 120 patients (72 in the Simultaneous group and 48 in the Optimized group).

The total time of follow-up from the time of successful implant was 3328.7 patient months. The average time of follow-up was 15.2 ± 4.3 (range 0.7 to 26.7) patient months.

Summary of V-V Optimization

At the time of the Baseline visit, all patients underwent echo guided optimization of their AV delay. Patients who were randomized to the Optimized group also underwent echo guided optimization of the interventricular pace delay (V-V delay). Optimization of the V-V delay was determined using the procedure defined in the protocol, which evaluated multiple V-V delays ranging from 20-80 ms with either the LV or RV chamber selected as the first chamber paced. This testing sequence was randomized to minimize any bias in performing this evaluation. The final programmed value for the V-V delay was determined based on the maximum left ventricular velocity time integral (VTI), which was assessed by pulse wave Doppler interrogation of the left ventricular outflow tract.

The distribution of the optimized V-V delay settings among the 48 patients in the Optimized group is shown in the following table. The optimized V-V settings were approximately evenly distributed among the patients. Only five patients (10.4%) were optimized to the simultaneous setting.

Table 303. Distribution of optimized V-V delay among optimized group

First Chamber Paced: V-V Delay	Number of Patients (N = 48)
LV First: 80 ms	6 (12.5%)
LV First: 40 ms	8 (16.7%)
LV First: 20 ms	9 (18.8%)
Simultaneous	5 (10.4%)
RV First: 20 ms	7 (14.6%)
RV First: 40 ms	6 (12.5%)
RV First: 80 ms	7 (14.6%)

Clinical Study Results

Three patients in the V-V Optimization Phase of the RHYTHM ICD study were not able to complete all the testing requirements at six months due to worsening heart failure. One patient was withdrawn prior to the six-month visit when he received a heart transplant. This patient did not complete a six-month CPET or echocardiographic evaluation. The other two patients completed a six-month echocardiographic evaluation, but were not able to complete a six-month CPET due to worsening heart failure.

A summary of the Peak VO2 and LVESD values at Baseline and six months, as well as the improvement from Baseline in the two treatment groups are shown in the following tables.

Table 304. Baseline and six-month peak VO2 (ml/kg/min)

	Simultaneous Mean ± SD (N = 72)	Optimized Mean ± SD (N = 45)
Baseline	11.3 ± 3.1	11.5 ± 3.5
Six-months	11.9 ± 3.3	12.4 ± 3.4
Change	0.57 ± 2.6	0.93 ± 3.2

Table 305. Baseline and six-month and LVESD (mm)

	Simultaneous Mean ± SD (N = 72)	Optimized Mean ± SD (N = 45)
Baseline	57.0 ± 9.8	54.1 ± 12.1

Table 305. Baseline and six-month and LVESD (mm)

	Simultaneous Mean ± SD (N = 72)	Optimized Mean ± SD (N = 45)
Six-months	52.2 ± 9.8	50.7 ± 11.9
Change	-4.7 ± 7.2	-3.4 ± 5.8

An analysis of the observed difference between the Optimized and Simultaneous groups was performed. A significant p-value ($p < 0.05$) meant that optimized pacing was not inferior to simultaneous pacing. The analysis compared patients that showed improvement in both Peak VO2 and LVESD. A summary of this analysis is shown in the following table. The observed difference in proportion improved between the Simultaneous and Optimized groups (i.e., $p_{sim} - p_{opt}$) is 0.6% and the 95% Blackwelder confidence interval for the difference is (-100%, 14.5%). The p-value was 0.0004. The null hypothesis was rejected, and therefore optimized V-V pacing is not inferior to simultaneous pacing. Overall, improvement in Peak VO2 and improvement in LVESD did not trend in the same direction. Simultaneous patients showed a greater improvement in LVESD and Optimized patients showed a greater improvement in Peak VO2.

Table 306. Percent of improvement in peak VO2 (ml/kg/min) and LVESD (mm)

	Simultaneous (N = 72)		Optimized (N = 45)	
	Peak VO2	LVESD	Peak VO2	LVESD
% Improved[515]	37.5%	47.2%	45.8%	43.8%
% No Change	38.9%	44.4%	27.1%	45.8%
% Worsened	23.6%	8.3%	27.1%	10.4%
% Improved[516] in Peak VO2 and LVESD	19.4%		18.8%	

Conclusions Drawn From the VV Optimization Phase of the RHYTHM ICD Study

Cardiac resynchronization therapy (CRT) with optimization of V-V delay was shown to be similar to CRT with simultaneous pacing in terms of the percentage of patients that were found to be responders.

Zephyr IDE Clinical Trial

The Zephyr IDE Clinical Trial was conducted using the Zephyr DR 5820 and Zephyr XL DR 5826 pulse generators. The Zephyr pulse generator was evaluated in a multicenter (15 US centers) clinical trial involving 161 patients.

There were four primary endpoints for the Zephyr IDE clinical study.

- Safety of the device system: Freedom from system related complications
- Safety of the VAC feature: Success rate of VAC (as determined by the presence of back up pulses on 24 hour Holter)
- Effectiveness of VAC: Difference in ventricular capture threshold determined by VAC and by a manual test (semi-automatic capture threshold test)
- Effectiveness of ACC: Difference in atrial capture threshold determined by ACC and by a manual test (semi-automatic capture threshold test)

Patient Population

The overall study population consisted of 161 enrolled patients. All patients were evaluated for safety of the device system, 142 patients were evaluated for VAC effectiveness, 82 patients were evaluated for ACC effectiveness, and 64 patients were evaluated for VAC safety. Of these patients, 91 (56.5%) were females and 70 (43.5%) were males. The mean age at implant was 71.8 ± 11.6 years. The primary indications for pulse generator implantation in the study population are summarized in the following table.

Table 307. Primary Indications for Implantation

Indication	No. of Patients (%)
Sinus Node Dysfunction	62 (38.5%)
Sinus Bradycardia	53 (32.9%)
Heart Block	36 (22.4%)
Syncope	8 (5.0%)

[515] Improvement in Peak VO2 was defined as an increase of at least 1.1ml/kg/min and improvement in LVESD was defined as a decrease of at least 5mm.
[516] Improvement in Peak VO2 was defined as an increase of at least 1.1ml/kg/min and improvement in LVESD was defined as a decrease of at least 5mm.

Table 307. Primary Indications for Implantation

Indication	No. of Patients (%)
Neurocardiogenic Syncope	2 (1.2%)

The mean duration of implant for all patients in the study was 5.1 ± 1.5 months (minimum duration: 0; maximum duration: 9.1 months).

Primary Safety Endpoint for the Zephyr Device System

System related complications of the Zephyr device through the 3 month visit

The system related complications at three months are shown in the following table. All 161 patients were included in this endpoint analysis. None of the complications were related to the investigational pulse generator. A total of 3 patients experienced 3 system related complications in this study.

The survival from system related complications at 3 months was estimated as 98.1% with a 95% lower confidence bound of 95.2%, using Greenwood's formula, which is greater than the objective performance criteria of 85%. Hence, the null hypothesis is rejected at the 5% significance level.

Table 308. System Related Complications

Event Description	# of Patients	# of Events
Lead Dislodgement or Migration - RV lead	1	1
Lead Body Prolapse - RA Lead	1	1
Phrenic Nerve/Diaphragmatic Stimulation - RA lead	1	1
Total	3	3

Primary Safety Endpoint for VAC

Safety of VAC at the 3 month follow up visit

The primary analysis was performed on all patients who had analyzable 24-hour Holter monitor testing results. Sixty-four patients were available in the "analyzable" patient cohort for the primary safety endpoint, which is greater than the required sample size of 62 patients. This analysis was carried out on all available 64 patients.

None of the patients included in the analysis had consecutive losses of capture not followed by a back up pulse. Therefore, the success rate of VAC at 3 months by Holter Monitor was estimated as 100%, with 95% confidence limits (94.3%, 100%). The p-value for the VAC safety endpoint is 0.01. Hence, the null hypothesis is rejected.

Primary Effectiveness Endpoint

Effectiveness of VAC at the 3 month follow up visit

The primary analysis was performed on the first 65 patients who had paired bipolar ventricular capture threshold measurements at 3 months. The data are summarized in the following table.

The 95% two-sided confidence limits on the difference in the median ventricular capture thresholds were calculated based on the distribution-free confidence intervals method for percentiles described in Hahn and Meeker and are shown in Table 5. The confidence interval is within the equivalence limit of (-0.25, 0.25) V, hence the null hypothesis is rejected at the 2.5% significance level. Since this safety endpoint is met at the stricter criterion of the 2.5% significance level, it is also met at the 5% significance level.

Table 309. Primary Analysis - Bipolar Ventricular Capture Thresholds at 3 months VAC Effectiveness Patient Cohort (N=65)

	VAC Test (V)	Semi-Automatic Threshold Test (V)	Difference VAC - Semi-Automatic (V)
Median	0.88	1.00	-0.13
Mean ± SD	1.0 + 0.51	1.1 + 0.52	-0.06 ± 0.21
Range	(0.38, 3.13)	(0.25, 2.75)	(-0.75, 0.88)
95% confidence limits on median difference (V)	(-0.13, 0.0)		

Effectiveness of ACC at the 3 month follow up visit

The primary analysis was performed on the first 41 patients who had paired atrial bipolar capture threshold measurements at 3 months. The data are summarized in the following table.

The 95% two-sided confidence limits on the difference in the median atrial capture thresholds are calculated based on the distribution-free confidence intervals method for percentiles described earlier, and are shown in Table 6. Since this endpoint is met at the stricter criterion of the 2.5% significance level, it is also met at the 5% significance level.

Table 310. Primary Analysis - Atrial Capture Thresholds at 3 months ACC Effectiveness Patient Cohort (N=41)

	ACC Test (V)	Semi-Automatic Threshold Test (V)	Difference ACC - Semi-Automatic (V)
Median	0.63	0.75	-0.13
Mean ± SD	0.73 + 0.30	0.79 + 0.32	-0.06 ± 0.10
Range	(0.38, 1.88)	(0.25, 2.0)	(-0.25, 0.25)
95% confidence limits on median difference (V)	(-0.13, 0.0)		

MultiPoint™ Pacing IDE Study

The purpose of this pivotal IDE study was to demonstrate that the MultiPoint™ Pacing (MPP) feature is safe, and that its efficacy is non-inferior to biventricular (BiV) pacing. Although this study was evaluated in patients receiving CRT-D devices, the results apply to CRT indicated patients (CRT-P and CRT-D). CRT therapy is indicated primarily for heart failure (HF) patients with electrical dyssynchrony regardless of the need for an ICD. Patients who receive CRT-P therapy are substantially similar to those who receive CRT-D therapy. As MPP therapy is an enhancement to the pacing options in CRT therapy with the goal of resynchronization, the clinical data on safety and efficacy of the MPP applies to CRT-P and CRT-D indicated patients.

Study Endpoints

The primary objective of this study was to assess safety and efficacy of the MPP feature in HF patients indicated for a CRT-D device; enrollment was not limited to patients with symptomatic HF. The safety objective of the study was addressed through an objective performance criterion and the efficacy objective through a non-inferiority study design. The study was not designed or powered to show superiority of the MPP feature as compared to BiV pacing.

- The primary safety endpoint: freedom from system-related complications >75% at 9 months
- The primary efficacy endpoint: non-inferiority of 9-month non-responders in the MPP vs. BiV arm (15% non-inferiority margin)

Study Design

The study was a prospective, randomized, double-blind, multi-center clinical study that was conducted at 49 investigational centers located in the U.S., and 506 subjects were enrolled. All subjects received BiV pacing from implant to the 3-month randomization visit. A Blinded Assessor evaluated subject's NYHA Class at all study visits through the 9-month visit and subject's Patient Global Assessment (PGA) at the 3, 6, and 9-month visits. At the 3-month visit, all subjects underwent acute measurement of cardiac performance (echocardiography) at various MPP™ feature combinations compared to BiV pacing. Only subjects with "equal or better" echocardiographic measurements with the MPP feature ON compared to BiV pacing were randomized. The randomization was a 1:1 ratio to one of the two study arms (BiV or MPP) and stratified by subject's responder status. Randomization was also blocked by investigational site. All other subjects were programmed to BiV pacing and were followed in the Observation arm for safety. At the 9-month visit, responder status was compared to the status at 3 months for the evaluation of the primary efficacy endpoint. All subjects were followed every 6 months thereafter until the end of the study.

Evaluation of Responder Status

Subjects' responder status was assessed using the Clinical Composite Score (CCS). The CCS includes four components: NYHA class, PGA, HF events, and cardiovascular death.

The NYHA Class assessment and PGA were determined by a Blinded Assessor interviewing subjects about their symptoms. Specifically, the PGA was a single interview question that asked the subject to categorize how they feel compared to their previous visits as either:

- Markedly better
- Better
- No change
- Worse
- Markedly worse

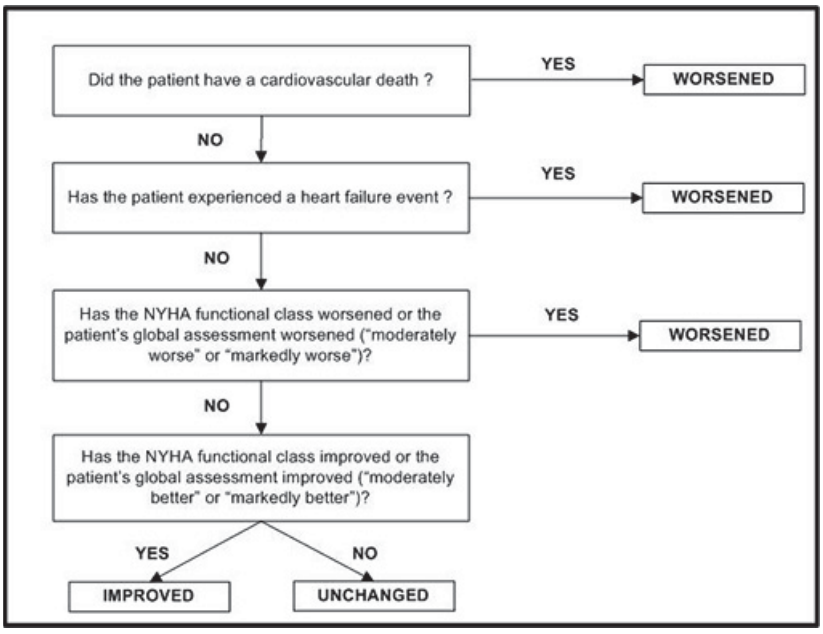
HF event was defined as any one of the following when the subject had symptoms and/or signs consistent with congestive heart failure:

- Hospitalization for HF ≥ 24 hours
- Clinic or hospital visit for HF <24 hours (i.e. outpatient treatment, observational care, ER, Urgent Care and physician's office visit) requiring administration of IV diuretics, inotropes, and/or vasodilators

Cardiovascular death was defined as sudden unexpected death; heart failure death; myocardial infarction related; or 'other' such as pulmonary embolism, peripheral thromboembolism, stroke, deaths due to vascular procedure, or other major cardiovascular event.

Using the CCS and decision algorithm (see figure below) subjects were categorized as Improved, Worsened or Unchanged.

Figure 54. Decision Algorithm to Classify CCS



The responder and non-responder status at both 3 months and 9 months based on the CCS is summarized in the table below. As described in this table, a responder at 9 months ("improved" or "unchanged" from 3 months) was defined differently from the definition of a responder at 3 months ("improved" from enrollment). Specifically, a responder was defined as a subject with improved status at 3 months and 9 months. In addition, a 3-month responder with unchanged status at 9 months was considered a responder at 9 months. Under this definition, arresting the progression of heart failure after randomization for 3-month responders (Unchanged status from 3 to 9 months) is considered a success.

Table 311. Responder/Non-Responder Definition at 3 and 9 Months

3-Month Responder/Non-Responder Definition	9-Month Responder/Non-Responder Definition[517]
Improved = Responder	Improved/Unchanged = Responder
	Worsened = Non-Responder
Unchanged/Worsened = Non-Responder	Improved = Responder
	Unchanged/Worsened = Non-Responder

Inclusion and Exclusion Criteria

Eligible patients met all of the following:

1. Meets current clinical indication for implantation of a CRT-D system for treatment of heart failure or life-threatening ventricular tachyarrhythmia(s).
2. Receiving a new CRT implant or undergoing an upgrade from an existing ICD or pacemaker implant with no prior LV lead placement.
3. Have the ability to provide informed consent for study participation and are willing and able to comply with the prescribed follow-up tests and schedule of evaluations.

Patients were excluded if they met any of the following:

1. Have had a recent Cerebrovascular Accident (CVA) or Transient Ischemic Attack (TIA) within 3 months of enrollment.
2. Have an existing Class I recalled lead.
3. Have a hypersensitivity to a single 1.0 mg dose of dexamethasone sodium phosphate.
4. Have a classification of Status 1 for cardiac transplantation or consideration for transplantation over the next 9 months.

[517] Relative to 3-month status.

5. Have permanent atrial fibrillation (AF).
6. Have undergone a cardiac transplantation within 40 days of enrollment.
7. Have had a recent myocardial infarction, unstable angina within 40 days or cardiac revascularization (PTCA, Stent or CABG) within 3 months of implant.
8. Are currently participating in a clinical investigation that includes an active treatment arm.
9. Are pregnant or planning to become pregnant during the duration of the study.
10. Have a life expectancy of less than 9 months due to any condition.
11. Are less than 18 years of age.

Clinical Study Results

Subject enrollment in the MPP IDE study began on April 25, 2013 and ended on July 2, 2014. For the 455 subjects who received a successful implant, the average duration of follow-up per subject was 13.72 ± 4.52 (range 0.13 to 23.56) months.

The table below summarizes demographic and medical history information on subjects enrolled and subjects who underwent implant in the MPP IDE study.

Table 312. Demograpic and Medical History

Demographic Variable	Enrolled Subjects (N=506)	Attemped Implant Subjects (N=469)
Age (years)		
Mean ± SD (n)	68 ± 10 (506)	68 ± 10 (469)
Range	(29, 94)	(29, 94)
Gender, n/N (%)		
Male	336/506 (66.4%)	309/469 (65.9%)
Ethnicity, n/N (%)		
Hispanic or Latino	18/506 (3.6%)	17/469 (3.6%)
Non-Hispanic or Latino	488/506 (96.4%)	452/469 (96.4%)
Race, n/N (%)		
White	444/506 (87.7%)	411/469 (87.6%)
Black or African American	51/506(10.1%)	49/469 (10.4%)
Asian	3/506 (0.6%)	3/469 (0.6%)
American Indian or Alaska Native	1/506 (0.2%)	0/469 (0.0%)
Other	7/506 (1.4%)	6/469 (1.3%)
NYHA Class at Baseline per Blinded Assessory, n/N (%)		
Class I	53/502 (10.6%)	49/469 (10.4%)
Class II	146/502 (29.1%)	137/469 (29.2%)
Class III	284/502 (56.6%)	264/469 (56.3%)
Class IV	19/502 (3.8%)	19/469 (4.1%)
History of Smoking, n/N (%)		
Yes	328/506 (64.8%)	304/469 (64.8%)
QRS Duration (ms)		
Mean ± SD (n)	155 ± 22 (472)	156 ± 22 (438)
Range	(80, 220)	(80, 220)
QRS Morphology		
LBBB	365/500 (73.0%)	343/465 (73.8%)
RBBB	58/500 (11.6%)	53/465 (11.4%)
IVCD	77/500 (15.4%)	69/465 (14.8%)
Cardiomyopathy Etiology, n/N (%)		
Ischemic	247/506 (48.8%)	230/469 (49.0%)
Non-Ischemic	254/506 (50.2%)	265/469 (50.1%)
None	5/506 (1.0%)	4/469 (0.9%)
Cardiovascular History, n/N (%)		
Coronary Artery Disease	326/506 (64.4%)	304/469 (64.8%)
Myocardial Infarction	180/506 (35.6%)	171/469 (36.5%)

Table 312. Demograpic and Medical History

Demographic Variable	Enrolled Subjects (N=506)	Attemped Implant Subjects (N=469)
Unstable Angina	35/506 (6.9%)	33/469 (7.0%)
Valvular Disease	176/506 (34.8%)	164/469 (35.0%)
CABG	141/506 (27.9%)	130/469 (27.7%)
PTCA/Stents/Atherectomy	153/506 (30.2%)	142/469 (30.3%)
Valvular Intervention	47/506 (9.3%)	40/469 (8.5%)
Ablation	45/506 (8.9%)	40/469 (8.5%)
Arrhythmia History, n/N (%)		
Ventricular Arrhythmias	115/506 (22.7%)	110/469 (23.5%)
Atrial Arrhythmias	173/506 (34.2%)	158/469 (33.7%)
Other Medical Conditions, n/N (%)		
Asthma	40/506 (7.9%)	37/469 (7.9%)
Cerebrovascular Disease	38/506 (7.5%)	34/469 (7.2%)
Chagas	0/506 (0.0%)	0/469 (0.0%)
COPD	93/506 (18.4%)	81/469 (17.3%)
Diabetes	221/506 (43.7%)	204/469 (43.5%)
Hyperlipidemia	373/506 (73.7%)	346/469 (73.8%)
Hypertension	387/506 (76.5%)	357/469(76.1%)
Liver Disease	8/506 (1.6%)	8/469 (1.7%)
Neoplasm	36/506 (7.1%)	32/469 (6.8%)
Peripheral Vascular Disease	56/506 (11.1%)	54/469 (11.5%)
Renal Disease	125/506 (24.7%)	118/469 (25.2%)
Sarcoidosis	2/506 (0.4%)	2/469 (0.4%)
Thyroid Disease	73/506 (14.4%)	65/469 (13.9%)
Other	194/506 (38.3%)	177/469 (37.7%)
Primary CRT-D Indication for Implant, n/N (%)		
HF with Wide QRS	416/506 (82.2%)	385/469 (82.1%)
Reduced EF with Frequent Dependence on V-Pacing	34/506 (6.7%)	32/469 (6.8%)
HF with Frequent Dependence on V-Paging	25/506 (4.9%)	23/469 (4.9%)
Other	31/506 (6.1%)	29/469 (6.2%)

Primary Safety Endpoint

The following definitions are useful when discussing the safety endpoint:

An *adverse event* is any unfavorable clinical event which impacts, or has the potential to impact the health or safety of a clinical study participant caused by or associated with a study device or intervention.

A *complication* is any adverse event resulting in an invasive intervention (e.g., lead dislodgement resulting in repositioning).

A *system related complication* is a complication related to the device system which includes pulse generator and leads, as adjudicated by the CEC.

The hypothesis is formally expressed as:

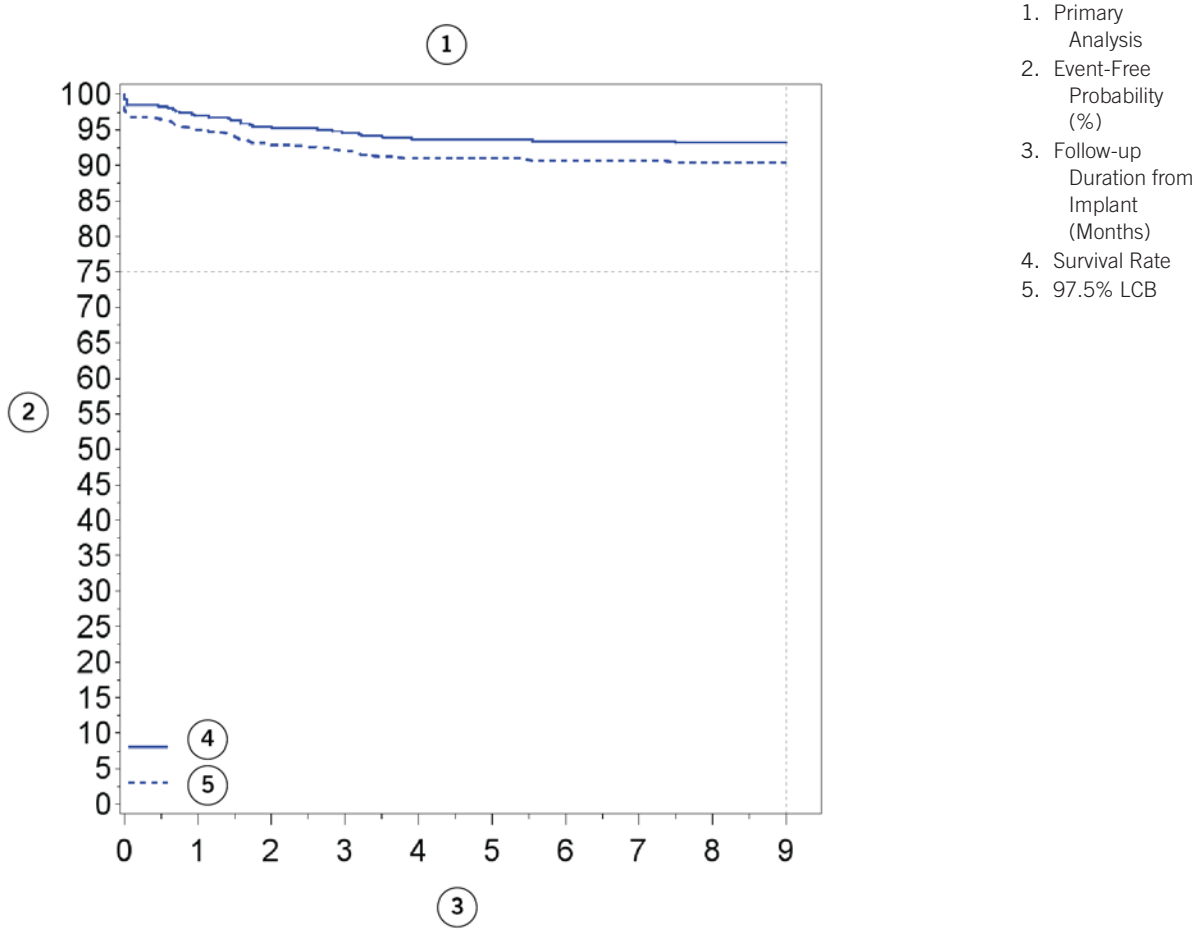
H_0 :Freedom from system-related complications through 9 months ≤ 75%

H_a: Freedom from system-related complications through 9 months > 75%

The desired outcome is to reject the null hypothesis. The hypothesis will be rejected at the 2.5% significance level if the one-sided 97.5% lower confidence bound (LCB) for freedom from system-related complications through 9 months is greater than 75%.

The figure below displays the Kaplan-Meier survival curve for freedom from system-related complications through 9 months.

Figure 55. Primary Safety Endpoint - Freedom from System-Related Complications through 9 Months (N = 469)



1. Primary Analysis
2. Event-Free Probability (%)
3. Follow-up Duration from Implant (Months)
4. Survival Rate
5. 97.5% LCB

Follow-up Duration from Implant (Months)

Data Category	0	1	2	3	4	5	6	7	8	9
At Risk	469	449	428	417	405	400	394	390	385	382
Event	3	14	21	25	29	29	30	30	31	31
Censors	1	6	20	27	35	40	45	49	53	56
Survival	99.4%	97.0%	95.4%	94.5%	93.6%	93.6%	93.4%	93.4%	93.2%	93.2%
97.5% LCB	98.0%	95.0%	93.1%	92.0%	91.0%	91.0%	90.7%	90.7%	90.4%	90.4%
Event Rate	0.6%	3.0%	4.6%	5.5%	6.4%	6.4%	6.6%	6.6%	6.8%	6.8%

The table below provides the Kaplan-Meier estimate of freedom from system-related complications through 9 months and the 97.5% LCB. Thirty one (31) subjects experienced system-related complications through 9 months. The Kaplan-Meier freedom from system-related complications through 9 months was estimated as 93.2% and the 97.5% LCB was 90.4%, which was well above the objective performance criterion of 75%. Hence, the primary safety was met.

Table 313. Primary Safety Endpoint - Freedom from System-Related Complications through 9 Months (N = 469)

Kaplan-Meier Estimate	97.5% Lower Confidence Bound (LCB)	Objective Performance Criterion (OPC)	Endpoint Met? (Yes/No)
93.2%	90.4%	75.0%	Yes

Primary Efficacy Endpoint

The efficacy objective of the study was addressed through a non-inferiority study design that enrolled CRT-D indicated subjects and was not limited to symptomatic HF subjects. The study was not designed or powered to show superiority of the MPP™ feature as compared to BiV pacing.

Treatment efficacy with MPP versus standard BiV pacing was evaluated by a test for non-inferiority for the proportion of 9-month non-responders in the MPP arm versus the BiV arm. The hypothesis is formally expressed as:

$H0: P_{BiV} - P_{MPP} \leq -0.15$
$Ha: P_{BiV} - P_{MPP} > -0.15$

where $P_{BiV} - P_{MPP}$ are the proportions of 9-month non-responders in the BiV and MPP arms, respectively. The desired outcome is to reject the null hypothesis. The hypothesis will be rejected at the 2.5% significance level if the 97.5% lower confidence bound (LCB) for the difference in the proportion of non-responders at 9 months between the BiV and MPP arms is greater than -0.15. The primary analyses were carried out on all randomized subjects (Intention To Treat, ITT population) as well as the population who received either MPP or BiV pacing at 9 months or at the last follow-up prior to 9 months (As Treated population).

In the primary analysis, the following definition of 9-month responder status is used:

If subject is a responder at 3 months:

- if subject improved or experienced no change from 3 months, subject is defined as a 9-month responder.
- if subject worsened from 3 months, subject is defined as a 9-month non-responder.

If subject is a non-responder at 3 months:

- if subject improved from 3 months, subject is defined as a 9-month responder.
- if subject experienced no change or worsened from 3 months, subject is defined as a 9-month non-responder.

As shown in the table below, the difference in 9-month non-responder rates between the BiV and MPP arms was -4.9% for the ITT population and -3.9% in the As Treated population. The 97.5% LCB for the difference in 9-month non-responder rates between the BiV and MPP arms in the ITT and As Treated populations were -13.8% and -12.9%, respectively, which are both greater than the non-inferiority margin of -15%. Hence, the efficacy endpoint was met.

Table 314. Primary Effectiveness Endpoint - 9 Month Non-Responder Rates (relative to response status at 3 months)

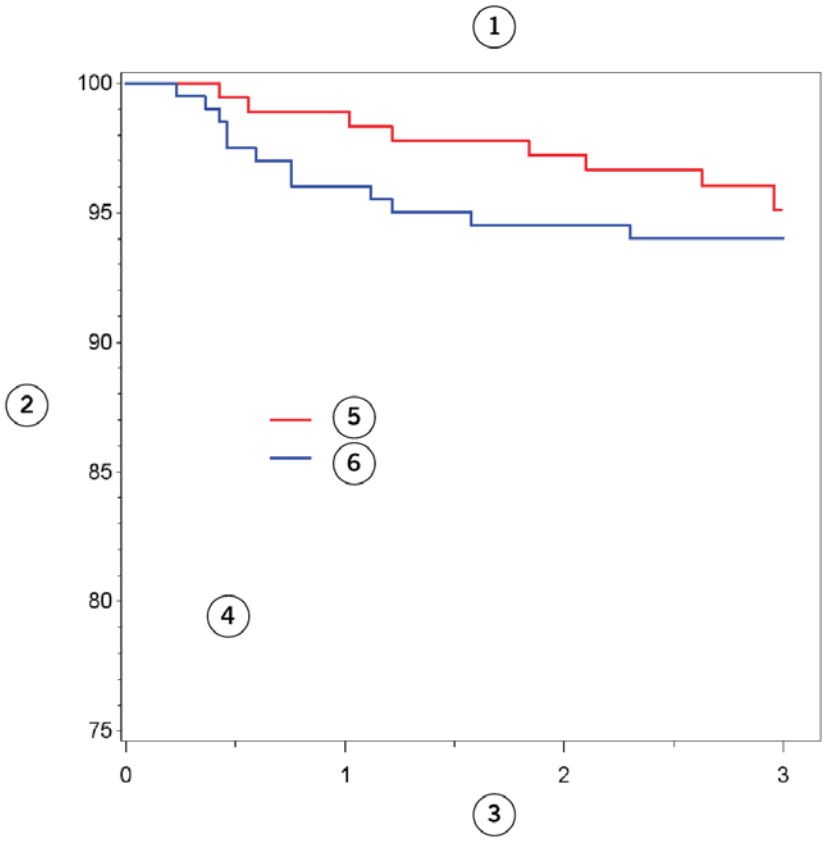
Analysis Population	BiV Arm % (n/N)	MPP Arm % (n/N)	Difference (BiV-MPP) (97.5% LCB[518])	p-value[519] (Non-Inf Margin = -15%)	Endpoint Met? (Yes/No)
ITT - [Last observation carried forward (LOCF)]	25.0% (45/180)	29.9% (60/201)	-4.9% (-13.8%)	0.0131	Yes
As Treated (LOCF)	25.8% (48/186)	29.7% (57/192)	-3.9% (-12.9%)	0.0078	Yes

Additional Analyses

Freedom from heart failure events from implant through randomization in the two arms is shown in the figure below. Through 3 months, all subjects received BiV pacing, therefore, there is no expectation for a difference in heart failure event rates between the two arms from the time of implant to the randomization time point. However, as shown in the figure, subjects in the MPP arm, although not statistically significant, tended to be sicker and experience more heart failure events than those in the BiV arm during this period.

[518] 97.5% LCB and p-value are calculated using the normal approximation for binomial proportions
[519] 97.5% LCB and p-value are calculated using the normal approximation for binomial proportions

Figure 56. Freedom from Heart Failure Event through 3 Months (Randomization) from Successful Implant



1. Intention to Treat
2. Event-Free Probability (%)
3. Follow-up Duration from Implant (months)
4. LOG RANK test: p=0.48
5. BiV Arm pre-Randomization
6. MPP Arm pre-Randomization

	Follow-up Duration from Implant (Months)			
BiV Arm	0	1	2	3
At Risk	180	178	175	92
HF Events	0	2	5	8
Censored	0	0	0	80
Survival	100%	98.9%	97.2%	95.1%
HF Event Rate	0.0%	1.1%	2.8%	4.9%

	Follow-up Duration from Implant (Months)			
MPP Arm	0	1	2	3
At Risk	201	193	190	82
HF Events	0	8	11	12
Censored	0	0	0	107
Survival	100%	96.0%	94.5%	94.0%
HF Event Rate	0.0%	4.0%	5.5%	6.0%

The table below shows that a large proportion of non-responders at 3 months in the BiV arm was converted to responders at 9 months (100% - 34.9% = 65.1%). This observation of continued improvement beyond the randomization time point in the comparator BiV arm is consistent with the echocardiographic findings in the following section. However, it is in contrast to data from previous studies that CRT response typically occurs within 3 months and that non-responders to CRT at 3 months would remain non-responders after 3 months.

Given that the comparator group demonstrated continued improvement beyond the randomization time point, a non-inferiority analysis comparing MPP™ and BiV pacing is most appropriate.

Table 315. 9-Month Non-Responder Rate by 3-Month Responder Status and Randomization Arm[520]

3-Month Responder Status	9-Month Non-Responder Rate: BiV Arm % (n/N)	9-Month Non-Responder Rate: MPP arm % (n/N)
Non-Responder	15/43 (34.9%)	19/45 (42.2%)
Responder	30/137 (21.9%)	41/156 (26.3%)
p-value[521]	0.8923	

Echocardiographic Data

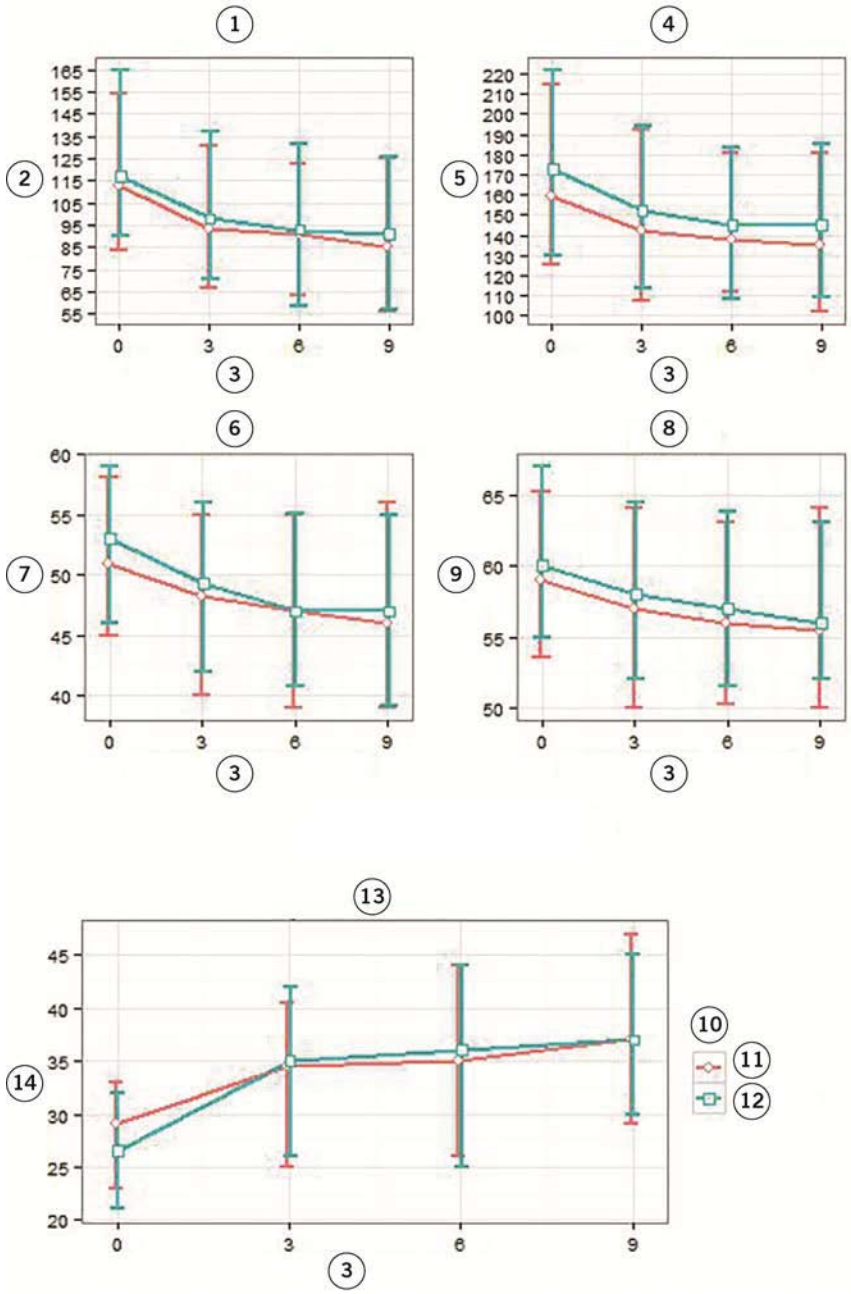
Echocardiographic measurements of left ventricular (LV) end systolic and diastolic volumes (LVESV and LVEDV) and dimensions (LVESD and LVEDD) and LV ejection fractions as reported by the investigator are summarized (median and interquartile range) at baseline, 3 months, 6 months and 9 months in the figures below. As shown, the BiV arm and MPP arm achieved comparable degree of reduction in LV volumes and dimensions at 9 months. Perhaps the most noteworthy observations are as follows:

- Consistent with the earlier observation of a sicker population in the MPP arm than in the BiV arm before randomization, shows that MPP arm subjects initially had a larger LV end systolic and diastolic volumes and dimensions than the BiV arm, which the figure below shows persisted through the 3 months prior to randomization.
- Left ventricular volumes and dimensions and left ventricular ejection fraction improved well beyond the 3-month randomization time point in both arms, and in particular the comparator BiV arm.

Despite the observation of a sicker population in the MPP arm and the continued improvement in the BiV arm through the study period, the MPP arm experienced comparable, if not greater, improvement in these echocardiographic measures at 9 months (refer to the figure below). Specifically, at 9 months MPP arm subjects tended to have greater percent reduction in LV end systolic and diastolic volumes than the BiV arm (-25.7% and -14.9% in MPP respectively vs. -22.8% and -10.6% in BiV).

[520] 9-month response status is relative to 3 months and 3-month response status is relative to baseline.
[521] Interaction p-value (from logistic regression model) for 9-month non-responder rate between 3-month responder status and randomization arm.

Figure 57. LV End Systolic and Diastolic Volumes[522] and Dimensions[523] and LV Ejection Fraction[524] at Baseline and Follow-up (Median, 25th and 75th percentile)



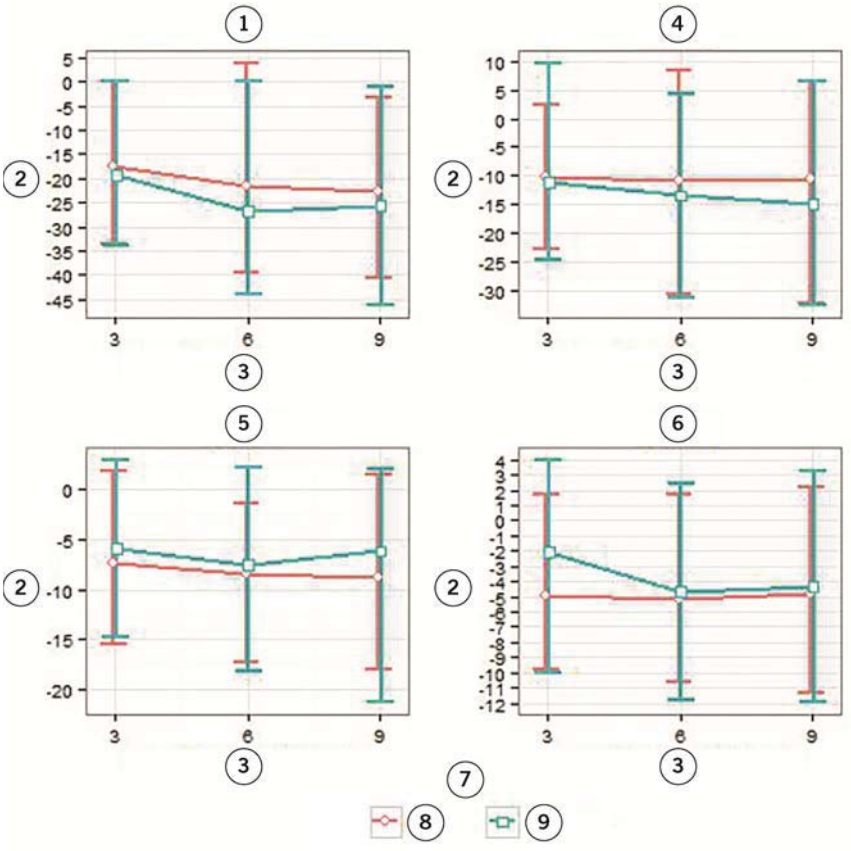
1. LVESV
2. LVESV (mL)
3. Follow Up Visit (Months)
4. LVEDV
5. LVEDV (mL)
6. LVESD
7. LVESD (mm)
8. LVEDD
9. LVEDD (mm)
10. Randomization Arm
11. BiV Arm
12. MPP Arm
13. Ejection Fraction
14. Ejection Fraction (%)

	Median			
Arm	0	3 Months	6 Months	9 Months
LV End Systolic Volume (mL)				
BiV	113.0	93.4	90.8	85.6
MPP	117.0	98.0	93.0	91.0
LV End Diastolic Volume (mL)				

[522] Echocardiographic measurements as reported by the investigator
[523] Echocardiographic measurements as reported by the investigator
[524] Echocardiographic measurements as reported by the investigator

Median				
Arm	0	3 Months	6 Months	9 Months
BiV	159.4	142.5	138.0	135.0
MPP	173.0	152.3	145.0	145.1
LV End Systolic Dimension (mm)				
BiV	51.0	48.2	47.1	46.0
MPP	53.0	49.3	47.0	47.0
LV End Diastolic Dimension (mm)				
BiV	59.0	57.0	56.0	55.5
MPP	60.0	58.0	57.0	56.0
Ejection Fraction (%)				
BiV	29.0	34.5	35.0	37.0
MPP	26.5	35.0	36.0	37.0

Figure 58. Percent Change from Baseline in LV End Systolic and Diastolic Volumes[525] and Dimensions[526] at Follow-up (Median, 25th and 75th percentile)



1. LVESV
2. % Change from Baseline
3. Follow-up Visit (Months)
4. LVEDV
5. LVESD
6. LVEDD
7. Randomization_Arm
8. BiV Arm
9. MPP Arm

Median % Change from Baseline			
Arm	3 Months	6 Months	9 Months
LV End Systolic Volume (% Change)			
BiV	-17.5%	-21.6%	-22.8%

[525] Echocardiographic measurements as reported by the investigator
[526] Echocardiographic measurements as reported by the investigator

Median % Change from Baseline			
Arm	3 Months	6 Months	9 Months
MPP	-19.4%	-26.8%	-25.7%
LV End Diastolic Volume (% change)			
BiV	-10.1%	-10.8%	-10.6%
MPP	-11.3%	-13.5%	-14.9%
LV End Systolic Dimension (% change)			
BiV	-7.3%	-8.5%	-8.8%
MPP	-6.0%	-7.5%	-6.2%
LV End Diastolic Dimension (% change)			
BiV	-4.9%	-5.2%	-4.8%
MPP	-2.1%	-4.7%	-4.3%

The table below presents the summary of % change in LVESV from Baseline by 9-month response status. At 9 months, reverse remodeling tended to be greater in the MPP arm as reflected by the percent reduction in LVESV in relation to baseline. Specifically, 9-month non-responders in the MPP arm benefited from reverse remodeling (20.0% median reduction in LVESV relative to baseline) at a level that is well above what is considered to be a clinically accepted standard for positive response (equal or more than a 15% reduction) to CRT. In contrast, 9-month non-responders in the BiV arm experienced a modest benefit of 12.9% median reduction in LVESV which is less than the threshold typically used to define a response to CRT.

Table 316. Summary of % Change in LVESV at 9 Months from Baseline by 9-Month Status

9-Month Status (relative to 3 months)	% Change in LVESV from Baseline Median (N)	
	BiV Arm	MPP Arm
Non-Responder	-12.9% (N = 40)	-20.0% (N = 55)
Responder	-26.1% (N = 133)	-28.9% (N = 140)
Total	-22.0% (N = 173)	-25.7% (N = 195)

Conclusion

The purpose of this pivotal IDE study was to demonstrate that the MultiPoint™ Pacing (MPP™) feature is safe, and that its efficacy is non-inferior to that of BiV pacing. The MPP IDE study showed that the response to the MPP feature is non-inferior to BiV pacing in patients who demonstrate an adequate acute hemodynamic response using the echocardiographic measure EA VTI when pacing with the MPP feature. MPP feature's effectiveness compared to BiV in patients with an inadequate acute hemodynamic response is not known. The MPP IDE study was designed to use acute measurement of cardiac performance (for example, EA VTI) to assess if the MPP feature is appropriate to be programmed and then to determine the ideal MPP feature settings. As such, acute hemodynamic assessment by echocardiography may be beneficial if the MPP feature is appropriate and to determine the ideal MPP feature settings. Reverse remodeling among patients receiving MPP therapy trended toward being greater than those who received BiV pacing. As a programmable feature that has been shown to be safe and no less effective than BiV pacing, clinicians may choose to evaluate MPP therapy options in CRT non-responders and responders. The results of the MPP IDE Study provide reasonable assurance of safety and efficacy of the CRT device system (with MPP feature) when used as indicated in accordance with the direction for use.

Summary of Published Literature using the MPP™ Technology

Study	References	Year	Site	Number of Subjects	Conclusion
Thibault, et al	1, 2 (page 436)	2013	Montreal Heart Institute, Montreal, Quebec, Canada	19	Use of the MPP feature improved acute LV dP/dtMax compared with BiV pacing using a pacing protocol designed to isolate changes due to cardiac effects
Rinaldi, et al	3, 4 (page 436)	2013, 2014	7 European centers	52	Use of the MPP feature was acutely safe, and a proportion of MPP pacing configurations resulted in a significant reduction in echocardiographic dyssynchrony and increase in radial strain compared with conventional CRT
Shetty, et al	5 (page 436)	2014	St. Thomas Hospital, London, United Kingdom	15	MPP therapy may be able to give some degree of haemodynamic benefit, and delivery via a single lead may be as efficacious as multisite LV pacing with multiple leads.

Study	References	Year	Site	Number of Subjects	Conclusion
Pappone, et al	6, 7, 8, 9 (page 436)	2014, 2015	Maria Cecilia Hospital, GVM Care & Research, Cotignola, Italy	44	MPP therapy significantly improved acute LV hemodynamic parameters assessed with pressure-volume loop measurements and improved mid- and long-term LV reverse remodeling compared to conventional CRT Multipoint LV pacing may provide additional improvement to LV function in patients receiving conventional CRT
Endrj, et al	10 (page 436)	2015	Ospedale Santa Croce e Carle, Cuneo, Italy	10	CRT with MPP therapy improved both endocardial and surface electrical parameters and hemodynamics in comparison with conventional biventricular pacing
Zanon, et al	11, 12 (page 436)	2015	Santa Maria Della Misericordia Hospital, Rovigo, Italy	29	MPP therapy yielded a small but consistent increase in hemodynamic response compared with BiV pacing at any LV site or with LV only pacing
Park, et al	13 (page 436)	2015	Samsung Medical Center, Seoul, Korea	8	MPP therapy resulted in better electrical and structural reverse remodeling after 6 months compared to using conventional bipolar lead in patients receiving CRT device implantation
Forleo, et al	14, 15 (page 436)	2015	Fifty-seven (57) Italian center survey	313	MPP therapy was programmable in 97% of patients; At follow-up QRS was reduced and EF improved with MPP relative to conventional BiV
Osca, et al	16 (page 436)	2015	Hospital Universitari i Politècnic La Fe, Valencia, Spain	25	In comparison to conventional CRT pacing, MPP therapy decreased further LV dyssynchrony indexes and resulted in an additional improvement in LVEF and in CO

References

1. Thibault B, et al. Acute haemodynamic comparison of multisite and biventricular pacing with a quadripolar left ventricular lead. Europace. 2013;15:984–91.
2. Thibault B, et al. Design of an Acute dP/dt Hemodynamic Measurement Protocol to Isolate Cardiac Effect of Pacing. J Card Fail. 2014;20(5):365-72.
3. Rinaldi CA, et al. Acute effects of multisite left ventricular pacing on mechanical dyssynchrony in patients receiving cardiac resynchronization therapy. J Card Fail. 2013; 19(11):731-8.
4. Rinaldi CA, et al. Improvement in acute contractility and hemodynamics with multipoint pacing via a left ventricular quadripolar pacing lead. J Interv Card Electrophysiol. 2014;40(1):75-80.
5. Shetty AK, et al. A comparison of left ventricular endocardial, multisite, and multipolar epicardial cardiac resynchronization: an acute haemodynamic and electroanatomical study. Europace. 2014;16(6):873-9.
6. Pappone C, et al. Multipoint left ventricular pacing improves acute hemodynamic response assessed with pressure-volume loops in cardiac resynchronization therapy patients. Heart Rhythm. 2014;11(3):394–401.
7. Pappone C, et al. Multipoint left ventricular pacing in a single coronary sinus branch improves mid-term echocardiographic and clinical response to cardiac resynchronization therapy. J Cardiovasc Electrophysiol. 2015;26(1):58-63.
8. Pappone C, et al. Improving cardiac resynchronization therapy response with multipoint left ventricular pacing: Twelve-month follow-up study. Heart Rhythm. 2015; 12(6):1250-8.
9. Pappone C, et al. Multipoint left ventricular pacing provides additional echocardiographic benefit to responders and non-responders to conventional cardiac resynchronization therapy. European Heart Journal Supplements. 2015;17(suppl A): A12-A17.
10. Endrj M, et al. Characterization of Ventricular Activation Pattern and Acute Hemodynamics during MultiPoint Left Ventricular Pacing. Heart Rhythm. 2015; 12(8):1762-9.
11. Zanon F, et al. Multipoint pacing by a left ventricular quadripolar lead improves the acute hemodynamic response to CRT compared with conventional biventricular pacing at any site. Heart Rhythm. 2015;12(5):975-81.
12. Zanon F, et al. Acute hemodynamic comparison of left ventricular, biventricular and multipoint pacing in CRT. Heart Rhythm. 2015;12(5):AB38-04.
13. Park SJ, et al. More favorable electrical and mechanical reverse remodeling after cardiac resynchronization therapy with quadripolar versus conventional bipolar lead. Heart Rhythm. 2015;12(5):AB28-05.

14. Forleo GB, et al. A new algorithm for multi point pacing in cardiac resynchronization therapy: feasibility from a multicenter experience. Heart Rhythm. 2015;12(5):P002-190.

15. Forleo GB, et al. Impact of multi-point left ventricular pacing on QRS duration and left ventricular ejection fraction: preliminary results from a multicenter prospective study. Heart Rhythm. 2015;12(5):P004-183.

16. Osca J, et al. Multipoint pacing in left ventricle with a quadripolar lead improves cardiac dyssynchrony and haemodynamics in comparison to conventional pacing. Heart Rhythm. 2015;12(5):P002-188.

Index

A

A Cap Confirm Capability 181
AAI Mode 161
AAT Mode 161
Abdominal Implantation 321
Accent Devices Technical Data 225
Active Button, Zone Therapy 107
Activity Recalibration 31
Acute IEGM Study 395
Adaptive Burst Cycle Length 111
Add Stimuli Per Burst, ATP Therapy 111
Add/Edit Clinical Comment, CorrVue Monitoring 32
Additional Parameters
  Capture Test 36
  Sense Tests 36
Additional Settings, PVC & PMT 85
Adjust Display 13
Advanced Hysteresis, Episode Triggers 144
AF Suppression Algorithm 89
AF Suppression/CRT-D Study 402
Alert Notification 135
  Percent Pacing Alert Triggers 139
  Test Notifier Button 135
Alert Triggers 135
Alerts 17
Amplitude Trend 35, 36
AMS
  AMS Log 29
  AMS Summary 29
AMS Base Rate 89
AMS Max Trigger Rate 89
AMS V. Triggering 88
AMS, see Auto Mode Switch 29
Anthem Technical Data 239
AOO Mode 162
Arrhythmia Unhiding 86
AT/AF
  AT/AF Summary 30
  Burden 29
  Definition 31
  Detection & Response Parameters 88
  Diagnostics 30
  Log 30
  V Rates During AT/AF 30
AT/AF Alert Notification 136
  High Ventricular Rate
Episode Trigger & Alert Trigger 136
    AT/AF Alert Triggers 136
AT/AF Alert Triggers 136
AT/AF Alert Triggers Capability 182
AT/AF Burden 29
ATP
  ATP Details Window 110
  ATP Therapy Details Episodes 23
  Parameters 110
  Pulse Amplitude 110
  Pulse Width 110
  Therapy Configurations 113
ATP Prior to Charging 109
ATP Therapy Prior to Charging 183
ATP Therapy While Charging 183
ATP While Charging 109
Atrial Episode, EGM Storage 144
Atrial Heart Rate Histogram 27
Atrial Max Sensitivity 78
Atrial Pace Refractory 84
Atrial Sense Refractory 85
Atrial Tachycardia Detection Rate 89
Audio Preferences 4
Auto Mode Switch 88
Auto Mode Switch Diagnostics, see Mode Switch Diagnostics 28
Automatic Pulse Amplitude 75
Automatic Test Option, Sense Tests 37
Automaticity Clinical Investigation 407
AutoSense Function 80
AutoSense Parameter 77
AV Association Delta 103
AV Delays Window 39
AV Interval Delta 97
AV Intervals Diagnostics 28

B

Backup Defibrillation, Reset Settings 177
Backup Pulse Configuration 78
Backup Safety Pulse 75
Base Rate 68
  Intervals at ERI 314
Basic Operation Parameters 63
Battery & Leads, Tests 39
Battery Details, Tests 39
Battery Model 2356 184
Battery Model 2555 184
Battery Model 2753 185
Battery Model 2850 185
Battery Model 2950 186
Battery Test Rate, see Magnet Rate 40
Battery Voltage
  Elective Replacement Indicator 324
  End of Life 325
  Out-of-Service/Explant/Patient Death 355
Battery Voltage at ERI 314
Beginning-of-Life (BOL) 40
Bigeminal Rhythm
  SVT Discrimination Timeout and 94
  Tachycardia Detection and 125
  VT Therapy Timeout and 107
BiVCap Confirm Capability 186
Block Rate 74
Brady Pacing, Emergency VVI 175
Brady Parameters 63
  AT/AF Detection & Response 88
  Basic Operation 63
  Capture & Sense 75
  Delays 71
  Leads 81
  Rates 68
  Rates & Refractories 90
  Refractories & Blanking 82
Bradycardia Device Longevity 293
Bradycardia Devices
  Clinician Use Information 293
Bradycardia Pacing, Testing at Implant 324
Burst Cycle Length
  Adaptive 111
  ATP Therapy 111
  Fixed 111
Burst Test
  Fibber 53
  Instructions (Fibber) 53
  Instructions (NIPS) 57
  NIPS 57

C

Cap Confirm Parameter 75
Cap Confirm Settings 78
Cap Confirm Trend 35, 36
Capabilities 181
Capacitor Maintenance
  Arrhythmia Detection during 41
  Details of 41
Capacitor Maintenance Window 124
Capacitor Test 41
Capacity, Stored EGM 142
Capture & Sense Parameters 75
Capture Test 33
  Additional Parameters 36
  Instructions 34
  Last Session 36
  Options 36
  This Session 35
Channel Control Buttons 5
Charge Interval 124
Clear Diagnostics Button 153
Clear ERI 39, 314
Clear Trends
  Patient Data 18
  Wrap-up Overview 153
Clinical Studies 433
  Acute IEGM Studies 395
  ADOPT-A Study 399
  AF Suppression/CRT-D Study 402
  DEFINITE Trial 411
  PAVE Study 421
  RHYTHM ICD Study 423
  V-V Optimization Phase of RHYTHM ICD Study 432
Clinician Use Information for Bradycardia Devices 293
Clinician Use Information for Tachycardia Devices 317
Commanded Shock, see Emergency Shock 175
Confirming Bradycardia Sensing and Pacing 324
Consecutive High Ventricular Rate Cycles 146
Consecutive PVCs, Episode Triggers 144
Continuous Time in AT/AF 137
CorVue Thoracic Impedance Monitoring Feature 147
CorVue Log 32
CorVue Thoracic Impedance Monitoring 31
CorVue Threshold 32
Crosstalk 86
CRT Toolkit Report 174
Current Technical Data 253
Custom EGM 14
  Source 144
Custom Sets 149
  Create and Save a Custom Set 149
  Delete a Custom Set 149
  Export a Custom Set 150
  Import a Custom Set 150
  Load a Custom Set 149
  Rename a Custom Set 150
Cycle Count, Hysteresis Rate 71

D

Daily Exercise Training 31
Date 3
DC Fibber Test 53
  Instructions 53
DDD Mode 155
DDI Mode 156
DDT Mode 157
Decay Delay 79
DecisionTx Programming 393
Defib Therapy Button 56
Defibrillation Testing 323
DeFT Response Technology Settings 116
Delays Parameters 71
Deliver Therapy Button 56
Detect Fluid Early from Intra-thoracic Impedance Monitoring (DEFEAT-PE STUDY) 374
Detection Criteria Parameters 91
Detection Interval/Rate 92
Device
  Bradycardia Device Longevity 293
  Tachycardia Device Longevity 325
Device-Based Testing 56, 323
  Confirming Bradycardia Sensing and Pacing 324
Devices Supported by Merlin 165
Diagnosis Details, Episodes 23
Diagnosis, SVT Discrimination 96
Diagnostic Settings 147
  CorVue Thoracic Impedance Monitoring Feature 147
Diagnostics 27
  AT/AF 30
  Mode Switch 28
Diagnostics, Select Diagnostics for Printing 173
DirectTrend Reports 173
DOO Mode 157
Duration, AT/AF Summary Diagnostics 30
Duration, Mode Switch Diagnostics 29
DVI Mode 158

E

ECG 5
ECG Configuration 14
EF Button 18
EGM Configuration 14
EGM Source Configuration, Episode Settings 143
EGM Storage
  Configuration 141
  Time 141
Elective Replacement Indicator 314, 324
Ellipse Technical Data 259
Emergency Operation 175
Emergency Shock 175
  RF Communication 175
Emergency VVI Pacing 175
End of Life 325
End-of-Life 293
Enhanced AT/AF Diagnostics Capability 29, 188, 189
Enhanced Diagnostic Trend (1-Year Daily Reports) Capability 189
Enhanced Diagnostic Trend Capability 189
Episodal Pacing Mode 65
Episode Directory 21
Episode Settings 141
Episode Tree 24
Episode Triggers 144
  Advanced Hysteresis, Episode Triggers 144
  Atrial Episode, EGM Storage 144
  Consecutive PVCs, Episode Triggers 144
  High Ventricular Rate 145
  Morphology Template Update, EGM Storage 144
  Noise Reversion, EGM Storage 144
  Non-sustained RV Lead Noise Episode Trigger 144
  Non-sustained VT/VF Episode Trigger 144
  PMT Termination, Episode Triggers 144
  PVC Count, Episode Triggers 144
  VF Episode Trigger 144
  VT Episode Trigger 144

Episodes....21
ATP Therapy Details....23
Detail....22
Diagnosis Details....23
HV Charging Panel, Episodes....26
Logs & Summaries....25
Other....21
SVT Criteria Statistics....24
SVT Diagnosis Summary and Morphology Template Details....25
Therapy Summary....26
Update Episodes Button....21
VT/VF Episodes....21
Episodes, Select Episodes for Printing....174
ERI, Clear Button....39
ERI, see Elective Replacement Indicator....314, 325
Events, Rates Diagnostics....27
Exercise & Activity Diagnostic Tools....31
Exercise & Activity Diagnostics....31
Explanting the Pulse Generator....355
Export
Data....153
Export Screen....4
Extrastimuli Test, NIPS....57
Instructions....57

F

FARI....88
FastPath Summary Screen....17
Feature capabilities....181
Fibber & NIPS Window....52
Fibber Device-Based Testing....56
1st Therapy Method....56
Parameters....56
Time to Therapy....57
Fibber Mode....53
Fibber Test....53
Instructions....53
Pulse Duration....55
RF Communication....53
S1 Count....55
S2 Shock Energy....55
Time Since Last Induction....53
Fibrillation Induction....53
Filtered Atrial Rate Interval....88
Fixed Burst Cycle Length....111
Follow-up EGM
Capture Test....36
Sense Test....36
Follow-up EGMs Capability....190
Follow-up Visits....324
Fortify Assura Technical Data....275
Fortify Devices Technical Data....271
Frontier II
Summary of Clinical Investigations....416

H

Hardware Reset, see Reset Function....177
Header Configurations....317
Heart In Focus Report....174
Heart Rate Histogram
Atrial....27
Ventricular....28
? Button....1
High V Rate EGM Max Duration....141
High V Rate Pre-Trigger Max Duration [Heading]....142
High Ventricular Rate
Episode Trigger & Alert Trigger....136
High Ventricular Rate, Episode Triggers....144
HV Lead Impedance....41
HVLI Monitoring
Lower Limit....82
Upper Limit....82
Hysteresis Rate....70, 78
Intervention Duration....71
Intervention Rate....71

I

Impedance Monitoring....31
Impedance, Lead....40
Implant Notes....18
Implantation
Abdominal....321
Lead Connection....322
Leads....322
Pectoral....321
Pocket Formation....322
Site 321
Implantation Testing....322
Brady Pacing....324
Brady Sensing....324
Pacing Thresholds....323
Include Battery & Leads Button, Test Results Settings....174
Include Old Episodes Button....21
Increment Test Option, Sense Tests....37
Initial Values, Restore....154
Instructions....13
Acquiring a Morphology Template....106
Capture Test....34
Emergency Shock....176
Fibber Test....53
Instructions for Conducting MultiVector Testing....49
NIPS Test....57
QuickOpt Optimization....52
Rhythm Display Setup....13
Sense Tests....37
Interval Stability
Description....127
Parameter....103
Window....102
Window Size....104
Intervention Duration....71
Intervention Rate....71
Interventricular Delay....64

L

Large Freezes, Test Result Settings....174
Last Session
Capture Test....36
Sense Tests....36
Lead Configurations....317
Lead Impedance....40
Changes Over Time....324
Lead Implantation....322
Lead Information, Patient Data....18
Lead Monitoring....82
Lead Type....81
Leadless ECG....14, 143
Leads Parameters....81
Legend, Rate Zone....126
Logs
AMS Log & AT/AF Log....29
AT/AF....30
Logs & Summaries, Episodes....25

Logs (Episodes) 24
Low Frequency Attenuation Capability 192
Low Frequency Attenuation Filter 81
Lower Limit
HVLI Monitoring 82
Impedance Monitoring 82

M

Magnet Rate 40
Magnet Response 64
Episode Triggers 144
Magnet Use 354
Main Programming Window 167
Marker Control Buttons 5
Markers 6
Brady Basic Event Markers 6
Brady Special Event Markers 8
Episode Trigger Event Markers 8
Interval and Refractory Markers (Full Markers) 7
Morphology Markers 10
Tachy Basic Event Markers 7
Tachy Charge Delivery Markers 10
Tachy Detection, Diagnosis, and Therapy Markers 9
User Initiated and Test Markers 11
Waveform Channel Markers 12
Match, see % Match 98
Max Sensitivity 79
Max Sensor Rate 66
Max Step, ATP Therapy 113
Max Track Rate 69
Maximum AF Suppression Rate 90
Measured Auto Slope 65
Measured Average Sensor 65
Minimum Burst Cycle Length 112
Mode 63
Descriptions 155
Mode Switch Diagnostics 28
Monitor Button, Zone Therapy 107
Monitor Only Zone 107
SVT Discrimination Timeout and 133
VT Therapy Timeout and 134
Morphology
Description 127
Parameter 97
Scores 106
Window Size 99
Morphology in AF/A Flutter 97
Morphology in Sinus Tach 98
Morphology No. of Matches 98
Morphology Scoring Parameter 107
Morphology Scoring Window 106
Morphology Template 105
Instructions 106
Morphology Template Update, EGM Storage 144
Morphology Window 97

N

Negative AV Hysteresis/Search 74
NIPS
Instructions 57
Parameters 58
Pulse Configuration 60
RF Communication 57
Test 57
Test Parameters 59
No. Intervals, Detection Criteria 92
Noise Reversion, EGM Storage 144
Nominal Value Icon 170
Noninvasive Programmed Stimulation, see NIPS 57
Non-sustained RV Lead Noise Episode Trigger 144
Non-sustained VT/VF Episode Capability 193
Non-sustained VT/VF Episode Trigger 144
Note 19
Number of Bursts, ATP Therapy 111
Number of Cycles (Consecutive High Ventricular Rate Cycles) 146
Number of Cycles/Step
Capture Test 36
Sense Tests 36
Number of Notifications 138
Number of Stimuli, ATP Therapy 111

O

Off Setting, Zone Configuration 125
1 Zone 125
On-Screen Keyboard 19
Onset Delta 105
Options
Capture Test 36
Sense Tests 36
Other Episodes 21
Out-of-Service/Explant/Patient Death 355
Overdrive Pacing Cycles 90

P

Paced AV Delay 72
Parameters
ATP 110
Brady 63
DeFT Response Technology 116
Episode Triggers 144
Interval Stability 102
Modes 155
Redetection & Post-Detection Criteria 121
Selection 170
SenseAbility Sensing Algorithm Settings 79
Sinus Tach Rate Branch Control 96
Stored EGM Configuration 141
Zone Therapy 107
Patient
Antiarrhythmic Drug Therapy 317
Counseling 317
Electrophysiologic Testing 317
Exercise Stress Testing 317
Follow-up 324
Information 317
Pre-Discharge EP Testing 324
Patient Data 18
Lead Information 18
Patient Information 18
Patient Notifier Delivery 138
PC Shock, see Emergency Shock 175
Select Episodes for Printing 174
PDFs 3
Peak A Rate
AT/AF Summary 30
Mode Switch Diagnostics 29
Pectoral Implantation 321
% Match 98
Percent Pacing Alert Duration (Duration) 139
Percent Pacing Alert Triggers 139
Percentage BiV Pacing Limit (Percent Pacing Less Than) 139
Percentage RV/V Pacing Limit (Percent Pacing Greater Than) 139

Perform Test
Capture Test....34
Sense Tests....34
Plugged Port Lead Type Capability....195
PMT Detection Rate....87
PMT Response....87
Additional Settings....85
PMT Settings....85
PMT Termination, Episode Triggers....144
Pocket Formation....322
Post Detection
Description....122
Interval/Rate....121
Post-Shock
Base Rate....123
Duration....124
Mode....123
Pause....124
Pulse Amplitude....124
Pulse Width....124
Post-Shock Pacing Window....123
Post-Ventricular Atrial Blanking (PVAB)....83
Preferences....4
Preview Changes....171
Print Screen....4
Printer Icon....167
Priority, Episode Triggers....144
Problem Solving
Low Acute Lead Impedance....323
Prolonged Arrhythmia Detection Times....323
Programmed Setting Icon....170
Programmer Commanded Shock, see Emergency Shock....175
Promote Devices Technical Data....279
Promote Q CRT-D and Quartet Left Ventricular Heart Lead Study....378
Pulse Amplitude....77
Post-Shock....124
Pulse Amplitude, ATP....110
Pulse Configuration....82
NIPS....60
Pulse Width....77
Post-Shock....124
Pulse Width, ATP....110
PVAB, see Post-Ventricular Atrial Blanking....83
PVARP....83
PVC & PMT Settings....85
PVC Count, Episode Triggers....144
PVC Response....87
PVC Response, Additional Settings....85

Q

QuickOpt Optimization....50
Clinical Study Results....395
Instructions....52
Manual Test....51

R

Ramp Step, ATP Therapy....113
Ramp, ATP Therapy....113
Rate Branch....96
Description....126
Rate Overlap....105
Rate Responsive Atrial Refractory Period, see Rate Responsive PVARP/V Ref....83
Rate Responsive AV Delay....72
Rate Responsive PVARP/V Ref....83
Rate Responsive Ventricular Refractory Period, see Rate Responsive PVARP/V Ref....83
Rate Zone Legend....126
Rate-Responsive Modes....162
Rates & Refractories....90
Rates Parameters....68
Reaction Time....66
Readaptive, ATP Therapy....112
Real-Time Measurements....33
Recommended Replacement Time, see Elective Replacement Indicator....314
Reconfirmation....134
Recovery Time....66
Redetection & Post-Detection Criteria Window....121
Refractories & Blanking Parameters....82
Refractory Period
A. Pace....84
A. Sense....85
V. Pace....85
V. Sense....85
Report Settings....174, 175
Reports, Print
CRT Toolkit Report....174
Select Diagnostics Reports for Printing....173
Select Episodes for Printing....174
Select Referral Reports for Printing....174
Wrap-up™ 개요 설정(보고서)....174
Reset Function....177
Rest Rate....69
Restore Initial Values Button....154
RF Communication....167
Emergency Shock....175
Fibber and NIPS....52
Fibber Test....53
NIPS....57
RF Telemetry....167
RF Telemetry Capability....196
Rhythm Display....5
Setup Instructions....13
Update Auto Gains Button....13
RRT, see Elective Replacement Indicator....314
RV Polarity Parameter, DeFT Response Settings....116

S

Safety Margin, Cap Confirm and V. AutoCapture....75
Scan Step, ATP Therapy....112
Scanning, ATP Therapy....112
Search Frequency....78
Search Interval....78
SecureSense....92
SecureSense Configuration....93
SecureSense Timeout Until Therapy....93
SecureSense™ RV Lead Noise Discrimination Capability....197
Select Diagnostics Reports for Printing....173
Select Episodes for Printing....174
Select Nominals Button....80
Select Referral Reports for Printing....174
Sense Configuration....82
Sense Tests....36
Additional Parameters....36
Automatic Option....37
Increment Option....37
Instructions....37
Last Session....36
Options....36
This Session....35
SenseAbility Sensing Algorithm Settings....79
Sensed AV Delay....72

Sensing Parameters, see SenseAbility Sensing Algorithm Settings 79
Sensitivity....78
AutoSense Function 80
Sensor 65
Sensor Threshold, see Threshold 65
Session Record 1
Audio Preferences.... 2
Find a Session Record.... 2
Import a Session Record.... 2
Review a Session Record.... 2
Select New Files Button.... 2
Session Records 2
Shock Configuration 116
Shock Impedance 117
Shock Waveform Parameters see DeFT Response Technology Settings 116
ShockGuard Technology Settings 91
Shock-on-T Fibber....53
Instructions....53
Shortest Atrial Refractory Period, see Shortest PVARP/V Ref84
Shortest AV Delay....73
Shortest PVARP/V Ref 84
Shortest Ventricular Refractory Period, see Shortest PVARP/V Ref....84
SIH Count....103
Sinus Interval History see SIH Count....103
Sinus Node Recovery Delay 60
Sinus Redetection 121
Sinus Tach Rate Branch Control 96
Slope....65
Small Freezes, Test Result Settings 174
Software Reset, see Reset Function....177
Stability Delta 103
Start Temporary Button....34, 171
Stat Shock, see Emergency Shock....175
Stored EGM Capacity....142
Stored EGM Configuration Parameters....141
Sudden Onset
Description 128
Rate Overlap....105
Sudden Onset Parameter....105
Summary Report
Settings 175
Summary Screen....17
Supported Devices 165
SVT Criteria Statistics....24
SVT Diagnosis Summary and Morphology Template Details 25
SVT Discrimination 93
AV Association Delta....103
AV Interval Delta 97
Description 126
Diagnosis....96
Interval Stability....103
Interval Stability Window Size....104
Morphology....97
Morphology No. of Matches 98
Morphology Scoring....107
Morphology Template....105
Morphology Window Size....99
Onset Delta....105
% Match....98
Programming Guidelines 128
SIH Count....103
Stability Delta....103
Sudden Onset....105
SVT Upper Limit....95
Template Auto Update 99
Template Match Criteria 98
Therapy After Timeout....95
SVT Discrimination Details Window 94
SVT Discrimination in Sinus Tach....96
SVT Discrimination Mode....94
SVT Discrimination Timeout....94
Description 133
SVT Discriminators....95
Interval Stability 102
Morphology Window....97
Rate Branch 96
SVT Upper Limit....95

T

Tachy
Parameters....91
Therapy....108
Tachyarrhythmia Detection
Description 125
Therapy Delivery Conditions....125
Tachyarrhythmia Therapy
Description 134
Tachycardia Device Longevity 325
Tachycardia Devices, Clinician Use Information 317
Technical Data
Accent Devices 225
Anthem Devices....239
Current Devices 253
Ellipse Devices....259
Fortify Assura Technical Data 275
Fortify Devices 271
Promote Devices....279
Unify Devices....289
Technical Support....165
Telemetry, RF 167
Template Auto Update....99
Template Match Criteria 98
Template, see Morphology Template 105
Temporary Pacing....60
Temporary Program 171
Test Result Settings....174
Test Results, Print Menu
CRT Toolkit Report....174
Testing at Implant
Brady Pacing....324
Brady Sensing 324
Defibrillation 323
Device-Based 323
Equipment....53
Pacing Thresholds 323
Tests
Battery & Leads 39
Capacitor....41
Capture 33
Fibber 53
NIPS 57
QuickOpt Optimization 50
Sense....36
Therapy After Timeout....95
Therapy Summary Details....26
Therapy Zone
Off 125
1 Zone....125
3 Zones....125
2 Zones....125
Therapy, Tachy....108
This Session
Capture Test....35
Sense Tests....35

3 Zones 125
Threshold 65
Threshold Search Frequency, see Search Interval 78
Threshold Start 80
Threshold Trend 75
Time Between Notifications 138
Time Since Last Induction, Fibber 53
Timeout Trigger 107
Tools 1
Total Daily Activity 31
Trend
  Amplitude 35, 36
  Clear Data 18
  HV Lead Impedance 41
  Ideal Battery Voltage 39
  Lead Impedance 40
  Voltage 39
Tuned Waveform Help 118
2 Zones 125

U

Undo 171
Unify Devices Technical Data 289
Update Auto Gains Button 13
Update Episodes Button 21
Update Sense 33
Upper Limit
  HLVI Monitoring 82
  Impedance Monitoring 82

V

V AutoCapture Capability 198
V Rates During AMS 29
V Rates During AT/AF 30
V. AutoCapture Parameter 75
V. AutoCapture Settings 78
V. Noise Reversion Mode 65
V. Support Rate 56
V. Triggering 64
V<A Rate Branch
  Morphology, see Morphology in AF/A Flutter 97
V=A Rate Branch
  Morphology, see Morphology in Sinus Tach 98
VectSelect Quartet MultiVector Testing
  Instructions for Conducting MultiVector Testing 49
Ventricular Blanking 85
Ventricular Defibrillator Max Sensitivity 78
Ventricular Heart Rate Histogram 28
Ventricular HV Lead Impedance 41
Ventricular Intrinsic Preference 73
Ventricular Pace Refractory 85
Ventricular Pacemaker Max Sensitivity 78
Ventricular Pacing 63
Ventricular Rate Threshold (High Ventricular Rate) 146
Ventricular Safety Standby 86
Ventricular Sense Refractory 85
Ventricular Triggering Capability 199
VF Episode Trigger 144
VF Shocks (Defib) 117
VIP see Ventricular Intrinsic Preference 73
Voltage Trend 39
VOO Mode 159
VOO(R)-AOO(R) Mode 163
VT Episode Trigger 144
VT Redetection 121
VT Shocks (CVRT) 117
VT Therapy Timeout 107
  Description 134
VT/VF EGM Max Duration 141
VT/VF Episodes 21
VT/VF Pre-Trigger Max Duration 142
VVI Mode 159
VVI(R)-AAI(R) Mode 163
VVT Mode 161
VVT(R)-AAT(R) Mode 163

W

Waveform Control Buttons 13
Waveform Help 118
Waveform Mode 116
Waveform Parameter 116
Window Size
  Interval Stability 104
  Morphology 99
Wrap-up Overview 153
  Wrap-up™ 개요 설정(보고서) 174

Z

Zone Configuration
  Parameter 91
  Window (ShockGuard Settings) 91
Zone Therapy Window 107

St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

sjm.com

February 2017
ARTEN100155182 C