When the programming interaction described in this scenario is present, a message will describe the interaction of Tachy Rate Threshold with LRL and AV Delay. Similar messages may describe the interaction of V-Blank After A-Pace with MTR, MPR, or LRL. Along with each message, the pertinent programmable parameters are displayed to assist you in resolving the interaction. Programming Dynamic VRP can be useful in resolving these types of interactions.

Programming Considerations

Certain programmed combinations of pacing parameters are known to interfere with ventricular tachy detection. The risk of ventricular tachy undersensing due to device refractory periods is indicated by the interactive warnings on the parameter screen.

As with all device programming, you should evaluate the benefits and the risks of the programmed features for each patient (for example, the benefit of Rate Smoothing with a long AV Delay versus the risk of ventricular tachy undersensing).

The following programming recommendations are provided to reduce the risk of ventricular undersensing due to the refractory period caused by an atrial pace (V-Blank after A-Pace):

- If a dual-chamber pacing mode with Rate Smoothing or Rate Adaptive Pacing is necessary:
  - Reduce the LRL
  - Shorten the AV Delay or use Dynamic AV Delay and reduce the minimum Dynamic AV Delay setting
  - Increase the Down Rate Smoothing percentage to the largest possible value
  - Decrease the recovery time for Rate Adaptive Pacing modes
  - Reduce the MTR or MPR if Down Rate Smoothing is on
  - Reduce the MSR if the pacing mode is rate adaptive

- If Rate Smoothing or Rate Adaptive Pacing are not required for the patient, consider programming these features Off. Programming these features Off can reduce the likelihood of atrial pacing at elevated rates.

- If atrial pacing is not required for the patient, consider using VDD rather than DDD pacing mode.

- In certain usage scenarios, you may elect to program long AV Delays to reduce ventricular pacing for patients with long PR intervals, while providing sensor pacing or rate smoothing to address other patient needs.

- In certain usage scenarios, if a pattern of atrial pacing and VT beats is detected, the AV delay is automatically adjusted to facilitate confirmation of a suspected VT. If no VT is present, the AV delay is returned to the programmed value. For programming scenarios where the automatic AV delay adjustment may occur, a specific Parameter Interaction Attention will not be displayed.

For discussion of details and additional information regarding these or other programmed settings, please contact Technical Services at the 24-Hour Consultation phone number on the back of this manual.

In summary, when programming the pulse generator pacing and tachy detection parameters, it is useful to consider the possible interactions of these features in light of the expected arrhythmias of a particular patient. In general, the interactions will be brought to your attention through Parameter Interaction Attention messages on the PRM screen and can be resolved by reprogramming the pacing rate, AV delay, and/or refractory/blanking periods.

SYSTEM DIAGNOSTICS

CHAPTER 6

This chapter contains the following topics:

BATTERY STATUS

Pulse generator battery summary information is displayed on the Summary screen. The Summary screen contains the following components:

- Time Remaining—screen area with the following items:
  - Battery status gauge—displays a visual indication of the battery capacity status, from BOL to explant recommendation
  - Approximate Time To Explant—displays the approximate time at which explant is recommended based on the pulse generator's programmed parameters and recent usage history
- Charge Time—displays the amount of time it took the pulse generator to charge for the most recent maximum-energy shock or capacitor re-formation
- Battery Detail icon—when selected, this icon displays the Battery Detail screen

Battery Status Indicators

The following battery status indicators appear in the battery status gauge. All indicated longevity projections are calculated based on the pulse generator's programmed parameters.

- BOL—the pulse generator's battery is at full capacity.
- One Year Remaining—the pulse generator's battery has approximately one year of full function remaining.

- Explant—the pulse generator's battery is nearing depletion and the pulse generator has reached the point at which explant is recommended. This status indicates that pulse generator replacement must be scheduled. Once Explant status is reached there is sufficient battery capacity to monitor and pace 100% under existing conditions for three months and to deliver six maximum-energy shocks. Once the battery capacity is depleted, pulse generator functionality is degraded.

  Once the battery capacity is depleted, the following occurs:

  – Number of zones reverts to one ventricular zone (VF) with a rate threshold of 165 bpm

  – ATP therapy and low-energy shocks are unavailable

  – The programmed mode reverts to VVI/BiV

  – LRL defaults to 50 ppm

  – The following features are disabled:

    – RF telemetry
    – Daily measurement trends
    – Brady enhancement features
    – Episode storage
    – Diagnostic and EP tests
    – Device programming (Brady Mode and Ventricular Tachy Mode can be programmed to Off)

  – Telemetry interrogation (using a wand) is still available and manual capacitor re-formation can be selected.

  If the device reaches a point where insufficient battery capacity is available for continued operation, the device will revert to Storage Mode.

NOTE: *The device uses the programmed parameters and recent usage history to predict time to Explant. Greater than normal battery usage may result in the subsequent day's approximate time to Explant to appear less than expected.*

Battery Detail Summary Screen

The Battery Detail summary screen provides the following information about pulse generator battery status (Figure 6-1 on page 6-5):

- Last Delivered Shock—date, energy, charge time, and shock impedance data
- Beep When Explant Is Indicated—if this feature is programmed to On, the pulse generator emits 16 beeping tones every six hours after it reaches the Explant indicator. The tone can then be programmed to Off. Once the battery capacity is depleted, Beep When Explant Is Indicated is enabled by the device.

  CAUTION: Patients should be advised to contact their physician immediately if they hear tones coming from their device.
- Last Capacitor Re-form—date and charge time
- Manual Re-form Capacitor—this feature is used to command a capacitor re-formation when needed.
- Charge Remaining (measured in ampere-hours)—the amount of charge remaining based on the pulse generator's programmed parameters until the battery is depleted.
- Power Consumption (measured in microwatts)—the amount of power being consumed by the battery based on the pulse generator's programmed parameters.
- Power Consumption longevity impact—compares the power consumption at the pulse generator's currently programmed parameters with the power consumption of the parameters used to quote device longevity.

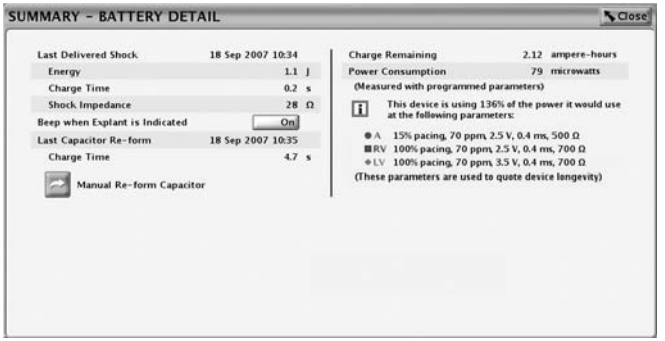

Figure 6-1. Battery Detail summary screen

Capacitor Re-formation

Automatic Capacitor Re-form. Capacitor deformation may occur during periods when no shocks are delivered, resulting in longer charge times. To reduce the effect of capacitor deformation on charge time, the capacitors are automatically re-formed. Tones will not be emitted from the pulse generator during automatic capacitor re-formations (even if the Beep During Capacitor Charge feature is programmed to On). During a capacitor re-formation, the Charge Time is measured and stored for later retrieval.

Manual Capacitor Re-form. Manual capacitor re-forms are not necessary, but may be commanded via the PRM as follows:

1. Select the Manual Re-form Capacitor button on the Battery Detail screen and ensure that telemetry communication is established. A message will appear indicating that the capacitors are charging. Warbling tones from the pulse generator (if the Beep During Capacitor Charge feature is programmed to On) will sound while the capacitors are charging.

2. The entire re-form cycle typically takes less than 15 seconds. After completion of the cycle, the capacitor energy is delivered to the pulse generator's internal test load. The initial Charge Time is displayed on the Battery Detail screen.

Charge Time Measurement

The pulse generator measures the Charge Time whenever its capacitors charge. The last measured value is stored in pulse generator memory and displayed by the PRM system on the Battery Detail screen.

Last Delivered Ventricular Shock

When a shock has been delivered to the patient, the following information from the last shock delivered is stored in the pulse generator's memory and displayed on the Battery Detail screen:

- Date
- Energy level
- Charge time
- Shocking lead impedance

This does not include auto capacitor re-forms or shocks that may have been diverted. If a fault condition is encountered (i.e., high or low impedance), the fault will be indicated so that corrective action may be taken.

NOTE: *For shocks of 1.0 J or less, the accuracy of the impedance measurement decreases.*

LEAD TESTS

The following lead tests are available (Figure 6-2 on page 6-6):

- Pace Impedance
- Shock Impedance
- Intrinsic Amplitude
- Pace Threshold

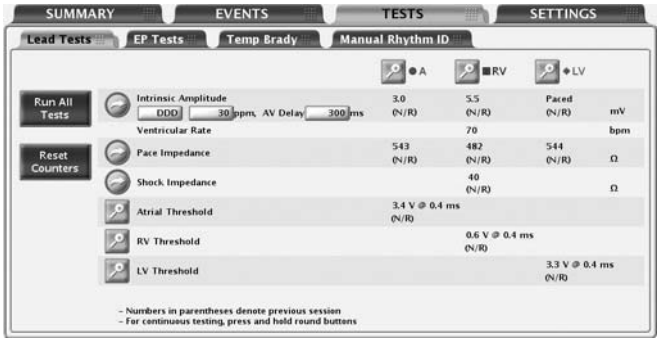

Figure 6-2. Lead Tests screen

Lead tests can be accessed by using the following steps:

1. From the main screen, select the Tests tab

2. From the Tests screen, select the Lead Tests tab

All lead tests may be performed following two different processes:

- Via the Lead Tests screen—allows you to perform the same lead tests across all chambers

- By selecting the desired chamber button—allows you to perform all tests on the same lead

Intrinsic Amplitude Test

The intrinsic amplitude test measures the intrinsic P- and R-wave amplitudes for the respective chambers.

An intrinsic amplitude test can be performed from the Lead Tests screen by completing the following steps:

1. You may change the following preselected values as necessary to elicit intrinsic activity in the chamber(s) being tested:

    - Programmed Normal Brady Mode
    - LRL at 30 ppm
    - AV Delay at 300 ms

2. Select the Intrinsic Amplitude button. During the test, a window will display the test's progress. Selecting and holding the Intrinsic Amplitude Button will cause measurements to be repeated for up to 10 seconds until the button is released. When the window closes, the same test can be performed again by selecting the Intrinsic Amplitude button. To cancel the test, select the Cancel button or press the DIVERT THERAPY key on the PRM.

3. When the test is complete, the intrinsic amplitude measurement will be displayed. If the test is repeated, the measurements from the previous session's test and the current test will be displayed.

NOTE: *The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Lead Tests screen. The measurements are also provided on the Quick Notes report.*

Lead Impedance Test

A lead impedance test can be performed and used as a relative measure of lead integrity over time.

A shock impedance test is a useful tool in detecting shocking lead integrity changes over time. Evaluating this information together with the Last Delivered Shock impedance (displayed on the Battery Detail screen) or a subsequent high-energy shock impedance and other non-invasive diagnostic techniques may help troubleshoot potential lead system conditions.

Pace and Shock lead impedance tests can be performed from the Lead Tests screen by completing the following steps:

1. Select the desired lead impedance test button. Selecting and holding a button will cause measurements to be repeated for up to 10 seconds until the button is released.

2. During the test, a window will display the test progress. When the window closes, the same test can be performed by once again selecting the desired lead impedance test button. To cancel the test, select the Cancel button or press the DIVERT THERAPY key on the PRM.

3. When the test is complete, the impedance measurement will be displayed. If the test is repeated, the impedance measurements from the previous session's test and the current test will be displayed.

NOTE: *The test results from the last measurement are stored in pulse generator memory, retrieved during the initial interrogation, and displayed on the Lead Tests screen. The measurements are also provided on the Quick Notes report.*

Pace Threshold Test

The Pace Threshold Test determines the minimum pace amplitude and/or pulse width needed for capture in a specific chamber. The minimum 2x voltage or 3x pulse width safety margin is recommended for each chamber based on the capture thresholds, which should provide an adequate safety margin and help preserve battery longevity.

Manual Pace Threshold Test

The test begins at a specified starting value and steps that value down (amplitude or pulse width) as the test progresses. The PRM beeps with each decrement. The values used during the threshold test are programmable. The parameters are only in effect during the test. Testing for a chamber is allowed only when pacing is active for that chamber in the mode specified in the start column.

NOTE: *The starting values for Amplitude and Pulse Width values are automatically calculated. The device retrieves the stored results for the previous pace threshold measurement (for the parameter being tested) and sets the parameter at three steps above the previous threshold measurement. The LRL is preselected at 90 ppm. For DDD mode, the LRL is further limited to 10 ppm below the MTR.*

NOTE: *If DDD mode is chosen, selecting either the atrial or ventricular test will cause the pacing output to decrease only in the chamber selected.*

CAUTION: During the LV threshold test, RV backup pacing is unavailable.

NOTE: *When VVI mode and a ventricular test are selected, only the pacing output of the selected ventricular chamber decreases; the other ventricular chamber is not affected.*

NOTE: *When DDD mode and a ventricular test are selected, only the pacing output of the selected ventricular chamber decreases; the atrium is paced at a continuous amplitude, and the other ventricular chamber is not paced.*

Once the test is started, the device operates with the specified brady parameters. Using the programmed number of cycles per step, the device then decrements (steps down) the selected test type parameter (Amplitude or Pulse Width) until the test is complete. Real-time electrograms and annotated event markers, which include the values being tested, continue to be available during threshold testing. The display will automatically adjust to reflect the chamber being tested.

During the threshold test, the programmer displays the test parameters in a window while the test is in progress. To pause the test or perform a manual adjustment, select the Hold button on the window. Select the + or − button to manually increase or decrease the value being tested. To continue the test, select the Continue button.

The threshold test is complete and all parameters are returned to the normal programmed values when any of the following occur:

- The test is terminated via a command from the PRM (e.g., pressing the End Test button or DIVERT THERAPY key)
- The lowest available setting for Amplitude or Pulse Width is reached and the programmed number of cycles has completed
- Telemetry communication is interrupted

A pace threshold test can be performed from the Lead Tests screen using the following steps:

1. Select the desired chamber to be tested
2. Select the Pace Threshold details button
3. Select the test type
4. Change the following parameter values as desired to elicit pacing in the chamber(s) being tested:

   - Mode
   - LRL
   - Paced AV Delay
   - Pacing Lead Config (programmable only for LV threshold test)
   - Amplitude
   - Pulse Width
   - Cycles per Step
   - LVPP (programmable only for LV threshold test)

   For DDD mode, the normal Brady MTR is used.

NOTE: *A long LVPP may inhibit left ventricular pacing at higher pacing rates. LVPP can be temporarily programmed (for example, to a shorter LVPP or Off) through the Pace Threshold Test screen.*

5. Watch the ECG display and stop the test by selecting the End Test button or pressing the DIVERT THERAPY key when loss of capture is observed. If the test continues until the programmed number of cycles at the lowest

setting have occurred, the test is automatically terminated. The final threshold test value will be displayed (the value is one step above the value when the test was terminated).

NOTE: *The threshold test result can be edited by selecting the Edit Today's Test button on the Threshold Test screen*

6. To perform another test, make changes to the test parameter values if desired, then begin again. Results of the new test will be displayed.

NOTE: *The test results from the most recent measurement are stored in pulse generator memory, retrieved during initial interrogation, and displayed on the Lead Tests screen and on the Lead Status screen. The measurements are also provided on the Quick Notes report.*

PATIENT DIAGNOSTICS

CHAPTER 7

This chapter contains the following topics:

THERAPY HISTORY

The pulse generator automatically records detection and therapy information for each detected episode. This data can be reviewed at various levels of detail using the PRM.

History data storage includes the following information for each episode:

- Episode detail
- Electrograms with annotated markers
- Intervals

The data includes information from all active electrodes. The device compresses the history data to store a maximum of 17 minutes of electrogram data (13 minutes with Patient Triggered Monitor enabled). However, the amount of time actually stored may vary based on the data being compressed (e.g., noise on the EGM or an episode of VF).

The priority, maximum number, and minimum number of episodes to be stored by the device for each episode type under normal conditions are specified (Table 7-1 on page 7-3). The device stores up to the maximum number of episodes for a specific episode type, unless the device memory is filled up first. The minimum number of episodes for each episode type protects a few low priority episodes from high priority episodes when device memory is full.

Once the device memory available for episode data is filled, the device attempts to prioritize the types of stored episodes and overwrite the stored episodes according to the following rules:

- If the device memory is full, and there are episode types that have more than the minimum number of episodes listed in the table, then the oldest of the lowest priority episodes from these episode types will be deleted. In this case, the low priority episodes are not deleted if their number of episodes is less than the minimum number listed in the table.

- If the device memory is full, and there are no episode types that have more than the minimum number of episodes listed in the table, then the oldest of the lowest priority episodes of all episode types will be deleted.

- For non-commanded episodes, the episode type for VT-1, VT, and VF episodes is determined according to the zone Duration that expires first. If no zone Duration expires during an episode, the episode type is nonsustained.

- An episode in progress has the highest priority until its type can be determined.

Table 7-1. Episode Priority

Episode Type	Priority	Minimum number of episodes stored	Maximum number of episodes stored
VF	1	5	10
Patient Triggered Monitor	1	1	1
VT/VT-1	2	3	5
Cmd V	3	0	2
NonSustV	3	1	2
ATR	4	1	3
PMT	4	1	3

Once the history data is saved to a disk, it can be accessed at any time without device interrogation.

TRENDS

Trends provide a graphical view of specific patient and device data. This data can be useful when evaluating your patient's condition and the effectiveness of programmed parameters. The following trends are available:

- Events—displays both atrial and ventricular events.
- Heart Rate—displays a trend of the patient's heart rate. Intervals used in this calculation must be valid sinus rhythm intervals. The validity of an interval and the Heart Rate Trend data for the 24-hour collection period is determined by the HRV collection criteria.
- Activity Level—displays a measure of the patient's daily activity.
- Atrial Burden—the amount of time spent in an ATR mode switch.
- Respiratory Rate —provides a trend of the patient's daily respiratory rate.
- SDANN—Standard Deviation of Averaged Normal R to R intervals. The HRV collection period comprises 288 5-minute segments (24 hours). The SDANN is the standard deviation of the averages of intrinsic intervals in the 288 5-minute segments. Only intervals that meet the HRV collection criteria are considered valid. If the HRV data for the collection period is invalid, then a value of "N/R" is displayed.

- HRV Footprint—displays the percentage of the graph area used by the HRV plot. The graph area portrays an “at-a-glance snapshot” of the distribution of variability versus heart rate over a 24-hour period. The trended percentage is a normalized score based on the footprint in the graph. If an HRV plot was not obtained for the 24-hour period, then the HRV Footprint is not calculated and a value of “N/R” is displayed.
- ABM (Autonomic Balance Monitor)—a device calculation based on R–R interval measurements; it mathematically functions as a surrogate measurement for LF/HF ratio.[1] Intervals used in the calculation must be valid sinus rhythm intervals as determined by the HRV collection criteria. If the HRV data is invalid for the 24-hour collection period, then the ABM is not calculated for that collection period and a value of "N/R" is displayed.
- Amplitude—provides amplitude measurements
- Impedance—provides impedance measurements

Follow the steps below to access Trends:

1. From the Events screen, select the Trends Tab

2. Choose the Select Trends button to specify the trends you want to view. You can choose from the following categories:

    - Heart Failure—includes Heart Rate, SDANN, and HRV Footprint trends
    - Atrial Arrhythmia—includes Events, Heart Rate, and Atrial Burden trends
    - Activity—includes Heart Rate, Activity Level, and Respiratory Rate trends
    - Custom—allows you to select three trends to customize the information displayed on the Trends screen

The display on the screen can be viewed in the following manners:

- Select the desired time on the View button to choose the length of visible trend data.

1. Parasympathetic tone is primarily reflected in the high-frequency (HF) component of spectral analysis. The low-frequency (LF) component is influenced by both the sympathetic and parasympathetic nervous systems. The LF/HF ratio is considered a measure of sympathovagal balance and reflects sympathetic modulations. (Source: ACC/AHA Guidelines for Ambulatory Electrocardiography—Part III, JACC VOL. 34, No. 3, September 1999:912–48)

- Adjust the start and end dates by moving the slider bar at the top of the window. You can also adjust these dates by selecting the left- and right-arrow buttons.

- Move the vertical axis across the graph by moving the slider bar at the bottom of the display window.

Valid Heart Rate Trend Events	Invalid Heart Rate Trend Events
AS with an interval not faster than MTR, followed by a VS	AP
AS followed by VP at the programmed AV Delay	AS with an interval faster than MTR
	Non-tracked VP events
	Consecutive AS events (no intervening V event)
	VP-Ns
	Rate Smoothing events (e.g., RVP↑)
	PVC

Heart Rate Trend data may not be reported for a variety of reasons; the most common are as follows:

- Less than 67% of the 24-hour collection period (approximately 16 hours) contains valid Heart Rate Trend events

- Brady parameters were programmed within the last 24 hours

ARRHYTHMIA LOGBOOK

The Arrhythmia Logbook screen provides the following information about each event (Figure 7-1 on page 7-6):

- The number, date, and time of the event

- The type of event with zone

- A summary of therapy delivered or attempted (if applicable)

- Whether or not intervals and EGMs are stored as indicated by the presence of details button

- Duration of the event

Figure 7-1. Arrhythmia Logbook screen

To display Arrhythmia Logbook data, use the following steps:

1. From the Events tab, select Arrhythmia Logbook. If necessary, the pulse generator will be automatically interrogated and current data will be displayed. Data from a patient disk also can be displayed:

   a. Select the Utilities button on the toolbar.

   b. From the Utilities screen, select the Disk tab. Choose the Read Disk option.

2. While retrieving the data, the programmer will display a window indicating the progress of the interrogation. No information will be displayed if you select the Cancel button before all of the stored data are retrieved.

3. Use the slider and View button to control the range of dates for the events you want to display in the table.

4. Select the Details button of an event in the table to display the event details. Event details, available if the details button is present, are useful in evaluating each detection or therapy sequence.

5. To sort events by date, type, therapy, or duration, select the corresponding column header button. To reverse the order, select the column header again.

6. To save specific events, select the event and choose the Save to Disk button. To print specific events, select the event and choose Reports from

the toolbar. Choose the selected Episodes Report and select the Print button.

NOTE: *An "in-progress" episode will not be saved; an episode must be complete before it will be saved by the application.*

Events Summary

The Events Summary screen displays additional details about the selected episode corresponding to the Arrhythmia Logbook.

The summary data include the following:

Episode Details

- Episode number, date, time, type (VF, VT, VT-1, spontaneous/induced, or PTM indicating a Patient Triggered Monitor episode)
- Average atrial and ventricular rates
- Type of therapy delivered
- For ATP therapy, the time of therapy delivery and the number of bursts
- For shock therapy, the start time of charging, charge time, impedance, energy level
- Time the episode ended

ATR Episodes

- Episode number, date, time, and type (ATR)
- Average atrial and ventricular rate during ATR mode switch
- Duration

PMT Episodes

- Episode number, date, time, and type (PMT)
- Atrial rate at PMT start
- Average atrial and ventricular rates

Follow the steps below to view episode detail:

1. Select the desired episode on the Arrhythmia Logbook screen. The Stored Event screen will appear.

2. From the Stored Event screen, select the EGM tab to view the detailed information for this episode.

3. Select the Previous Event or the Next Event button to display a previous or more current episode, one episode at a time.

4. Select the Print Event button to print the episode detail being viewed.

5. Select the Save to Disk button to save the episode detail to a patient data disk.

Stored Electrograms

The pulse generator can store annotated electrograms sensed from the following leads prior to the onset of an episode around duration met, and around therapy start and end:

- Shock lead
- RV pace/sense lead
- LV pace/sense lead
- Atrial pace/sense lead

The particular electrograms stored depend upon the episode type. The EGM storage capacity varies depending on EGM signal condition and heart rate. The stored data are shared by all events. The total amount of stored EGM data associated with an episode may be limited; EGMs from the middle of the episode may be removed for episodes greater than 4 minutes in duration.

When the memory allocated to EGM storage is full, the device overwrites older EGM data segments in order to store the new EGM data. The EGM is recorded in segments consisting of episode Onset, Attempt, and End EGM storage. Each segment of data is visible when the left caliper is in the specific section. The following information is retained:

- Onset retains up to 25 seconds of data prior to Duration expiring

- Reconfirmation retains up to 20 seconds of data prior to therapy delivery

- Therapy data is displayed. In the case of ATP therapy, a maximum of 4 bursts and up to 20 seconds of data, for each burst, will be retained
- Post-therapy or diverted therapy retains up to 10 seconds of data

Episode onset refers to the period of time (measured in seconds) of EGM prior to the first attempt. Onset includes the following information:

- Type of event
- Average RA Rate at the start of Event
- Average RV Rate at start of Event
- Programming of Detection Enhancements (Rate only, Rhythm ID, or Onset/stability)

Attempt information may be displayed as Attempt or In Progress, if an attempt is in progress. Attempt includes the following information:

- Detection information:
  - Average RA Rate at start of Attempt
  - Average RV Rate at start of Attempt
  - Rate Zone
- Measured Values of Detection Enhancements
- Therapy Attempt Information:
  - Attempt Number
  - Type (diverted, commanded, or inhibited)
  - Number of bursts (ATP attempt)
  - Charge time
  - Lead impedance
  - Lead polarity
  - Shock faults
  - Reason for No Therapy

The End EGM storage starts following therapy delivery and stores up to 10 seconds of EGM (Figure 7-2 on page 7-10).

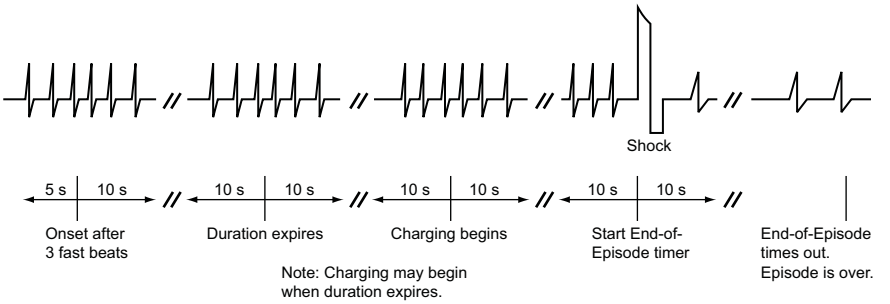

Figure 7-2. Relationship between ventricular tachy episode EGM storage and surface ECG strip chart recording

To view the EGM data, select the desired episode on the Arrhythmia Logbook screen. Use the following steps to view specific details about each episode:

1. Select the EGM tab to view the stored EGMs on the screen.

    - EGM strips for the appropriate sources are displayed. Each strip includes the EGMs sensed during the episode with the corresponding annotated markers. Blue vertical bars indicate the segment (Onset, Attempt, End) boundaries.

    - You can move the calipers along the trace and will display the time interval between the calipers.

    - A speed button changes the trace speed in millimeters/seconds.

2. Select the Previous Event or Next Event button to display a different event strip. If EGMs are not available for an episode, the Episode Detail screen will be displayed.

3. To print the entire episode report, select the Print Event button. To save the entire episode report, select the Save to Disk button.

NOTE: *Refer to "Use of Atrial Information" on page 3-5 for additional information about device performance when the atrial lead is programmed to Off.*

Intervals

The pulse generator stores event markers and associated time stamps. The PRM derives event intervals from the event markers and time stamps.

To view the episode intervals, use the following steps:

1. From the Stored Event screen, select the Intervals tab. If all of the episode data is not visible in the window, use the scroll bar to view more data.

2. Select the Previous Event or the Next Event button to display a previous or more current episode, one episode at a time.

3. Select the Print Event button to print the entire episode report.

4. Select the Save to Disk button to save the entire episode report to a patient data disk.

Histograms

The Histograms feature retrieves information from the pulse generator and displays the total number and percentage of paced and sensed events for the chamber.

Histograms data can provide the following clinical information:

- The distribution of the patient's heart rates

- How the ratio of paced to sensed beats varies by rate

- How the ventricle responds to paced and sensed atrial beats across rates

When combined with verified biventricular capture, Histograms can be used to determine the amount of CRT delivery. The percentage of paced and sensed ventricular events indicates delivery of biventricular pacing.

Use the following steps to access the Histograms screen:

1. From the Events screen, select the Patient Diagnostics tab.

2. The initial display shows the paced and sensed data since the last time the counters were reset.

3. Select the Details button to display the data type and time period.

4. Select the Rate Counts button on the Details screen to view rate counts by chamber.

Heart Rate Variability (HRV)

Heart Rate Variability (HRV) is a measure of the changes in a patient's intrinsic heart rate within a 24-hour collection period.

This feature can assist in evaluating the clinical status of heart failure patients.

The HRV monitor feature provides the following information using the intrinsic interval data from the 24-hour collection period that meets the HRV collection criteria (Figure 7-3 on page 7-13):

- Date and time the 24-hour collection period was completed.

- % of Time Used—displays the percentage of time during the 24-hour collection period in which there are valid intrinsic beats. If the % of Time Used falls below 67%, data will not be displayed for that collection period.

- HRV footprint plot—shows the percentage of the graph area used by the HRV plot. The graph area portrays an "at-a-glance snapshot" of the distribution of variability versus heart rate over a 24-hour period. The trended percentage is a normalized score based on the footprint in the graph.

- Standard Deviation of Averaged Normal R to R intervals (SDANN)—the HRV collection period comprises 288 5-minute segments (24-hours) of intrinsic intervals. The SDANN is the standard deviation of the averages of intrinsic intervals in the 288 5-minute segments. This measurement is also available in the Trends.

- Current Normal Brady/CRT parameters—Mode, LRL, MTR, Sensed AV Delay, and Pacing Chamber with LV Offset.

- An HRV plot for current and previous collection periods including a line that shows the mean heart rate. The HRV plot summarizes the cardiac variation on a cycle-to-cycle basis. The x-axis shows the heart rate range; the y-axis shows the beat-to-beat variability displayed in milliseconds. The color indicates the frequency of beats at any particular heart rate and heart rate variability combination.

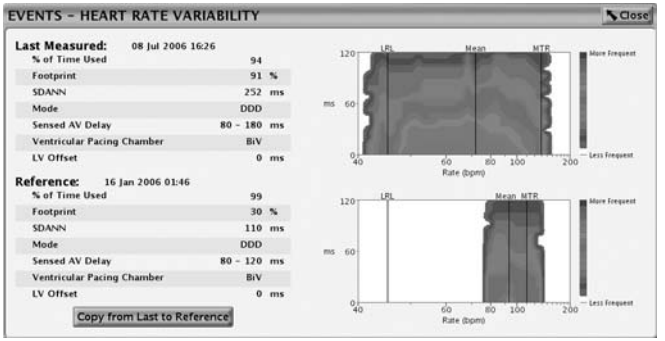

Figure 7-3. Heart Rate Variability display

Consider the following information when using HRV:

- The cardiac cycle (R–R interval) in HRV is determined by RV sensed and paced events (LV paced events when the pacing chamber is programmed to LV).
- Programming the pacing parameters causes the data acquired for the current 24-hour collection period to be invalid.
- The device saves only one set of values and corresponding HRV plot for the Reference portion of the screen. Once the values are copied from Last Measured to Reference, older data cannot be retrieved.
- The first time the HRV feature is used, the Reference screen will show the data from the first valid 24-hour collection period.

Follow the steps below to view HRV:

1. To access the HRV monitor screen, select the Events tab.
2. From the Events screen, select the Patient Diagnostics tab.
3. Once the device is interrogated, Last Measured and Reference data is displayed.
4. Select the Heart Rate Variability Details button to view the Last Measured and Reference data.
5. To copy the Last Measured HRV measurements into the Reference section, select the Copy From Last to Reference button.

The HRV monitor screen displays a set of measurements and a HRV plot based on the most recent 24-hour collection period in the Last Measured portion of the screen; measurements from a previously saved collection period are displayed in the Reference portion of the screen. Both collection periods can be viewed simultaneously to compare data that could show trends in the patient's HRV changes over a period of time. By saving the Last Measured values to the Reference portion of the screen, you can view the last measured data during a later session.

HRV Collection Criteria

The pulse generator only collects interval data for HRV when the Normal Brady/CRT mode is programmed to non-rate-responsive tracking modes (VDD or DDD). In addition, only valid sinus rhythm intervals are used in the HRV data calculations. For HRV, valid intervals are those which include only valid HRV events. HRV event validation criteria are listed below:

Valid HRV Events	Invalid HRV Events
AS with an interval not faster than MTR, followed by a VS	AP
AS followed by VP at the programmed AV Delay	AS with an interval faster than MTR
	Non-tracked VP events
	Consecutive AS events (no intervening V event)
	VP-Ns
	Rate Smoothing events (e.g., RVP↑)
	PVC

HRV data may not be reported for a variety of reasons; the most common are as follows:

- Brady mode is not DDD or VDD
- Less than 67% of the 24-hour collection period (approximately 16 hours) contains valid HRV events
- Brady Parameters were programmed within the last 24 hours

An example of how HRV data is recorded is shown (Figure 7-4 on page 7-15). In this example, the HRV data in the first collection period is invalid because the Brady parameters were programmed after the device was taken out of Storage. HRV data is successfully calculated and reported at the end of the second 24-hour collection period. Subsequent HRV data is not reported until the end of Collection Period 5.

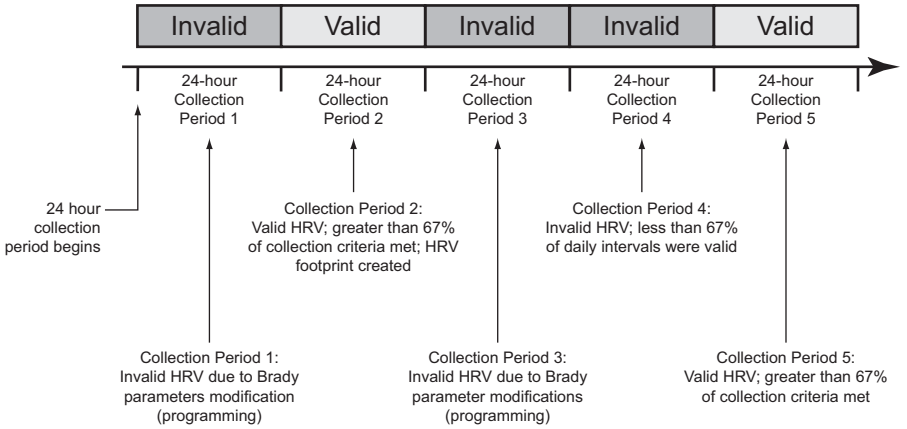

Figure 7-4. Example of HRV data collection

Counters

The following counters are recorded by the pulse generator and displayed on the Patient Diagnostics screen:

- Ventricular Tachy
- Brady/CRT

Ventricular Tachy Counters

Information about Ventricular Tachy Counters is available by selecting the Ventricular Tachy Counters button. This screen displays both Ventricular Tachy Episode and Therapy counters. For each counter, the number of events since last reset and device totals are displayed. Ventricular Tachy Episode counters contains the following data:

- Total episodes
- Treated—VF, VT, VT-1, and Commanded

- Nontreated—No Therapy Programmed, Nonsustained, and Other Untreated Episodes

Ventricular Tachy Therapy counters consist of ventricular shock and ATP therapy attempts. They can provide useful data about the effectiveness of a patient's therapy prescription. These counters include the following information:

- ATP Delivered
- ATP % Successful—the percent of time that the arrhythmia is converted and the episode ends without delivery of a programmed shock
- Shocks Delivered
- First Shock % Successful—the percent of time that the arrhythmia is converted and the episode ends without requiring a second programmed shock
- Shocks Diverted

The ventricular ATP counter is incremented at the start of the delivery of the first burst of an ATP scheme. Subsequent ATP bursts in the same scheme are not counted individually during the same episode.

An ATP scheme is counted as diverted only if it is diverted prior to delivery of the first burst.

Brady/CRT Counters

Information about Brady/CRT Counters are displayed by selecting the Brady/CRT Counters button. This screen displays the Brady/CRT episode counters. For each counter, the number of events since last reset and reset before last are displayed. Brady/CRT counters contains the following details:

- Percent of atrial paced
- Percent of RV paced

NOTE: *The RV pace event for a BiVentricular Trigger pace will be counted as an RV sense.*

- Percent of LV paced

- Intrinsic Promotion—includes Rate Hystereses % successful
- Atrial burden—includes Episodes by Duration and Total PACs
- Ventricular counters—includes total PVCs and Three or More PVCs

PATIENT TRIGGERED MONITOR

Patient Triggered Monitor allows the patient to trigger the storage of EGMs, intervals, and annotated marker data during a symptomatic episode by placing a magnet over the device.

Patient Triggered Monitor is enabled by selecting Store EGM as the desired magnet response. This can be found in the Magnet and Beeper section on the V-Tachy Therapy Setup screen. When enabled, the device will store up to 2 minutes of patient monitor data prior to and up to 1 minute after triggering the monitoring. The stored data include the episode number, the atrial and ventricular rates at magnet application, and the start time and date of magnet application.

When data are stored, the corresponding episode type is recorded as PTM in the Arrhythmia Logbook.

Use care when enabling Patient Triggered Monitor, because the following conditions will exist:

- All other magnet features are disabled, including inhibiting therapy (until the EGM is stored). The Magnet/Beeper feature will not indicate magnet position.
- Device longevity is impacted. Once the patient has triggered this feature to store episode data or the feature is disabled, the impact on device longevity is no longer present. To help reduce the longevity effect, this feature is automatically disabled after 60 days from the day it was enabled.
- Once the EGM is stored, the device magnet response automatically will be set to Inhibit Therapy.

To program the Patient Triggered Monitor feature, follow these steps:

1. From the Settings tab on the main screen, select Settings Summary.
2. From the Settings Summary tab, select Ventricular Tachy Therapy.

3. From Ventricular Tachy Therapy, select the V-Tachy Therapy Setup details button.

4. Program the Magnet Response to Store EGM.

   CAUTION: Determine if the patient is capable of activating this feature prior to being given the magnet and prior to enabling Patient Triggered Monitor. Remind the patient to avoid strong magnet fields so the feature is not inadvertently triggered.

   CAUTION: Consider having the patient initiate a stored EGM at the time Patient Triggered Monitor is enabled to assist with patient education and feature validation. Verify the activation of the feature on the Arrhythmia Logbook screen.

   WARNING: Ensure that Patient Triggered Monitor is enabled prior to sending the patient home by confirming the magnet response is programmed to Store EGM. If the feature is inadvertently left in the Inhibit Therapy setting, the patient could potentially disable tachyarrhythmia detection and therapy.

   WARNING: Once the Patient Triggered Monitor feature has been triggered by the magnet and an EGM has been stored, or after 60 days have elapsed from the day that Store EGM was enabled, the Magnet Response programming automatically will be set to Inhibit Therapy. When this happens, the patient should not apply the magnet because tachyarrhythmia therapy could be inhibited.

   NOTE: *When the Magnet Response programming has automatically been set to Inhibit Therapy, magnet application will cause the device to emit beeping tones. Inform the patient that if they hear tones coming from their device after applying the magnet, they should remove the magnet.*

5. Patient Triggered Monitor can only be enabled for a 60-day period of time. To disable the feature within the 60-day time period, reprogram the magnet response to a setting other than Store EGM. When 60 days have passed since enabling Patient Triggered Monitor, the feature will automatically disable itself and the magnet response will revert to Inhibit Therapy. To re-enable the feature, repeat these steps.

For additional information, contact Technical Services at the number shown on the back cover of this manual.

ELECTROPHYSIOLOGIC TESTING

CHAPTER 8

This chapter contains the following topics:

EP TEST FEATURES

Electrophysiologic (EP) Testing features enable you to induce and terminate arrhythmias noninvasively in order to monitor and test the effectiveness of selected detection criteria and therapies. The EP Test features can be used in conjunction with the ECG display so that real-time traces may be viewed. The status of the pulse generator/patient interaction is also displayed.

The features allowing noninvasive EP testing of arrhythmias include the following:

- VFib induction
- Shock on T induction
- PES induction
- 50 Hz/Manual Burst pacing induction
- Commanded Shock therapy
- Commanded ATP therapy

Temporary EP Mode

Temporary EP Mode allows you to program the device mode to a temporary value for EP test delivery, and ensures that the normal device mode remains unchanged.

Backup Ventricular Pacing During Atrial EP Testing

Backup ventricular pacing is available during atrial EP testing (PES, 50 Hz/Manual Burst) regardless of the programmed Normal or Post-therapy pacing modes. (The mode can also be programmed to Off.) Program the backup pacing parameters by selecting the EP Test Pacing button displayed on the relevant atrial EP tests.

EP Test Screen

The EP Test screen displays the real-time status of the detection and therapy process of the pulse generator when telemetry communication is occurring. Viewing this display allows you to induce and test either a programmed detection/therapy prescription or optional therapies while monitoring the pulse generator's progress.

Refer to the EP Test screen (Figure 8-1 on page 8-3):

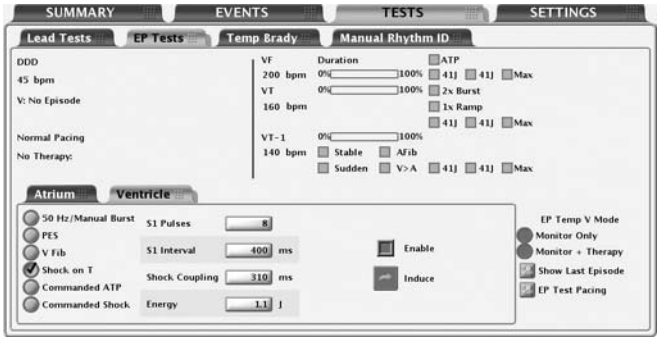

Figure 8-1. EP Test Screen

The screen provides the following information:

- Status messages indicate detection and therapy status and are described below:
  - Ventricular episode status—if an episode is occurring, the duration of the episode is displayed. (If it is greater than 10 minutes, then it is displayed as > 10:00 m:s).
  - Ventricular detection status—if an episode is occurring, it indicates whether ventricular detection is in Initial Detection, Redetection, or the zone in which that detection is met. If no episode is occurring, the programmer will also display the text Time since last V therapy along with the continually updated time in minutes (up to 10).
  - Brady pacing and SRD status.
  - The type of therapy initiated and the zone.
  - The status of the therapy such as In progress, Diverted, or Delivered.

- Duration timer—Progression of the duration timer is graphically displayed using a scale. The bar in the scale moves from left to right to show the percent complete of programmed duration. When duration is expired and therapy delivery begins, the bar is removed.
- Detection status—The status for each programmed detection enhancement is displayed. When enhancement criteria are met, a mark appears in the adjacent box.

- Therapy prescriptions—Only those therapy prescriptions that are programmed are displayed. As each therapy is delivered, a check mark or number will appear in the box adjacent to the respective therapy. ATP therapies indicate the scheme type as well as the programmed number of bursts in the scheme. A number will appear and increment (1, 2, etc.) in the ATP therapy box each time an ATP burst is delivered. Shock therapies indicate the programmed energy level for the programmable shocks. A number will appear and increment (1, 2, etc.) in the Max box each time a maximum-energy shock is delivered.

Follow the steps below to perform EP Test functions:

1. Select the Tests tab, then select the EP Tests tab.

2. Establish telemetry communication. Telemetry communication between the programmer and the pulse generator should be maintained throughout all EP test procedures.

3. Program the EP Temp V mode appropriate to the EP Test method (Table 8-1 on page 8-4).

Table 8-1. EP Temp V Mode for EP Test Functions

	EP Temp V Mode		
EP Test Method[a]	**Monitor + Therapy[d]**	**Monitor Only[e]**	**Off**
50 Hz/Manual Burst[b]	X		
PES[b]	X		
VFib[c]	X		
Shock on T[c]	X		
Commanded ATP[c]		X	
Commanded Shock[c]	X	X	

a. EP functions cannot be performed if the pulse generator is in Storage Mode.
b. Available method for both atrial and ventricular induction.
c. Available method only for ventricular induction.
d. The Ventricular Tachy Mode must be programmed to Monitor + Therapy.
e. The Ventricular Tachy Mode must be programmed to Monitor Only or Monitor + Therapy.

INDUCTION METHODS

Each induction method available from the EP Test screen is described below with instructions for performing the induction. During any type of induction delivery, the pulse generator recognizes the induction and performs no other

activity until the induction delivery is ceased, at which time the programmed mode will take effect and the pulse generator will respond accordingly.

Consider the following information when using these methods:

- Ventricular PES, Shock on T wave, and Ventricular ATP are BiV.
- All inductions and tachycardia therapy delivery are inhibited when a magnet is positioned over the pulse generator (if magnet response is set to Inhibit Therapy).
- Pacing pulses during induction are delivered at the programmed EP Test pacing parameters.

VFib Induction

VFib induction uses the shocking electrodes to stimulate the right ventricle at very fast rates.

The following settings are available to allow use of the minimum energy necessary for induction:

- VFib Low delivers a stimulation waveform of 9 volts
- VFib High delivers a stimulation waveform of 15 volts

Performing VFib Induction

NOTE: *The patient should be sedated prior to delivery of fibrillation induction pulses. The large surface area of the shocking electrodes tends to stimulate the surrounding muscle and can be uncomfortable.*

1. Select the VFib option. Buttons for each test and an Enable checkbox are displayed.
2. Select the Enable checkbox.
3. Select the desired Hold for Fib button to initiate delivery of the fibrillation induction train. The induction train is delivered up to 15 seconds as long as the button is held and the telemetry link is maintained.

   During induction the pulse generator is automatically disabled from detecting, and automatically re-enabled following induction delivery. If VFib induction is initiated during an episode, the end-of-episode is

declared before the VFib induction pulses are started. A new episode (with initial detection and therapy) can be declared after the VFib induction is completed. Event markers and EGMs are interrupted during VFib induction and will automatically restart following induction.

4. To stop the induction train, release the button (the button will become dimmed again).

5. To deliver another fibrillation induction, repeat these steps.

Shock on T Induction

A Shock on T wave induction method allows the device to deliver a drive train (up to 30 equally timed pacing pulses, or S1 pulses) through the ventricular pace/sense electrodes followed by shock delivery through the shocking electrodes (Figure 8-2 on page 8-6).

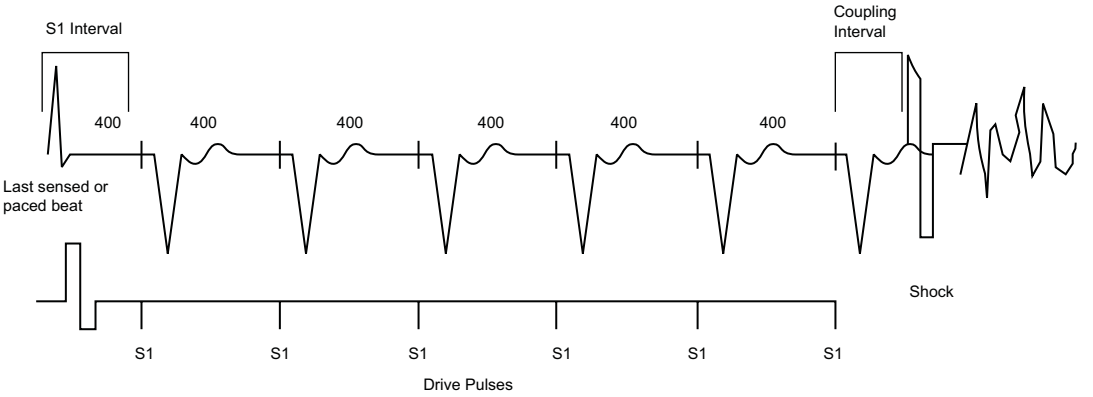

Figure 8-2. Shock on T induction drive train

The initial S1 pulse follows the last sensed or paced event at the S1 interval. The shock is coupled to the last S1 pulse of the drive train.

Performing Shock on T Induction

1. Select the Shock on T option. The programmable induction parameters will be displayed.

2. Select the desired value for each parameter.

3. Select the Enable checkbox. The Induce button will no longer be dimmed.

4. Select the Induce button to begin delivery of the drive train. The pulses are delivered in sequence until the programmed number of pulses is reached. Once induction is initiated, the drive train delivery will not stop if you interrupt telemetry communication. You can press the DIVERT THERAPY key to stop the induction delivery command.

5. Shock on T induction is complete when the drive train and shock are delivered, at which time the pulse generator automatically restarts detection.

NOTE: *Prior to drive train delivery, tones will be heard indicating capacitor charging in preparation for shock delivery.*

NOTE: *The shock delivered during Shock on T induction does not increment episode or therapy counters.*

Programmed Electrical Stimulation (PES)

PES induction allows the pulse generator to deliver up to 30 equally timed pacing pulses (S1) followed by up to 4 premature stimuli (S2–S5) to induce or terminate arrhythmias. Drive pulses, or S1 pulses, are intended to capture and drive the heart at a rate slightly faster than the intrinsic rate. This ensures that the timing of the premature extra stimuli will be accurately coupled with the cardiac cycle (Figure 8-3 on page 8-7).

The initial S1 pulse is coupled to the last sensed or paced beat at the S1 interval. All pulses are delivered in XOO modes (where X is the chamber) at the programmed EP Test pacing parameters.

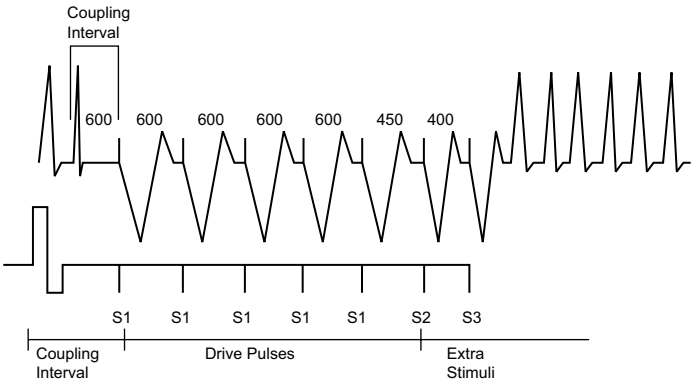

Figure 8-3. PES induction drive train

Performing PES Induction

1. Select the PES option. Buttons for the S1–S5 pulses and the corresponding burst cycle lengths are displayed.

2. Select the desired value for the S1–S5 intervals (Figure 8-4 on page 8-8). You can either select a value box for the desired S interval and choose a value from the box or use the plus or minus symbols to change the value visible in the value box.

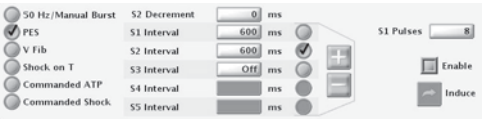

Figure 8-4. PES induction options

3. Select the Enable checkbox.

4. Select (do not hold) the Induce button to begin delivery of the drive train. When the programmed number of S1 pulses is delivered, the pulse generator will then deliver the programmed S2–S5 pulses. The pulses are delivered in sequence until a pulse is encountered that is set to Off (e.g., if S1 and S2 are set to 600 ms, and S3 is Off, then S3, S4, and S5 will not be delivered). Once induction is initiated, the PES delivery will not stop if you interrupt telemetry communication. (You can press the DIVERT THERAPY key to stop induction delivery.) If PES induction is initiated during an episode, the end-of-episode is declared before the PES induction pulses are started. A new episode (with initial detection and therapy) can be declared after the PES induction is completed.

5. PES induction is complete when the drive train and extra stimuli are delivered, at which time the pulse generator automatically restarts detection.

NOTE: *Ensure the PES induction is complete before beginning another induction.*

NOTE: *When PES is used to terminate an arrhythmia that has been detected (and an episode declared), the episode is terminated when the PES is commanded regardless of whether it is successful or not. The PES itself is not recorded in therapy history; this may result in several episodes being counted in therapy history.*

50 Hz/Manual Burst Pacing

50 Hz/Manual Burst pacing induction is used to induce or terminate arrhythmias and allows two separate pacing inductions, both of which can be delivered to either the atrium or ventricle.

Manual Burst pacing pulses are delivered in XOO mode (where X is the chamber) at the programmed EP Test pacing parameters through the rate-sensing leads. For Atrial Manual Burst, backup pacing parameters are provided.

Performing Manual Burst Pacing

1. Select the 50 Hz/Manual Burst option.

2. Select the desired value for the Burst Interval, Minimum, and Decrement. This indicates the cycle length of the intervals in the drive train.

3. Select the Enable checkbox.

4. To deliver the burst, select and hold the Hold for Burst button.

   The ventricular Manual Burst will be delivered up to 30 seconds as long as the Hold for Burst button is held and the telemetry link is maintained.

   The atrial Manual Burst will be delivered up to 45 seconds as long as the Hold for Burst button is held and the telemetry link is maintained. The intervals will continue to be decremented until the minimum interval is reached, then all further pulses will be at the Minimum interval.

5. To stop the burst delivery, release the Hold for Burst button. The Hold for Burst button will become dimmed again.

6. To deliver additional Manual Burst pacing, repeat these steps.

Performing 50 Hz Burst Pacing

1. Select the 50 Hz/Manual Burst option.

2. Select the Enable checkbox.

3. To deliver the burst, select and hold the Hold for 50 Hz Burst button.

The ventricular 50 Hz Burst will be delivered up to 30 seconds as long as the Hold for Burst button is held and the telemetry link is maintained.

The atrial 50 Hz Burst will be delivered up to 45 seconds as long as the Hold for Burst button is held and the telemetry link is maintained.

NOTE: *During Hold for 50 Hz Burst pacing, the S1 interval is automatically set to 20 ms and the decrement to 0. These values will not be displayed on the screen.*

4. To stop the burst delivery, release the Hold for 50 Hz Burst button. The Hold for 50 Hz Burst button will become dimmed again.

5. To deliver additional 50 Hz Burst pacing, repeat these steps.

COMMANDED THERAPY METHODS

The commanded EP test methods, Commanded Shock and Commanded ATP, may be delivered independently of the programmed detection and therapy parameters. If the pulse generator is in the process of delivering therapy when a commanded method is initiated, the EP Test function overrides and aborts the therapy in process. If an episode is not in progress, then a Commanded Ventricular Episode will be recorded in the Arrhythmia Logbook. Commanded Shock and Commanded ATP delivery is inhibited when a magnet is positioned over the pulse generator, if it is programmed to Inhibit Therapy.

Commanded Shock

The Commanded Shock feature allows delivery of a shock with programmable energy and coupling interval.

All Commanded Shocks are Committed and delivered R-wave synchronously when the coupling interval is programmed to Sync. Shock waveform and polarity are identical to detection-initiated shocks but a programmed coupling interval may be specified. The coupling interval is initiated at the point where the shock would have been delivered in Sync mode, but is instead delivered at the programmed coupling interval. Following any Commanded Shock delivery, Post-shock Redetection is used and post-shock pacing is activated.

Performing Commanded Shock Delivery

1. Select the Commanded Shock option.

2. Select the desired values for the Coupling interval and Shock Energy.

3. Select the Enable checkbox. The Deliver Shock button will become available.

4. Select the Deliver Shock button to initiate shock delivery. The Commanded Shock is recorded in therapy history.

5. To deliver subsequent shocks, repeat these steps.

Commanded ATP

Commanded ATP allows you to manually deliver ATP schemes, independent of the programmed detection and therapy parameters. You can configure the Commanded ATP by either selecting the type of ATP scheme or by programming ATP parameters on the Details screen in order to deliver Commanded ATP.

The EP Temp V Mode must be programmed to Monitor Only to ensure the Commanded ATP does not interfere with detection-initiated ATP.

Performing Commanded ATP

1. If the pulse generator Ventricular Tachy Mode is not currently programmed to Monitor Only, select the Monitor Only EP Temp V Mode option.

2. Select the type of ATP scheme and select the value for Number of Bursts.

3. Select the Start ATP button to initiate the first burst in the selected ATP scheme. The Bursts Remaining counter will decrement as each burst is completed.

4. Select the Continue button for each additional burst delivery desired. If all bursts in a scheme have been delivered, the Bursts Remaining counter will return to the initial count, and the Continue button will be dimmed.

5. Other ATP schemes may be selected at any time; select the desired scheme and repeat the above sequence. The Commanded ATP is recorded as a physician-commanded therapy counter and displayed on the counters screen.

6. After using Commanded ATP, remember to program the EP Temp V Mode to Monitor + Therapy or leave the screen so that the EP Temp V Mode is ended and the permanent Tachy Mode is resumed.

NOTE: *If any button other than the Continue button is selected during delivery of a Commanded ATP scheme, the scheme will be reset and the Bursts Remaining box will be restored to its initial value. The Start ATP button must be reselected to initiate the scheme again.*

IMPLANT INFORMATION

CHAPTER 9

This chapter contains the following topics:

IMPLANTING THE PULSE GENERATOR

Step A: Check Equipment

Step B: Interrogate and Check the Pulse Generator

Step C: Implant the Lead System

Step D: Take Baseline Measurements

Step E: Form the Implantation Pocket

Step F: Connect the Leads to the Pulse Generator

Step G: Evaluate Lead Signals

Step H: Program the Pulse Generator

Step I: Implant the Pulse Generator

Step J: Complete and Return the Implantation Form

Step A: Check Equipment

It is recommended that instrumentation for cardiac monitoring, defibrillation, and lead signal measurement should be available during the implant procedure. This includes the PRM system with its related accessories and the software application. Before beginning the implantation procedure, become completely familiar with the operation of all the equipment and the information in the respective operator's and user's manuals. Verify the operational status of all equipment that may be used during the procedure. Sterile duplicates of all implantable items and the following accessories should be available in case of accidental damage or contamination:

- Internal defibrillator paddles
- External defibrillator paddles
- Torque and non-torque wrenches

During the implantation procedure, a standard transthoracic defibrillator with external pads or internal paddles should be available for use during defibrillation threshold testing.

Step B: Interrogate and Check the Pulse Generator

To maintain sterility, test the pulse generator as described below before opening the sterile blister tray. The pulse generator should be at room temperature to ensure accurately measured parameters.

1. Interrogate the pulse generator using the PRM. Verify that the pulse generator's Tachy mode is programmed to Storage. If otherwise, call Technical Services at the phone number provided on the back of this manual.

2. Perform a manual capacitor re-formation.

3. Review the pulse generator's current battery status. Counters should be at zero. If the pulse generator battery status is not at BOL, do not implant the pulse generator. Call Technical Services at the phone number provided on the back of this manual.

Step C: Implant the Lead System

The pulse generator requires a lead system for sensing, pacing, and delivering shocks. The pulse generator uses its case as a defibrillating electrode.

Selection of lead configuration and specific surgical procedures is a matter of professional judgement. The following lead system configurations are available for use with the pulse generator:

- ENDOTAK endocardial cardioversion/defibrillation and pacing lead system
- Ventricular endocardial bipolar lead
- Atrial bipolar lead
- Guidant transvenous coronary venous (pace/sense) lead
- Unipolar sutureless myocardial leads and, if necessary, an appropriate Guidant lead adapter
- Superior vena cava lead coupled with a ventricular patch lead
- Two-patch epicardial leads configuration

NOTE: *If the coronary venous lead cannot be used and the physician's medical judgment indicates that a limited left thoracotomy is justified to place an epicardial lead, the use of sutureable, steroid-eluting pace/sense epicardial leads is recommended.*

CAUTION: The absence of a lead or plug in a lead port may affect device performance. If a lead is not used, be sure to properly insert a plug in the unused port.

Whichever lead configuration is used for both pacing/sensing and defibrillating, several considerations and cautions should be heeded. Such factors as cardiomegaly or drug therapy may necessitate repositioning of the defibrillating leads or substituting one lead for another to facilitate arrhythmia conversion. In some instances, no lead configuration may be found that provides reliable arrhythmia termination at energy levels available from the pulse generator; implantation of the pulse generator is not recommended in these cases.

Implant the leads via the surgical approach chosen.

CAUTION: Do not suture directly over the lead body as this may cause structural damage. Use the lead stabilizer to secure the lead lateral to the venous entry side.

Step D: Take Baseline Measurements

Once the leads are implanted, take baseline measurements. Evaluate the lead signals. If performing a pulse generator replacement procedure, existing leads should be reevaluated, (e.g., signal amplitudes, pacing thresholds, and impedance). The use of radiography may help ensure lead position and integrity. If testing results are unsatisfactory, lead system repositioning or replacement may be required.

- Connect the pace/sense lead(s) to a pacing system analyzer (PSA). Pace/sense lead measurements, measured approximately 10 minutes after placement, are listed below (Table 9-1 on page 9-5). Note that the pulse generator measurements may not exactly correlate to the PSA measurements due to signal filtering.

Table 9-1. Lead measurements

	Pace/sense lead (acute)	Pace/sense lead (chronic)	Shocking lead (acute)	Shocking lead (chronic)
R-wave amplitude[a] [b]	> 5 mV	> 5 mV	> 1.0 mV	> 1.0 mV
P-wave amplitude[a] [b]	> 1.5 mV	> 1.5 mV		
R-wave duration[b] [c] [d]	< 100 ms	< 100 ms		
Pacing threshold (right ventricle)	< 1.5 V endocardial < 2.0 V epicardial	< 3.0 V endocardial < 3.5 V epicardial		
Pacing threshold (left ventricle)	< 2.5 V coronary venous < 2.0 V epicardial	< 3.5 V coronary venous < 3.5 V epicardial		
Pacing threshold (atrium)	< 1.5 V endocardial	< 3.0 V endocardial		
Lead impedance (at 5 V and 0.5 ms atrium and ventricle)	200–2000 Ω	200–2000 Ω	20–80 Ω	20–80 Ω
Lead impedance (at 5 V and 0.5 ms left ventricle)	200–2000 Ω	200–2000 Ω	20–80 Ω	20–80 Ω

a. Amplitudes less than 2 mV cause inaccurate rate counting in the chronic state, and result in inability to sense a tachyarrhythmia or the misinterpretation of a normal rhythm as abnormal.
b. Lower R-wave amplitudes and longer duration may be associated with placement in ischemic or scarred tissues. Since signal quality may deteriorate chronically, efforts should be made to meet the above criteria by repositioning the leads to obtain signals with the largest possible amplitude and shortest duration.
c. Durations longer than 135 ms (the pulse generator's refractory period) may result in inaccurate cardiac rate determination, inability to sense a tachyarrhythmia, or in the misinterpretation of a normal rhythm as abnormal.
d. This measurement is not inclusive of current of injury.

Step E: Form the Implantation Pocket

Using standard operating procedures to prepare an implantation pocket, choose the position of the pocket based on the implanted lead configuration and the patient's body habitus. Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure. Pulse generators are typically implanted subcutaneously in order to minimize tissue trauma and facilitate explant. However, deeper implantation (e.g., subpectoral)

may help avoid erosion or extrusion in some patients. Verify magnet function and wanded telemetry to ensure the pulse generator is within acceptable range.

Consider the following situations during the implant the procedure:

- If an abdominal implant is suitable, it is recommended that implantation occur on the left abdominal side.
- Tunnel the leads if necessary. If a Guidant tunneler is not used, cap the lead terminal pins, gently tunnel the leads subcutaneously to the implantation pocket, and reevaluate the lead signals to determine if any of the leads have been damaged during the tunneling procedure. A Penrose drain, large chest tube, or tunneling tool may be used to tunnel the leads.
- If the lead terminal pins are not connected to a pulse generator at the time of lead implantation, they must be capped before closing the incision.

Step F: Connect the Leads to the Pulse Generator

Lead connections are illustrated below.

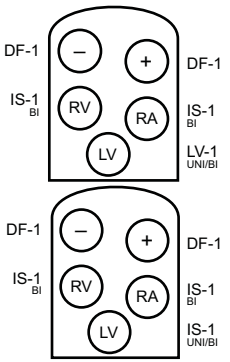

Figure 9-1. Lead connections

Setscrew locations are illustrated below.

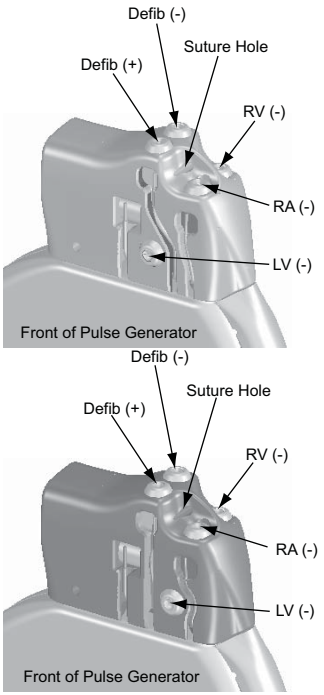

Figure 9-2. Setscrew and suture hole locations

Lead to pulse generator connections

CAUTION: Do not insert a lead into the pulse generator connector without first visually verifying that the setscrew is sufficiently retracted to allow insertion. Fully insert each lead into its lead port and then tighten the setscrew onto the electrodes.

1. As each lead is inserted into the pulse generator, secure the lead in place by tightening the setscrew with the torque wrench.

    a. Insert the wrench into the center, preslit depression of the seal plug.

    b. Place pressure on the lead to maintain its position in the pulse generator lead port. Be certain that the lead remains fully inserted in the lead port.

    c. The large-handled torque wrench is preset to apply the proper amount of force to the captive setscrew. Tighten the setscrew, making sure it is not crooked, until the wrench ratchets; additional force is unnecessary.

d. Apply gentle traction to the leads to ensure a secure connection.

2. In models with IS-1 connectors, insert and secure the right ventricular pace/sense lead terminal into the RV lead port.

NOTE: *When connecting leads to a device header, connect the RV lead first. An RV lead is required to establish RV-based timing cycles that yield appropriate sensing and pacing in all chambers, regardless of the programmed configuration.*

3. In models with atrial connectors, insert and secure the atrial pace/sense lead terminal into the A lead port.

4. Insert and secure the left ventricular coronary venous pace/sense lead terminal into the LV lead port.

5. In models with DF-1 connectors, insert the defibrillating lead anode (+, proximal) into the pulse generator's (+) Defib lead port. For proper connection, be certain that the lead terminal pin is fully inserted in the pulse generator lead port. When viewed through the side of the header, the pin tip should extend through the terminal block.

6. Insert and secure the defibrillating cathode (–, distal) in the (–) Defib lead port in a similar manner as above.

CAUTION: For IS-1/DF-1 leads, never change the shock waveform polarity by physically switching the lead anodes and cathodes in the pulse generator header—use the programmable Polarity feature. Device damage or nonconversion of the arrhythmia post-operatively may result if the polarity is switched physically.

CAUTION: The absence of a lead or plug in a lead port may affect device performance. If a lead is not used, be sure to properly insert a plug in the unused port.

Consider the following lead connection information during the implant procedure:

- The IS-1 pace/sense lead port(s) has one setscrew for securing the terminal pin.

- The DF-1 port has one setscrew for securing the terminal pin.

- The LV-1 pace/sense lead port(s) has one setscrew for securing the terminal pin.

- Avoid allowing blood or other body fluids to enter the lead ports in the pulse generator header. If fluid inadvertently enters the ports, they should be thoroughly cleaned using sterile water.

- To connect leads to the pulse generator, use only the tools provided in the pulse generator tray or accessory kit to avoid damage to the seal plugs. Failure to properly insert the wrench in the preslit depression of the seal plug may result in damage to the plug and its sealing properties. Failure to use the supplied torque wrench may result in damage to the screw or connector threads. Do not implant the pulse generator if the seal plugs appear to be damaged. Retain the tools until all testing procedures are complete and the pulse generator is implanted.

- If necessary, lubricate the lead connectors sparingly with sterile water to make insertion easier.

- If a lead terminal encounters resistance on insertion into the lead port, insert the wrench into the preslit depression of the seal plug and angle it gently to open the valve and allow excess air to bleed out of the seal plug.

- Significant amounts of fluid or sterile water in a lead bore may make it difficult to fully insert leads. If significant amounts of fluid or sterile water are present, insert the torque wrench into the setscrew before inserting the leads. This will allow fluid to drain from the lead bore.

- For proper connection of an IS-1 lead to the pulse generator, be certain that the connector pin visibly extends through the connector block at least 1 mm.

Step G: Evaluate Lead Signals

1. Take the pulse generator out of power-saving Storage mode by programming the Tachy Mode to Off.

CAUTION: To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode is programmed to Off when not in use and before handling the device. For tachyarrhythmia therapy, verify that the Tachy Mode is activated.

2. Evaluate the pace/sense and defibrillation lead signals by viewing the real-time EGMs and markers. The signal from the implanted defibrillation leads should be continuous and without artifact, similar to a body-surface

ECG. A discontinuous signal may indicate a poor connection, lead fracture or otherwise damaged lead, or an insulation break that would necessitate lead replacement. Inadequate signals may result in failure of the pulse generator system to detect an arrhythmia, inability to deliver programmed therapy, or unnecessary delivery of therapy. Lead measurements should reflect those in (Table 9-1 on page 9-5).

CAUTION: Take care to ensure that artifacts from the ventricles are not present on the atrial channel, or atrial oversensing may result. If ventricular artifacts are present in the atrial channel, the atrial lead may need to be repositioned to minimize its interaction.

3. Evaluate all lead impedances using the Lead Impedance test accessed from the Diagnostic Evaluation tool.

CAUTION: Never implant the device with a lead system that has less than 15 Ω total shock lead impedance. Device damage may result. If a shocking lead impedance is less than 20 Ω, reposition the shocking electrodes to allow a greater distance between the shocking electrodes.

CAUTION: Patients should be tested for diaphragmatic stimulation by pacing the LV lead through the pulse generator at 7.5 V and adjusting the lead position as necessary. PSA testing at higher outputs (e.g., 10.0 V) may also be considered to better characterize stimulation margins. The probability of diaphragmatic stimulation increases when a pacing system includes an LV lead because of this lead's proximity to the phrenic nerve.

Step H: Program the Pulse Generator

1. Check the programmer clock and set and synchronize the pulse generator as necessary so that the proper time appears on printed reports and PRM strip chart recordings.

2. It may be useful to program the Beep During Capacitor Charge feature to On during conversion testing and implantation to help recognize when the pulse generator is charging to deliver shock.

3. Perform a manual capacitor re-formation if not already performed.

4. Program the pulse generator to desired parameters appropriate for the patient for necessary testing.

5. Shocks intended for VF therapy should be programmed with a 10 J safety margin above the shock energy level that the physician determines is required for successful VF conversion.

CAUTION: To prevent inappropriate shocks, ensure that the pulse generator's Tachy Mode is programmed to Off when not in use and before handling the device. For tachyarrhythmia therapy, verify that the Tachy Mode is activated.

Step I: Implant the Pulse Generator

1. Program the Tachy Mode to Off.

2. Ensure that the pulse generator has good contact with surrounding tissue of the implantation pocket. Suture hole locations are illustrated below. Gently coil excess lead and place adjacent to the pulse generator. Flush the pocket with saline solution, if necessary, to avoid a dry pocket.

   WARNING: Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture.

   CAUTION: Improper insertion can cause insulation damage near the terminal end that could result in lead failure.

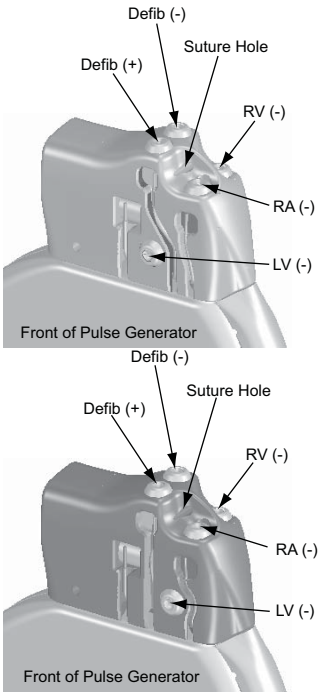

Figure 9-3. Setscrew and suture hole locations

3. Close the implantation pocket. Consideration should be given to place the leads in a manner to prevent contact with suture materials. It is recommended that absorbable sutures be used for closure of tissue layers.

4. Complete any electrocautery procedures before reactivating the pulse generator.

5. Program the Tachy Mode to the desired setting and confirm final programmed parameters.

6. Print out parameter reports and save all data to disk using the programmer's Save to Disk option.

Step J: Complete and Return the Implantation Form

Within ten days of implantation, complete the Warranty Validation and Lead Registration form and return the original to Boston Scientific along with a copy of the patient data disk. This information enables Boston Scientific to register each implanted pulse generator and set of leads, initiate the warranty period, and provide clinical data on the performance of the implanted system. Keep a

copy of the Warranty Validation and Lead Registration form and programmer printouts, and the original patient data disk for the patient's file.

Complete the temporary patient identification card and give it to the patient. After receiving the validation form, Boston Scientific sends the patient a permanent identification card.

NOTE: *A registration form is packaged with each pulse generator lead. If completing the pulse generator Warranty Validation and Lead Registration form for the pulse generator, completing separate validation forms for each lead is not necessary.*

POST IMPLANT INFORMATION

CHAPTER 10

This chapter contains the following topics:

FOLLOW UP TESTING

It is recommended that device functions be evaluated during follow-up testing.

WARNING: Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue.

Predischarge Follow Up

During the pre-discharge follow-up test, the following procedures should be performed via telemetry using the PRM:

1. Interrogate the pulse generator and review the Summary screen.

2. Perform pacing thresholds and lead impedance tests, and intrinsic amplitude measurements.

3. Review Histograms.

4. When all testing is complete, perform a final interrogation and save all the data to a patient data disk.

5. Print the Quick Notes and Patient Data reports to retain in your files for future reference.

6. It is important to clear the therapy counters so that at the next follow-up session the most recent episode data will be displayed. Note that the histogram counters can be cleared from either the Brady or Tachy Counters screen as well.

NOTE: *Echo-Doppler studies may be used to evaluate AV Delay and other programming options non-invasively post-implant.*

Routine Follow Up

You should conduct routine follow-up examinations one month after the pre-discharge study and every three months thereafter. During the routine follow-up test, the following procedures should be performed via telemetry using the programming system:

1. Interrogate the device and review the Summary screen.

2. Perform pacing thresholds and lead impedance tests, and intrinsic amplitude measurements.

3. Print and review the Quick Notes report, and retain it in your files for future reference.

4. For episodes of interest, review the Arrhythmia Logbook screen and print episode details and stored electrogram information.

5. It is important to clear the therapy counters so that at the next follow-up session the most recent episode data will be displayed.

CAUTION: Verify with a conversion test that the patient's tachyarrhythmias can be detected and terminated by the pulse generator system if the patient's status has changed or parameters have been reprogrammed.

POST IMPLANT FEATURES

Sensitivity Adjustment

The Sensitivity Adjustment feature allows you to shift the atrial sensing range to make it less sensitive (i.e., a larger signal would be required for the device to detect). It allows shifting the ventricular sensing range to make it less or more sensitive. While the Nominal setting is primarily indicated for both atrial and ventricular sensing, an adjustment can be made if, in a rare situation, atrial or ventricular oversensing/undersensing has been observed post-implant (i.e., inhibition of bradycardia pacing or inappropriate tachy therapy).

WARNING: Left ventricular lead dislodgment to a position near the atria can result in atrial oversensing or left ventricular pacing inhibition.

Should it become necessary to adjust the sensing range in a chamber, always choose the setting that allows the greatest sensitivity, but resolves oversensing/undersensing:

- To reduce oversensing, program the sensitivity to a higher value.

- To reduce undersensing, program the sensitivity to a lower value.

After any change to sensitivity, evaluate for appropriate sensing for both bradycardia pacing and tachycardia detection.

If proper sensing cannot be restored with an adjustment or if any undersensing is observed after making a change, consider repositioning the lead or implanting a new sensing lead and then programming the setting back to nominal.

CAUTION: Following any sensing range adjustment or any modification of the sensing lead, always verify appropriate sensing.

Beeper Feature

The pulse generator contains a beeper that emits audible tones to communicate status information. The beeper includes both programmable and nonprogrammable features.

Programmable Features

The following beeper features are programmable:

- Beep During Capacitor Charge—When programmed to On, regardless of the Tachy mode, a warbling tone will sound continuously while the pulse generator is charging (except when charging during an auto capacitor re-form). The tone will continue until charging is complete. When this feature is programmed to Off, there is no audible indication that the pulse generator is charging. This feature is useful during EP testing.

- Beep When Explant Is Indicated—When this feature is programmed to On, the pulse generator emits tones upon reaching Explant. The Explant indicator consists of 16 tones repeated every six hours after the pulse generator reaches Explant until the feature is turned off via the programmer. When this feature is programmed to Off, there is no audible indication of Explant.

Perform the following steps to program the magnet and beeper features:

Magnet and Beeper Response

1. Select the Settings tab.

2. From Ventricular Tachy, select the Therapy button.

3. Select the V-Tachy Therapy Setup button.

4. Enter the desired values.

Beep when Explant is indicated

1. Select the Summary tab.

2. Select the Battery button.

3. From the Battery Status summary screen, select the Battery Detail button.

4. From the Battery Detail summary screen, select the desired value for Beep when Explant is indicated.

NOTE: *When the Magnet Response is programmed to Inhibit Therapy, magnet application will cause other types of beeping tones to be emitted, depending on the device mode. Refer to "Magnet Feature" on page 10-5 for more information.*

Nonprogrammable Features

The following beeper features are nonprogrammable:

- Battery capacity depleted—Regardless of whether Beep When Explant Is Indicated is programmed to On or Off, once the battery capacity is depleted, the pulse generator will emit the explant indicator tones

- Fault code tones—For certain fault codes or when safety mode is entered, the pulse generator will beep 16 times every 6 hours.

NOTE: *Beeping tones may emit under nonprogrammable scenarios in response to device self-diagnostic testing. Advise patients to have their pulse generator checked whenever they hear tones coming from the device. Contact Technical Services at the phone number on the back of this manual for assistance.*

Magnet Feature

The magnet feature allows certain device functions to be triggered when a magnet is placed in close proximity to the pulse generator (Figure 10-1 on page 10-6).

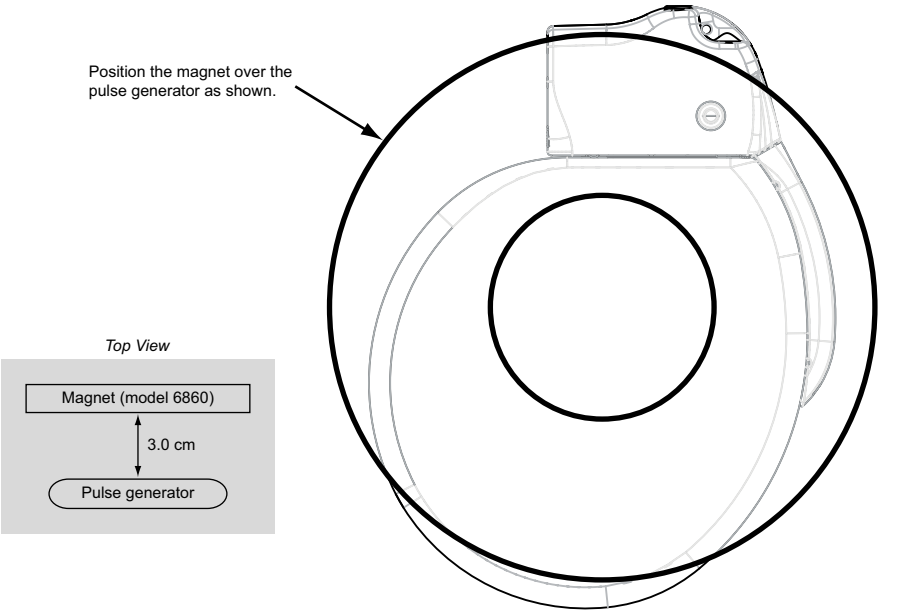

Figure 10-1. Proper position of magnet Model 6860 to activate the pulse generator magnet feature

The pulse generator Magnet Response settings can be programmed to control the behavior of the pulse generator when a magnet is detected. The Magnet Response settings are located in the Magnet and Beeper section of the V-Tachy Therapy Setup screen. The following Magnet Response settings are available:

- Off—no response
- Store EGM—patient monitoring data will be stored
- Inhibit Therapy—therapy will be stopped

Off

When the Magnet Response is programmed to Off, application of the magnet will have no effect on the pulse generator.

Store EGM

When the Magnet Response is programmed to Store EGM, application of the magnet will activate the patient triggered monitor functionality. Refer to "Patient Triggered Monitor" on page 7-17 for additional information.

Inhibit Therapy

When the Magnet Response is programmed to Inhibit Therapy, application of the magnet will inhibit and/or divert charging for a shock, divert a shock that is about to be delivered, or inhibit and/or divert further ATP therapy.

When Magnet Response is programmed to Inhibit Therapy, initiation of tachyarrhythmia therapy and arrhythmia induction is inhibited any time the magnet is properly positioned over the pulse generator. The tachyarrhythmia detection process continues, but therapy or induction cannot be triggered. When a magnet is placed over the pulse generator, the following will occur:

- If the Tachy mode is Monitor + Therapy or Off when the magnet is applied, the Tachy mode changes temporarily to Monitor Only mode and will remain in Monitor Only mode as long as the magnet is applied. Three seconds after the magnet is removed, the mode will return to the previously programmed mode.

- If the pulse generator is charging to deliver shock therapy when the magnet is applied, the charging continues but is then terminated within one to two seconds of magnet application, and the charge is diverted. (This delay occurs in case the magnet is inadvertently passed over the device when therapy inhibition is not desired.) The pulse generator remains in temporary Monitor Only mode while the magnet is applied. No further therapy is initiated until the magnet is removed; however, detection will continue.

- If charging is complete or completes within the 1–2 second delay period, holding the magnet over the pulse generator for more than two seconds will divert the shock. (If the magnet is removed during the delay period, the shock could still be delivered.) Shocks will not be delivered with the magnet in place.

- If the pulse generator is initiating fibrillation induction or ATP pulses, it terminates the delivery after one to two seconds of magnet application. No further induction or ATP pulse sequences are initiated until the magnet is removed.

- If the Tachy Mode is Monitor Only or Off, magnet application will produce a constant tone to indicate that the device is in a non-therapy mode.

- If the Tachy Mode is Monitor + Therapy or the pulse generator is in Electrocautery Protection Mode, magnet application will cause the pulse generator to beep once per second to indicate that the device is in a therapy mode.

NOTE: *If tachy detection occurs while the magnet is in place, detailed therapy history will indicate that therapy was not delivered because the device was in Monitor Only mode.*

EXPLANTATION

An Observation/Complication/Out-of-Service Reporting form should be completed and sent to Boston Scientific when a product is removed from service. Return all explanted pulse generators and leads with product performance allegations or warranty considerations to Boston Scientific. Examination of explanted devices provides information for continued improvement in device reliability and will permit calculation of any warranty replacement credit use.

In the event of patient death (regardless of cause), the explanted pulse generator and/or lead should be returned to Boston Scientific along with the Observation/Complication/Out-of-Service Reporting form and copies of the autopsy report, if performed. For other observation or complications reasons, also complete and return to Boston Scientific the Observation/Complication/Out-of-Service Reporting form.

NOTE: *Disposal of explanted devices is subject to local, state, and federal regulations. Contact your sales representative or call the phone number on the back cover of this manual for a Returned Product Kit.*

NOTE: *Discoloration of the pulse generator may have occurred due to a normal process of anodization, and has no effect on the pulse generator function.*

CAUTION: Be sure that the pulse generator is removed before cremation. Cremation and incineration temperatures might cause the pulse generator to explode.

CAUTION: Before explanting, cleaning, or shipping the device, complete the following actions to prevent unwanted shocks, overwriting of important therapy history data, and audible tones:

- Program the pulse generator Tachy and Brady Modes to Off.
- Program the Magnet Response feature to Off.
- Program the Beep When Explant is Indicated feature to Off.

Consider the following items when explanting and returning the pulse generator:

- Interrogate the pulse generator and print a Combined Follow-up report.
- Deactivate the pulse generator before explantation.
- Disconnect the leads from the pulse generator.
- If leads are also explanted, attempt to remove them intact. Do not remove leads with hemostats or any other clamping tool that may damage the leads. Resort to tools only if manual manipulation cannot free the lead.
- Wash, but do not submerge, the pulse generator and leads to remove body fluids and debris using a disinfectant solution. Do not allow fluids to enter the pulse generator's lead ports.
- Use a Boston Scientific Returned Product Kit to properly package the pulse generator.
- Complete the Observation/Complication/Out-of-Service Reporting form.
- Send the form and the Returned Product Kit to Boston Scientific.

PROGRAMMABLE OPTIONS

APPENDIX A

Table A-1. ZIP Telemetry settings

Parameter	Programmable Values	Nominal
Communication Mode	Enable use of ZIP telemetry (May require limited use of wand), Use wand for all telemetry	Enable use of ZIP telemetry (May require limited use of wand)

Table A-2. Tachy Mode parameter

Parameter	Programmable Values	Nominal
Tachy Mode	Off, Monitor Only, Monitor + Therapy, Enable Electrocautery Protection	Storage

Table A-3. Ventricular Zones parameter

Parameter	Programmable Values	Nominal
Ventricular Zones	1, 2, 3	2

Table A-4. Detection parameters for 1-zone, 2-zone, and 3-zone configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Rate[a] (bpm) 3 zones (intervals in ms)	90, 95, ..., 200 (667–300)	110, 115, ..., 210 (545–286) 220 (273)	130, 135, ..., 210 (462–286), 220, 230, 240, 250 (273–240)	140 (Tolerance ± 5 ms) for VT-1 Zone 160 (Tolerance ± 5 ms) for VT Zone 200 (Tolerance ± 5 ms) for VF Zone
Rate[a] (bpm) 2 zones (intervals in ms)	– –	90, 95, ..., 210 (667–286) 220 (273)	110, 115, ..., 210 (545–286) 220, 230, 240, 250 (273–240)	160 (Tolerance ± 5 ms) for VT Zone 200 (Tolerance ± 5 ms) for VF Zone
Rate[a] (bpm) 1 zone (intervals in ms)	– –	– –	90, 95, ..., 210 (667–286) 220 (273)	200 (Tolerance ± 5 ms)
Initial Duration[b] (sec) 3 zones	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, ..., 60.0	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, 30.0	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	2.5 (Tolerance ± 1 cardiac cycle) for VT-1 Zone 2.5 (Tolerance ± 1 cardiac cycle) for VT Zone 1.0 (Tolerance ± 1 cardiac cycle) for VF Zone

Table A-4. Detection parameters for 1-zone, 2-zone, and 3-zone configurations (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Initial Duration[b] (sec) 2 zones	– –	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, 30.0	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	2.5 (Tolerance ± 1 cardiac cycle) for VT Zone 1.0 (Tolerance ± 1 cardiac cycle) for VF Zone
Initial Duration[b] (sec) 1 zone	– –	– –	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	1.0 (Tolerance ± 1 cardiac cycle)
Redetection Duration[b] (sec) 3 zones	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle) for all zones
Redetection Duration[b] (sec) 2 zones	– –	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle) for all zones
Redetection Duration[b] (sec) 1 zone	– –	– –	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle)
Post-shock Duration[b] (sec) 3 zones	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, ..., 60.0	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, 30.0	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle) for all zones
Post-shock Duration[b] (sec) 2 zones	– –	1.0, 1.5, ..., 5.0, 6.0, 7.0, ..., 15.0, 20.0, 25.0, 30.0	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle) for all zones
Post-shock Duration[b] (sec) 1 zone	– –	– –	1.0 (nonprogrammable)	1.0 (Tolerance ± 1 cardiac cycle)

a. The Rate difference between each tachy zone must be at least 20 bpm. The lowest Tachy Rate Threshold must be ≥ 5 bpm higher than the Maximum Tracking Rate, Maximum Sensor Rate, and the Maximum Pacing Rate; and the lowest Tachy Rate Threshold must be ≥ 15 bpm higher than the Lower Rate Limit.
b. The Duration in a zone must be equal to or greater than the Duration in the next highest zone.

Table A-5. Ventricular Detection Enhancement Type for 2-zone and 3-zone configurations

Parameter	Programmable Values	Nominal
Detection Enhancement Type	Off, Rhythm ID, Onset/Stability	Onset/Stability

Table A-6. Onset/Stability detection enhancement parameters for 2-zone and 3-zone configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
V Rate > A Rate 3 zones	Off, On	– –	– –	On
V Rate > A Rate 2 zones	– –	Off, On	– –	On

Table A-6. Onset/Stability detection enhancement parameters for 2-zone and 3-zone configurations (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
AFib Rate Threshold (bpm) 3 zones	Off, 100, 110, ..., 300	– –	– –	170 (Tolerance ± 5 ms)
AFib Rate Threshold (bpm) 2 zones	– –	Off, 100, 110, ..., 300	– –	170 (Tolerance ± 5 ms)
Stability (ms) 3 zones	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	– –	– –	20 (Tolerance ± 5 ms)
Stability (ms) 2 zones	– –	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	– –	20 (Tolerance ± 5 ms)
Shock If Unstable (ms) 3 zones	– –	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	– –	30 (Tolerance ± 5 ms)
Shock If Unstable (ms) 2 zones	– –	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	– –	Off (Tolerance ± 5 ms)
Onset (% or ms) 3 zones	Off, 9, 12, 16, 19, ..., 37 41, 44, 47, 50% or 50, 60, ..., 250 ms	– –	– –	9% (Tolerance ± 5 ms)
Onset (% or ms) 2 zones	– –	Off, 9, 12, 16, 19, ..., 37, 41, 44, 47, 50% or 50, 60, ..., 250 ms	– –	9% (Tolerance ± 5 ms)
Stability And/Or Onset 3 zones	And, Or	– –	– –	And
Stability And/Or Onset 2 zones	– –	And, Or	– –	And
Sustained Rate Duration (min:sec) 3 zones	Off, 00:10, 00:15, ..., 00:55 01:00, 01:15, ..., 02:00 02:30, 03:00, ..., 10:00 15:00, 20:00, ..., 60:00	– –	– –	03:00 (Tolerance ± 1 cardiac cycle)
Sustained Rate Duration (min:sec) 2 zones	– –	Off, 00:10, 00:15, ..., 00:55 01:00, 01:15, ..., 02:00 02:30, 03:00, ..., 10:00 15:00, 20:00, ..., 60:00	– –	03:00 (Tolerance ± 1 cardiac cycle)
Detection Enhancement 3 zones	Off, On	Off, On	– –	On (VT-1) Off (VT)

Table A-6. Onset/Stability detection enhancement parameters for 2-zone and 3-zone configurations (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Detection Enhancement 2 zones	– –	Off, On	– –	On
Atrial Tachyarrhythmia Discrimination 3 zones	Off, On	– –	– –	On
Atrial Tachyarrhythmia Discrimination 2 zones	– –	Off, On	– –	On
Sinus Tachycardia Discrimination 3 zones	Off, On	– –	– –	On
Sinus Tachycardia Discrimination 2 zones	– –	Off, On	– –	On
Polymorphic VT Discrimination 3 zones	– –	Off, On	– –	On
Polymorphic VT Discrimination 2 zones	– –	Off, On	– –	Off

Table A-7. Rhythm ID detection enhancement parameters for 2-zone and 3-zone configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Detection Enhancement 3 zones	Off, On	Off, On	– –	On (VT-1) Off (VT)
Detection Enhancement 2 zones	– –	Off, On	– –	Off
Sustained Rate Duration (min:sec) 3 zones	Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	– –	03:00 (VT-1 and VT) (Tolerance ± 1 cardiac cycle)
Sustained Rate Duration (min:sec) 2 zones	– –	Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	– –	03:00 (Tolerance ± 1 cardiac cycle)

Table A-7. Rhythm ID detection enhancement parameters for 2-zone and 3-zone configurations (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Passive Method 3 zones (one value for all zones)	Off, On	Off, On	– –	On
Passive Method 2 zones (one value for all zones)	– –	Off, On	– –	On
Active Method 3 zones (one value for all zones)	Off, On	Off, On	– –	On
Active Method 2 zones (one value for all zones)	– –	Off, On	– –	On
Temp LRL (ppm) (one value for all zones)	Use Norm LRL, 30, 35, ..., 105	Use Norm LRL, 30, 35, ..., 105	– –	Use Norm LRL (Tolerance ± 5 ms)
Temp LRL 2 zones (ppm) (one value for all zones)	– –	Use Norm LRL, 30, 35, ..., 105	– –	Use Norm LRL (Tolerance ± 5 ms)
Atrial Tachy Discrimination 3 zones (one value for all zones)	Off, On	Off, On	– –	On
Atrial Tachy Discrimination 2 zones (one value for all zones)	– –	Off, On	– –	On
AFib Rate Threshold (bpm) 3 zones (one value for all zones)	100, 110, ..., 300	100, 110, ..., 300	– –	170 (Tolerance ± 5 ms)
AFib Rate Threshold (bpm) 2 zones (one value for all zones)	– –	100, 110, ..., 300	– –	170 (Tolerance ± 5 ms)
Stability (ms) 3 zones (one value for all zones)	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	– –	20 (Tolerance ± 5 ms)
Stability (ms) 2 zones (one value for all zones)	– –	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	– –	20 (Tolerance ± 5 ms)

Table A-8. Post-shock Onset/Stability detection enhancement parameters for 2-zone and 3-zone configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock V Rate > A Rate 3 zones	Off, On	– –	– –	On
Post-shock V Rate > A Rate 2 zones	– –	Off, On	– –	On
Post-shock AFib Rate Threshold (bpm) 3 zones	Off, 100, 110, ..., 300	– –	– –	170 (Tolerance ± 5 ms)
Post-shock AFib Rate Threshold (bpm) 2 zones	– –	Off, 100, 110, ..., 300	– –	170 (Tolerance ± 5 ms)
Post-shock Stability (ms) 3 zones	Off, 6, 8, ..., 32, 35, 40, ..., 60, 70, 80, ..., 120	– –	– –	20 (Tolerance ± 5 ms)
Post-shock Stability (ms) 2 zones	– –	Off, 6, 8, ..., 32, 35, 40, ..., 60, 70, 80, ..., 120	– –	20 (Tolerance ± 5 ms)
Post-shock Sustained Rate Duration (min:sec) 3 zones	Off, 00:10, 00:15, ..., 00:55, 01:00, 01:15, ..., 02:00, 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	– –	– –	00:15 (Tolerance ± 1 cardiac cycle)
Post-shock Sustained Rate Duration (min:sec) 2 zones	– –	Off, 00:10, 00:15, ..., 00:55, 01:00, 01:15, ..., 02:00, 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	– –	00:15 (Tolerance ± 1 cardiac cycle)

Table A-9. Post-shock Rhythm ID detection enhancement parameters for 2-zone and 3-zone configurations

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock Detection Enhancement 3 zones	Off, On	Off, On	– –	Off
Post-shock Detection Enhancement 2 zones	– –	Off, On	– –	Off

Table A-9. Post-shock Rhythm ID detection enhancement parameters for 2-zone and 3-zone configurations (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock Sustained Rate Duration (min:sec) 3 zones	Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	– –	0:15 (Tolerance ± 1 cardiac cycle)
Post-shock Sustained Rate Duration (min:sec) 2 zones	– –	Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	– –	0:15 (Tolerance ± 1 cardiac cycle)

Table A-10. Ventricular ATP parameters (specified into a 750 Ω load)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
ATP Type 3 zones	Off, Burst, Ramp, Scan, Ramp/Scan	Off, Burst, Ramp, Scan, Ramp/Scan	– –	Off (VT-1); Burst (VT ATP1); Ramp (VT ATP2)
ATP Type 2 zones	– –	Off, Burst, Ramp, Scan, Ramp/Scan	– –	Burst (VT ATP1); Ramp (VT ATP2)
Number of Bursts (per scheme) 3 zones	Off, 1, 2, ..., 30	Off, 1, 2, ..., 30	– –	Off (VT-1); 2 (VT ATP1); 1 (VT ATP2)
Number of Bursts (per scheme) 2 zones	– –	Off, 1, 2, ..., 30	– –	2 (VT ATP1); 1 (VT ATP2)
Initial Pulse (pulses) 3 zones	1, 2, ..., 30	1, 2, ..., 30	– –	4 (VT-1); 10 (VT)
Initial Pulse (pulses) 2 zones	– –	1, 2, ..., 30	– –	10
Pulse Increment (pulses) 3 zones	0, 1, ..., 5	0, 1, ..., 5	– –	0
Pulse Increment (pulses) 2 zones	– –	0, 1, ..., 5	– –	0
Maximum Number of Pulses 3 zones	1, 2, ..., 30	1, 2, ..., 30	– –	4 (VT-1); 10 (VT)
Maximum Number of Pulses 2 zones	– –	1, 2, ..., 30	– –	10
Coupling Interval (% or ms) 3 zones	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	– –	81% (Tolerance ± 5 ms)

Table A-10. Ventricular ATP parameters (specified into a 750 Ω load) (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Coupling Interval (% or ms) 2 zones	– –	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	– –	81% (Tolerance ± 5 ms)
Coupling Interval Decrement (ms) 3 zones	0, 2, ..., 30	0, 2, ..., 30	– –	0 (Tolerance ± 5 ms)
Coupling Interval Decrement (ms) 2 zones	– –	0, 2, ..., 30	– –	0 (Tolerance ± 5 ms)
Burst Cycle Length (BCL) (% or ms) 3 zones	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	– –	81% (Tolerance ± 5 ms)
Burst Cycle Length (BCL) (% or ms) 2 zones	– –	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	– –	81% (Tolerance ± 5 ms)
Ramp Decrement (ms) 3 zones	0, 2, ..., 30	0, 2, ..., 30	– –	0 (VT-1); 0 (VT ATP1); 10 (VT ATP2) (Tolerance ± 5 ms)
Ramp Decrement (ms) 2 zones	– –	0, 2, ..., 30	– –	0 (VT ATP1); 10 (VT ATP2) (Tolerance ± 5 ms)
Scan Decrement (ms) 3 zones	0, 2, ..., 30	0, 2, ..., 30	– –	0 (Tolerance ± 5 ms)
Scan Decrement (ms) 2 zones	– –	0, 2, ..., 30	– –	0 (Tolerance ± 5 ms)
Minimum Interval (ms) 3 zones	120, 130, ..., 400	120, 130, ..., 400	– –	220 (Tolerance ± 5 ms)
Minimum Interval (ms) 2 zones	– –	120, 130, ..., 400	– –	220 (Tolerance ± 5 ms)
Right Ventricular ATP Pulse Width[a] (ms) 3 zones (one value for all zones)	0.1, 0.2, ..., 2.0	0.1, 0.2, ..., 2.0	– –	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Right Ventricular ATP Pulse Width[a] (ms) 2 zones (one value for all zones)	– –	0.1, 0.2, ..., 2.0	– –	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)

Table A-10. Ventricular ATP parameters (specified into a 750 Ω load) (continued)

Parameter	VT-1 Zone	VT Zone	VF Zone	Nominal
Left Ventricular ATP Pulse Width[a] (ms) 3 zones (one value for all zones)	0.1, 0.2, ..., 2.0	0.1, 0.2, ..., 2.0	– –	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Left Ventricular ATP Pulse Width[a] (ms) 2 zones (one value for all zones)	– –	0.1, 0.2, ..., 2.0	– –	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Right Ventricular ATP Amplitude[a] (V) 3 zones (one value for all zones)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	– –	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
Right Ventricular ATP Amplitude[a] (V) 2 zones (one value for all zones)	– –	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	– –	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
Left Ventricular ATP Amplitude[a] (V) 3 zones (one value for all zones)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	– –	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
Left Ventricular ATP Amplitude[a] (V) 2 zones (one value for all zones)	– –	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	– –	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
ATP Time-out[b] (seconds) 3 zones	Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	– –	60 (Tolerance ± 1 cardiac cycle)
ATP Time-out[b] (seconds) 2 zones	– –	Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	– –	60 (Tolerance ± 1 cardiac cycle)
QUICK CONVERT ATP (VF Only) 3 zones	– –	– –	Off, On	On
QUICK CONVERT ATP (VF Only) 2 zones	– –	– –	Off, On	On

a. The programmed Amplitude and Pulse Width values affect Post Therapy Brady Pacing, but are separately programmable from Normal Brady Pacing, Temporary Brady Pacing, and EP Test.
b. The VT-1 ATP Time-out must be greater than or equal to the VT ATP Time-out.

Table A-11. Ventricular Shock Parameters

Parameter	Programmable Values	Nominal
Shocks 1 and 2 energy (J)[a b c] (stored energy)	Off, 0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36 (HE), 41 (HE)	41 J (Tolerance ± 60% for ≤ 0.3 J, ± 40% for ≤ 0.6–3 J, ± 20% for 5–36 J, ± 10% for 41 J)
Energy of Remaining Shocks (J)[a c] (stored energy)	Off, 41 (HE)	41 J (Tolerance ± 10% for 41 J)
Lead Polarity[d]	Initial, Reversed	Initial
Committed Shock	Off, On	Off
Shock Lead Vector	RV Coil to RA Coil and Can, RV Coil to Can, RV Coil to RA Coil	RV Coil to RA Coil and Can

a. Biphasic energy is specified.
b. The Shock 2 energy level must be greater than or equal to the Shock 1 energy level.
c. In a VT-1 zone of a 3-zone configuration or a VT zone of a 2-zone configuration, all or some of the shocks may be programmed to Off while other shocks in that zone are programmed in joules.
d. A commanded STAT SHOCK is delivered at the programmed Polarity.

Table A-12. Pacing therapy parameters (Normal, Post-Therapy, and Temporary) (specified into a 750 Ω load)

Parameter	Programmable Values	Nominal
Mode[a b g]	DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off; Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off	DDD
Lower Rate Limit (LRL)[a c] (ppm)	30, 35, ..., 185	45 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR) [g j] (ppm)	30, 35, ..., 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR)[g j] (ppm)	30, 35, ..., 185	130 (Tolerance ± 5 ms)
Pulse Amplitude[a d e f] (atrium) (V)	0.1, 0.2, ... 3.5, 4.0, ..., 5.0	3.5 (5.0 post-therapy) (Tolerance ± 15% or ± 100mV, whichever is greater)
Pulse Amplitude[a d e f] (right ventricle) (V)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	3.5 (5.0 post-therapy) (Tolerance ± 15% or ± 100mV, whichever is greater)
Pulse Width[a d e f] (atrium, right ventricle) (ms)	0.1, 0.2, ..., 2.0	0.4 (1.0 post-therapy) (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Atrial Pace/Sense Configuration[a g]	Bipolar, Off	Bipolar
Activity Threshold[g j]	Very High, High, Medium High, Medium, Medium Low, Low, Very Low	Medium
Reaction Time[g j] (sec)	10, 20, ..., 50	30

Table A-12. Pacing therapy parameters (Normal, Post-Therapy, and Temporary) (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
Response Factor[g] [j]	1, 2, ..., 16	8
Recovery Time[g] [j] (min)	2, 3, ..., 16	2
Maximum PVARP[a] [g] (ms)	150, 160, ..., 500	280 (Tolerance ± 5 ms)
Minimum PVARP[a] [g] (ms)	150, 160, ..., 500	240 (Tolerance ± 5 ms)
PVARP After PVC[a] [g] (ms)	Off, 150, 200, ..., 500	400 (Tolerance ± 5 ms)
RV-Blank After A-Pace[a] [h] (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-Pace[a] [h] (ms)	85, 105, 125, Smart	Smart (Tolerance ± 5 ms)
A-Blank After RV-Sense[a] [h] (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
Maximum VRP (right ventricle)[a] [i] (ms)	150, 160, 170, ..., 500	250 (Tolerance ± 5 ms)
Minimum VRP (right ventricle)[a] [i] (ms)	150, 160, ..., 500	230 (Tolerance ± 5 ms)
Maximum Paced AV Delay[a] [g] (ms)	30, 40, ..., 300	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay[a] [g] (ms)	30, 40, ..., 300	180 (Tolerance ± 5 ms)
Maximum Sensed AV Delay[a] [g] (ms)	30, 40, ..., 300	120 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a] [g] (ms)	30, 40, ..., 300	120 (Tolerance ± 5 ms)
Respiratory Sensor[a] [g]	Off, On	On
Tracking Preference[g] [j]	Off, On	On
Rate Hysteresis Hysteresis Offset[g] [j] (ppm)	-80, -75, ... ,-5, Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis[g] [j] (cycles)	Off, 256, 512, 1024, 2048, 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (up, down)[g] [j] (%)	Off, 3, 6, 9, 12, 15, 18, 21, 25	Off (Tolerance 1%)
Noise Response[a] [g]	AOO, VOO, DOO, Inhibit Pacing	DOO for DDD(R) and DDI(R) modes; VOO for VDD(R) and VVI(R) modes; AOO for AAI(R) mode

Table A-12. Pacing therapy parameters (Normal, Post-Therapy, and Temporary) (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal
Maximum Pacing Rate[ag] (ppm)	30, 35, ... ,185	130 (Tolerance ± 5 ms)
Post-therapy Pacing Period (min:sec) (available post-shock only)	00:15, 00:30, 00:45, 01:00, 01:30, 02:00, 03:00, 04:00, 05:00, 10:00, 15:00, 30:00, 45:00, and 60:00	00:30 (Tolerance ± 1 cardiac cycle)

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. Refer to the NASPE/BPEG codes below for an explanation of the programmable values. The identification code of the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG) is based on the categories listed in the table.
c. The basic pulse period is equal to the pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry inhibits bradycardia pacing above 205 ppm. Magnet application does not affect pacing rate (test pulse interval).
d. Separately programmable for ATP/Post-Shock, Temporary Brady, and EP Test.
e. The minimum value of energy delivered at 5 V and 0.5 ms is 20 µJ with 200–500 Ω, and 12 µJ with 1000 Ω resistive load at 37°C ± 1°C for BOL and Explant.
f. Values are not affected by temperature variation within the range 20°–43°C.
g. This parameter is used globally in Normal Brady pacing and Post-shock Brady pacing. Changing the value for Normal Brady will change the value for Post-shock Brady.
h. This parameter is automatically set to at least 85 ms for Post-Shock Brady.
i. This parameter is automatically adjusted in Post-Shock Brady to allow appropriate sensing.
j. This parameter is disabled during Temporary Brady.

Table A-13. Brady/CRT left ventricular pacing parameters (specified into a 750 Ω load)

Parameter	Programmable Values	Nominal[a]
Ventricular Pacing Chamber[b]	RV Only, BiV	BiV
LV Offset[b g] (ms)	-100, -90, ..., 0	0 (Tolerance ± 5 ms)
Pulse Amplitude[c d e] (left ventricle) (V)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	3.5 (5.0 post therapy) (Tolerance ± 15% or ± 100mV) (whichever is greater)
Pulse Width[c d e] (left ventricle) (ms)	0.1, 0.2, ..., 2.0	0.4 (1.0 post therapy) (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
LV-Blank After A-Pace[f] (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
LVRP[b] (ms)	250, 260, ..., 500	250 (Tolerance ± 7.5 ms)
LVPP[b] (ms)	300, 350, ..., 500	400 (Tolerance ± 5 ms)
BiV Trigger[b]	Off, On	On
Left Ventricular Electrode Configuration[b]	Dual, Single, None	None

Table A-13. Brady/CRT left ventricular pacing parameters (specified into a 750 Ω load) (continued)

Parameter	Programmable Values	Nominal[a]
Left Ventricular Pace Configuration[b]	Single or Dual: LVtip>>Can LVtip>>RV Dual Only: LVring>>Can LVring>>RV LVtip>>LVring LVring>>LVtip	Single: LVtip>>RV Dual: LVtip>>LVring
Left Ventricular Sense Configuration[b]	Single or Dual: LVtip>>Can LVtip>>RV Off Dual Only: LVring>>Can LVring>>RV LVtip>>LVring	Single: LVtip>>RV Dual: LVtip>>LVring

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. This parameter is used globally in Normal Brady pacing and Post-shock Brady pacing. Changing the value for Normal Brady will change the value for Post-shock Brady.
c. Separately programmable for ATP/Post-Shock, Temporary Brady, and EP Test.
d. The minimum value of energy delivered at 5 V and 0.5 ms is 20 µJ with 200–500 Ω, and 12 µJ with 1000 Ω resistive load at 37°C ± 1°C for BOL and Explant.
e. Values are not affected by temperature variation within the range 20°–43°C.
f. This parameter is automatically set to at least 85 ms for Post-Shock Brady.
g. When the LV Offset is 0 the LV Pace follows the RV Pace by 2.5 ms

Table A-14. Atrial Tachy Parameters

Parameter	Programmable Values	Nominal
ATR Mode Switch[a b]	Off, On	On
ATR Trigger Rate[a b] (bpm)	100, 110, ..., 300	170 (Tolerance ± 5 ms)
ATR Duration[a b] (cycles)	0, 8, 16, 32, 64, 128, 256, 512, 1024, 2048	8 (Tolerance ± 1 cardiac cycle)
Entry Count[a b] (cycles)	1, 2, ..., 8	8
Exit Count[a b] (cycles)	1, 2, ..., 8	8
ATR Fallback Mode[a b]	VDI, DDI, VDIR, DDIR	DDI
ATR Fallback Time[a b] (min:sec)	0, 0:15, 0:30, 0:45, 1:00, 1:15, 1:30, 1:45, 2:00	0:30
ATR/VTR Fallback LRL[a b] (ppm)	30, 35, ..., 185	70 (Tolerance ± 5 ms)
ATR VRR[a b]	Off, Min, Med, Max	Min
ATR Maximum Pacing Rate[a b] (ppm)	30, 35, ..., 185	130
ATR BiV Trigger[a b]	Off, On	On

Table A-14. Atrial Tachy Parameters (continued)

Parameter	Programmable Values	Nominal
Atrial Flutter Response[b] [c]	Off, On	Off
Atrial Flutter Response Rate[b] [c] (bpm)	100, 110, ..., 300	170 (Tolerance ± 5 ms)
PMT Termination[b] [c]	Off, On	On
VRR[b] [c]	Off, Min, Med, Max	Off

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.
b. This parameter is used globally in Normal Brady pacing and Post-shock Brady pacing. Changing the value for Normal Brady will change the value for Post-shock Brady.
c. This parameter gets disabled during Temporary Brady.

Table A-15. Brady Mode values based on NASPE/BPEG codes

Position	I	II	III	IV	V
Category	**Chambers Paced**	**Chambers Sensed**	**Response to Sensing**	**Programmability, rate modulation**	**Antitachyarrhythmia Functions**
Letters	0–None	0–None	0–None	0–None	0–None
	A–Atrium	A–Atrium	T–Triggered	P–Simple Programmable	P–Pacing (Antitachyarrhythmia)
	V–Ventricle	V–Ventricle	I–Inhibited	M–Multiprogrammable	S–Shock
	D–Dual (A&V)	D–Dual (A&V)	D–Dual (T&I)	C–Communicating	D–Dual (P&S)
				R–Rate Modulation	
Mfrs. Designation Only	S–Single (A or V)	S–Single (A or V)			

Table A-16. Magnet and Beeper functions

Parameter	Programmable Values	Nominal
Magnet Response	Off, Store EGM, Inhibit Therapy	Inhibit Therapy
Beep During Capacitor Charge	Off, On	Off
Beep When Explant is Indicated	Off, On	On

Table A-17. Sensitivity Adjustment

Parameter	Programmable Values	Nominal
Atrial Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 0.25

Table A-17. Sensitivity Adjustment (continued)

Parameter	Programmable Values	Nominal
Right Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 0.6
Left Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 1.0

Table A-18. Ventricular Commanded ATP

Parameter[a]	Programmable Values	Nominal
Commanded Ventricular ATP (Type)	Burst, Ramp, Scan, Ramp/Scan	Burst
Number Of Bursts	1, 2, ..., 30	30
Initial Pulses per Burst (pulses)	1, 2, ..., 30	4
Pulse Increment (pulses)	0, 1, .., 5	0
Maximum Number of Pulses	1, 2, ..., 30	4
Coupling Interval (% or ms)	50, 53, 56, 59; 63, 66, ..., 84; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81% (Tolerance ± 5 ms)
Coupling Interval Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Burst Cycle Length (BCL) (% or ms)	50, 53, 56, 59; 63, 66, ..., 84; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81% (Tolerance ± 5 ms)
Ramp Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Scan Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Minimum Interval (ms)	120, 130, ..., 400	200 (Tolerance ± 5 ms)

a. The ventricular Commanded ATP Pulse Width and Amplitude values are the same as programmed for ventricular ATP therapy.

Table A-19. 50 Hz/Manual Burst Pacing

Parameter[a]	Programmable Values	Nominal
Burst Interval (ms)	20, 30, ..., 750	600 (Tolerance ± 5 ms)

Table A-19. 50 Hz/Manual Burst Pacing (continued)

Parameter[a]	Programmable Values	Nominal
Minimum Interval (ms)	20, 30, ...,750	200 (Tolerance ± 5 ms)
Decrement (ms)	0, 10, ..., 50	50 (Tolerance ± 5 ms)

a. Applied to the atrium or ventricle depending on the chamber selected.

Table A-20. Ventricular Commanded Shock

Parameter	Programmable Values	Nominal
Shock (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36 (HE), 41 (HE)	41 (Tolerance ± 60% for ≤ 0.3 J; ± 40% for ≤ 0.6–3 J; ± 20% for 5–36 J, ± 10% for 41 J)
Coupling Interval (ms)	Sync, 50, 60, ..., 500	Sync

Table A-21. VFib (Ventricular Fibrillation) Induction

Parameter	Values
VFib High	15V (nonprogrammable) (Tolerance ± 10V)
VFib Low	9V (nonprogrammable) (Tolerance ± 7V)

Table A-22. Shock on T Induction

Parameter	Programmable Values	Nominal
Shock (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36 (HE), 41 (HE)	1.1 J (Tolerance ± 60% for ≤ 0.3 J; ± 40% for ≤ 0.6–3 J; ± 20% for 5–36 J, ± 10% for 41 J)
Number of S1 Pulses	1, 2, ..., 30	8
S1 Interval (ms)	120, 130, ..., 750	400
Coupling Interval (ms)	Sync, 10, 20, , ..., 500	310

Table A-23. PES (Programmed Electrical Stimulation)

Parameter[a]	Programmable Values	Nominal
Number of S1 Intervals (pulses)	1, 2, ..., 30	8
S2 Decrement	0, 10, ..., 50	0
S1 Interval (ms)	120, 130, ..., 750	600 (Tolerance ± 5 ms)
S2 Interval (ms)	Off, 120, 130, ..., 750	600 (Tolerance ± 5 ms)
S3 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)

Table A-23. PES (Programmed Electrical Stimulation) (continued)

Parameter[a]	Programmable Values	Nominal
S4 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)
S5 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)

a. Applied to the atrium or right ventricle as commanded by the programmer.

CLINICAL STUDY - COMPANION

APPENDIX B

CLINICAL STUDY POPULATIONS

Guidant CRT-Ds, when compared to OPT alone, have been demonstrated with reasonable assurance, to be safe and effective in significantly reducing: the risk of a composite of all-cause mortality or first hospitalization by 20%, the risk of all-cause mortality by 36%, and heart failure symptoms in patients who have moderate to severe heart failure (NYHA III/IV) including left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥120 ms and remain symptomatic despite stable, optimal heart failure drug therapy, based on the Guidant sponsored COMPANION clinical study. (Guidant devices were the only devices studied in the COMPANION clinical trial.)

SUMMARY

The COMPANION clinical study was designed to determine whether combined all-cause mortality or first hospitalization in heart failure patients receiving optimal pharmacologic therapy (OPT) can be reduced by combining OPT and either of the following:

- Biventricular pacing therapy alone (CRT-P)
- Biventricular pacing with defibrillation (CRT-D)

All-cause mortality or first hospitalization (time to first event) analyzed from the time of randomization, was the primary endpoint of the study.

Guidant conducted the COMPANION study in part to demonstrate the safety and effectiveness of Guidant CRT-D and CRT-P devices in the COMPANION patient population. Trial objectives included establishing that OPT combined with biventricular pacing with defibrillation (CONTAK CD) is superior to OPT alone in improving exercise performance (Sub-study), reducing combined all-cause mortality or first hospitalization (Primary endpoint), reducing cardiac morbidity (Secondary endpoint) and reducing all-cause mortality (Secondary endpoint).

The COMPANION trial utilized a Steering Committee, Data Safety Monitoring Board (DSMB), and Morbidity and Mortality Committee for study conduct, safety, and event adjudication respectively.

The clinical study began January 20, 2000 and was conducted at 128 centers within the United States.

The COMPANION clinical study was monitored using a sequential design and on November 18, 2002, after review of the data by the Data Safety and Monitoring Board, enrollment in the study was stopped. The CRT-D arm of the trial had reached the target number of events for the combined primary all-cause mortality or first hospitalization endpoint, as well as the secondary all-cause mortality endpoint. All effectiveness follow-ups ended by December 1, 2002.

OBSERVED ADVERSE EVENTS

Prior History

The CONTAK RENEWAL 3, CONTAK RENEWAL, and CONTAK CD devices provide the same defibrillation and cardiac resynchronization therapy (biventricular pacing) and have the same Indications for Use. Therefore, the Comparison of Medical, Pacing, and Defibrillation Therapies in Heart Failure (COMPANION) clinical trial data (based on CONTAK CD devices) used to support expanding Guidant CRT-D indications to the COMPANION patient population, are also applicable to CONTAK RENEWAL and CONTAK RENEWAL 3.

The primary difference between CONTAK CD devices and CONTAK RENEWAL/CONTAK RENEWAL 3 devices is that CONTAK CD utilizes an electrically common RV and LV sensing/pacing circuit whereas CONTAK RENEWAL and CONTAK RENEWAL 3 incorporate an independent RV and LV sensing/pacing circuit. Additional clinical analysis was conducted with CONTAK RENEWAL, in a European study, to provide confirmation that the independent sensing and pacing capability did not adversely affect the ability of the device to detect ventricular tachyarrhythmias or provide continuous biventricular pacing therapy.

Study Background

The Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) Study was a prospective, open-label, randomized, controlled, multi-center, unblinded study conducted at 128 sites and enrolled a total of 1638 patients, of which 1520 were randomized. Patients were randomly assigned 1:2:2 to receive optimal pharmacological therapy (OPT, 308 patients) or a cardiac resynchronization therapy pacemaker (CRT-P, 617 patients) or a cardiac resynchronization therapy pacemaker with defibrillator (CRT-D, 595

patients). Of the 1520 patients randomized, 903 were randomized to OPT and CRT-D. This summary focuses on data and analyses for the CRT-D and OPT groups, only, with the exception of the Exercise Performance results, which are based on pooled CRT-D and CRT-P data.

The CRT-D devices (CONTAK CD) in this trial, were approved for commercial distribution via the CONTAK CD study, which provided a reasonable assurance of safety. A similar safety analysis was applied to the COMPANION patient population. The results were consistent with safety measurements obtained in the CONTAK CD trial.

Adverse Event Definitions

Adverse events were defined as any undesirable clinical occurrence, whether it was related to the device or not. Table B-1 on page B-3 includes adverse events occurring in the first six months related to the device (pulse generator and leads) and implant procedures (including attempts). Table B-2 on page B-6 includes adverse events occurring in the first six months related to patient condition (i.e., worsening heart failure). Adverse events are listed in descending order by total number of patients experiencing the event.

Adverse events related to the device were further reported using two sub-categories based on the nature of the intervention. These events were defined as a complication if the event resulted in invasive intervention, loss of significant device function, and death or permanent disability. An observation was a device-related adverse event that was resolved non-invasively. Forty-nine percent of CRT-D patients reported a device and/or procedure-related adverse event.

Table B-1. Device- and procedure-related adverse events

	Total Events (Patients)	% Comps (Patients)	% Obs (Patients)
Total Adverse Events[a]	498 (290)	13.1 (77)	43.4 (255)
Post surgical wound discomfort	68 (62)	0.0 (0)	10.5 (62)
Phrenic nerve/diaphragm stimulation	77 (59)	1.4 (8)	9.0 (53)
Brady capture - LV	38 (36)	4.3 (25)	2.2 (13)
Hematoma	37 (34)	0.3 (2)	5.4 (32)
Inappropriate shock above rate cutoff	26 (24)	0.0 (0)	4.1 (24)
Multiple counting - tachy	22 (17)	0.3 (2)	2.9 (17)
Pocket infection	19 (17)	0.5 (3)	2.6 (15)

Table B-1. Device- and procedure-related adverse events (continued)

	Total Events (Patients)	% Comps (Patients)	% Obs (Patients)
Dissection, coronary sinus	15 (15)	0.0 (0)	2.6 (15)
Brady capture - atrium	14 (12)	1.5 (9)	0.5 (3)
Inappropriate shock due to oversensing	11 (11)	0.0 (0)	1.9 (11)
Pneumothorax	10 (10)	1.0 (6)	0.7 (4)
Hypotension	10 (9)	0.2 (1)	1.4 (8)
Brady capture - RV	8 (8)	0.9 (5)	0.5 (3)
Physical trauma	8 (8)	0.2 (1)	1.2 (7)
AV Block - heart block, complete	7 (7)	0.2 (1)	1.0 (6)
Pacemaker-mediated tachycardia (PMT)	7 (6)	0.0 (0)	1.0 (6)
Physiological reaction[b]	6 (6)	0.0 (0)	1.0 (6)
Arrhythmia - atrial fibrillation	5 (5)	0.0 (0)	0.9 (5)
Bleeding/fluid accumulation	5 (5)	0.0 (0)	0.9 (5)
Perforation, coronary venous	5 (5)	0.5 (3)	0.3 (2)
Renal failure	5 (5)	0.0 (0)	0.9 (5)
Thrombosis	5 (5)	0.0 (0)	0.9 (5)
Vascular related	5 (5)	0.0 (0)	0.9 (5)
Oversensing - atrium pace sense	4 (4)	0.3 (2)	0.3 (2)
Allergic reaction	3 (3)	0.0 (0)	0.5 (3)
Congestive heart failure	3 (3)	0.0 (0)	0.5 (3)
Nausea (2), Constipation (1)	3 (3)	0.0 (0)	0.5 (3)
High DFTs - tachy	3 (3)	0.2 (1)	0.3 (2)
Oversensing - ventricle rate - tachy	3 (3)	0.2 (1)	0.3 (2)
Respiratory related	3 (3)	0.2 (1)	0.3 (2)
Ventricular tachycardia	3 (3)	0.2 (1)	0.3 (2)
Cardiac tamponade	2 (2)	0.3 (2)	0.0 (0)
Dyspnea (shortness of breath)	2 (2)	0.0 (0)	0.3 (2)
Electrolyte/lab	2 (2)	0.0 (0)	0.3 (2)
Hemorrhage	2 (2)	0.2 (1)	0.2 (1)
Insulation breach suspected	2 (2)	0.3 (2)	0.0 (0)
Migration of device	2 (2)	0.0 (0)	0.3 (2)

Table B-1. Device- and procedure-related adverse events (continued)

	Total Events (Patients)	% Comps (Patients)	% Obs (Patients)
Muscle stimulation	2 (2)	0.0 (0)	0.3 (2)
Myocardial infarction	2 (2)	0.0 (0)	0.3 (2)
Numbness	2 (2)	0.0 (0)	0.3 (2)
Perforation, venous	2 (2)	0.0 (0)	0.3 (2)
Phantom shock	2 (2)	0.0 (0)	0.3 (2)
Undersensing - atrium pace sense - brady	2 (2)	0.2 (1)	0.2 (1)
Altered hemodynamic status	1 (1)	0.0 (0)	0.2 (1)
Arrhythmia	1 (1)	0.0 (0)	0.2 (1)
Arrhythmia - sinus tachycardia	1 (1)	0.0 (0)	0.2 (1)
Bruise	1 (1)	0.0 (0)	0.2 (1)
Cardiac arrest	1 (1)	0.2 (1)	0.0 (0)
Change in arrhythmia - SVT	1 (1)	0.0 (0)	0.2 (1)
Change in arrhythmia - brady	1 (1)	0.0 (0)	0.2 (1)
Change in arrhythmia - junctional	1 (1)	0.0 (0)	0.2 (1)
Change in physical status	1 (1)	0.0 (0)	0.2 (1)
Chest pain	1 (1)	0.0 (0)	0.2 (1)
Dizziness, cause undetermined	1 (1)	0.0 (0)	0.2 (1)
Edema	1 (1)	0.0 (0)	0.2 (1)
Fatigue	1 (1)	0.0 (0)	0.2 (1)
Febrile	1 (1)	0.0 (0)	0.2 (1)
Unable to urinate	1 (1)	0.0 (0)	0.2 (1)
Helix related (screw tip), broken or stretched	1 (1)	0.2 (1)	0.0 (0)
Hemoglobin drop	1 (1)	0.2 (1)	0.0 (0)
Hypertension	1 (1)	0.0 (0)	0.2 (1)
Infection	1 (1)	0.2 (1)	0.0 (0)
Insulation breech observed	2 (1)	0.2 (1)	0.0 (0)
Malfunction, memory problem	1 (1)	0.2 (1)	0.0 (0)
Materials unretrieved in body	1 (1)	0.2 (1)	0.0 (0)
Pacemaker mediated tachycardia (PMT)	1 (1)	0.0 (0)	0.2 (1)
Pacemaker syndrome	1 (1)	0.0 (0)	0.2 (1)

Table B-1. Device- and procedure-related adverse events (continued)

	Total Events (Patients)	% Comps (Patients)	% Obs (Patients)
Pericardial effusion	1 (1)	0.2 (1)	0.0 (0)
Pericarditis	2 (1)	0.0 (0)	0.2 (1)
Placement difficulty, stylet related	1 (1)	0.2 (1)	0.0 (0)
Pleural effusion	1 (1)	0.2 (1)	0.0 (0)
Pleurisy	2 (1)	0.0 (0)	0.2 (1)
Pocket erosion/extrusion	1 (1)	0.2 (1)	0.0 (0)
Anxiety	1 (1)	0.0 (0)	0.2 (1)
Respiratory arrest	1 (1)	0.2 (1)	0.0 (0)
Ventricular fibrillation	1 (1)	0.0 (0)	0.2 (1)

a. Observations and complications may not sum to total because some patient may have events in both categories.
b. Physiological reaction includes: swelling, rash, and/or drainage.

Table B-2. Patient-related adverse events

	Total Events (Patients)		% of Patients with Events		Events/Patient Year	
	CRT-D	OPT	CRT-D N = 595 Patients	OPT N = 308 Patients	CRT-D 281 Years	OPT 134 Years
Total Patient Related Adverse Events	**1437 (443)**	**625 (207)**	**74.5**	**67.2**	**5.11 (1437)**	**4.66 (625)**
Cardiovascular Related Events	814 (351)	399 (176)	59.0	57.1	2.90 (814)	2.98 (399)
Congestive heart failure[a]	269 (166)	185 (111)	27.9	36.0	0.96 (269)	1.38 (185)
Chest pain	83 (65)	50 (37)	10.9	12.0	0.30 (83)	0.37 (50)
Supraventricular tachyarrhythmia	69 (56)	11 (11)	9.4	3.6	0.25 (69)	0.08 (11)
Ventricular tachyarrhythmia	66 (51)	16 (15)	8.6	4.9	0.23 (66)	0.12 (16)
Electrolyte/lab	51 (42)	17 (16)	7.1	5.2	0.18 (51)	0.13 (17)
Hypotension	42 (40)	16 (15)	6.7	4.9	0.15 (42)	0.12 (16)
Dizziness, cause undetermined	33 (30)	26 (23)	5.0	7.5	0.12 (33)	0.19 (26)
Renal failure	40 (29)	16 (14)	4.9	4.5	0.14 (40)	0.12 (16)
Fatigue	27 (25)	12 (12)	4.2	3.9	0.10 (27)	0.09 (12)
Bradyarrhythmia	32 (30)	5 (5)	5.0	1.6	0.11 (32)	0.04 (5)

Table B-2. Patient-related adverse events (continued)

	Total Events (Patients)		% of Patients with Events		Events/Patient Year	
	CRT-D	OPT	CRT-D N = 595 Patients	OPT N = 308 Patients	CRT-D 281 Years	OPT 134 Years
Vascular	14 (11)	11 (10)	1.8	3.2	0.05 (14)	0.08 (11)
Syncope	12 (12)	7 (7)	2.0	2.3	0.04 (12)	0.05 (7)
GI bleed	14 (13)	4 (4)	2.2	1.3	0.05 (14)	0.03 (4)
Arrhythmia	12 (10)	6 (6)	1.7	1.9	0.04 (12)	0.04 (6)
Hypertension	12 (9)	6 (5)	1.5	1.6	0.04 (12)	0.04 (6)
Palpitations	9 (9)	3 (3)	1.5	1.0	0.03 (9)	0.02 (3)
Myocardial infarction	7 (7)	4 (4)	1.2	1.3	0.02 (7)	0.03 (4)
Stroke syndrome or CVA	7 (7)	2 (2)	1.2	0.6	0.02 (7)	0.01 (2)
Deep vein thrombosis	4 (4)	0 (0)	0.7	0.0	0.01 (4)	0.00 (0)
Transient ischemic attack (TIA)	3 (3)	1 (1)	0.5	0.3	0.01 (3)	0.01 (1)
Hematuria	3 (3)	0 (0)	0.5	0.0	0.01 (3)	0.00 (0)
Ischemia	2 (2)	1 (1)	0.3	0.3	0.01 (2)	0.01 (1)
Coagulopathy	2 (2)	0 (0)	0.3	0.0	0.01 (2)	0.00 0(0)
Bleeding/fluid accumulation	1 (1)	0 (0)	0.2	0.0	0.00 (1)	0.00 (0)
Non-cardiovascular Related Events	623 (293)	226 (119)	49.2	38.6	2.22 (623)	1.69 (226)
Respiratory related[b]	130 (108)	53 (41)	18.2	13.3	0.46 (130)	0.40 (53)
GI[c]	124 (95)	30 (24)	16.0	7.8	0.44 (124)	0.22 (30)
Pain	82 (66)	40 (32)	11.1	10.4	0.29 (82)	0.30 (40)
Physiological reaction[d]	76 (61)	20 (18)	10.3	5.8	0.27 (76)	0.15 (20)
Infection	54 (37)	18 (15)	6.2	4.9	0.19 (54)	0.13 (18)
Endocrine	41 (35)	16 (14)	5.9	4.5	0.15 (41)	0.12 (16)
Psychological effects	24 (19)	13 (12)	3.2	3.9	0.09 (24)	0.10 (13)
Change in physical status	20 (18)	9 (9)	3.0	2.9	0.07 (20)	0.07 (9)
Physical trauma	26 (22)	4 (4)	3.7	1.3	0.09 (26)	0.03 (4)
Neurologic	14 (14)	6 (6)	2.4	1.9	0.05 (14)	0.04 (6)
Genitourinary	9 (7)	5 (4)	1.2	1.3	0.03 (9)	0.04 (5)
Cancer, other	5 (5)	6 (5)	0.8	1.6	0.02 (5)	0.04 (6)

Table B-2. Patient-related adverse events (continued)

	Total Events (Patients)		% of Patients with Events		Events/Patient Year	
	CRT-D	OPT	CRT-D N = 595 Patients	OPT N = 308 Patients	CRT-D 281 Years	OPT 134 Years
Febrile	7 (7)	0 (0)	1.2	0.0	0.02 (7)	0.00 (0)
Respiratory failure	4 (4)	1 (1)	0.7	0.3	0.01 (4)	0.01 (1)
Tumors, growths	1 (1)	2 (2)	0.2	0.6	0.00 (1)	0.01 (2)
Ulceration	2 (1)	2 (2)	0.2	0.6	0.01 (2)	0.01 (2)
Diabetes complications	2 (2)	0 (0)	0.3	0.0	0.01 (2)	0.00 (0)
Pulmonary embolism	1 (1)	1 (1)	0.2	0.3	0.00 (1)	0.01 (1)
Pneumonia (respiratory infection)	1 (1)	0 (0)	0.2	0.0	0.00 (1)	0.00 (0)

a. Congestive heart failure includes: congestive heart failure, dyspnea, volume overload, edema, pulmonary edema, change in drug therapy.
b. The most frequent three events in this category were: upper respiratory infection, bronchitis, and influenza.
c. The most frequent three events in this category were: nausea, diarrhea, and abdominal pain.
d. The most frequent three events in this category were: swelling, rash, and weight gain.

Deaths

There were a total of 182 deaths (77 OPT, 105 CRT-D) that occurred during the trial and recorded through November 30, 2002. Table B-3 on page B-8 presents cause of death stratified by treatment group.

Table B-3. CRT-D and OPT cause of death

Cause of Death	OPT Arm (N = 308)	CRT-D Arm (N = 595)	Total (N = 903)
Cardiac	58 (18.8%)	76 (12.8%)	134 (14.8%)
Vascular	0 (0.0%)	3 (0.5%)	3 (0.3%)
Non-Cardiac	11 (3.6%)	21 (3.5%)	32 (3.5%)

Table B-3. CRT-D and OPT cause of death (continued)

Cause of Death	OPT Arm (N = 308)	CRT-D Arm (N = 595)	Total (N = 903)
Unknown/ Unclassified	8 (2.6%)	5 (0.8%)	13 (1.4%)
Total Deaths	**77 (25.0%)**	**105 (17.6%)**	**182 (20.2%)**

NOTE: *After the study was stopped in November 2002, follow-up for safety continued for approximately one more year on 151 OPT and 449 CRT-D patients with the final data cut-off on November 26, 2003. During this post-trial follow-up period, an additional 54 deaths were reported, consisting of 14/151 (9.3%) OPT patients and 40/449 (8.9%) CRT-D patients.*

The mortality rates are approximately equal during this post-trial follow-up period. This may be because CRT devices were made available to OPT patients. Thus, most patients were receiving the same therapy during this interval.

STUDY DESIGN

The COMPANION study design and study results have been previously described in the medical literature.[1,2]

The COMPANION study was a prospective, randomized (1:2:2 to OPT, CRT-P [delivered by the CONTAK TR device], or CRT-D [delivered by the CONTAK CD device]), controlled, multi-center study. Both of these devices became commercially available during the course of the study.

Randomization was stratified by centers and by beta-blocker use to assure proper balance between the treatment groups within each center. Each randomized patient remained counted as a member of the original randomization assignment (intention-to-treat) regardless of subsequent crossover or protocol adherence.

Eligible patients were also enrolled in a sub-study designed to measure improvement in exercise performance in patients randomized to CRT (CRT-P and CRT-D pooled data) therapy compared to OPT.

1. Bristow MR, Feldman AM, Saxon LA. Heart failure management using implantable devices for ventricular resynchronization: Comparison of Medical Therapy, Pacing, and Defibrillation in Chronic Heart Failure (COMPANION) trial. J Card Fail. 2000;6(3):276-285.
2. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med. 2004;350:2140-2150.

INCLUSION/EXCLUSION CRITERIA

The study population consisted of patients with moderate to severe heart failure, New York Heart Association Classification III or IV, left ventricular ejection fraction ≤ 35%, and QRS width ≥ 120 ms due to ischemic or non-ischemic cardiomyopathy.

All patients were required to have been treated with a stable dose of beta-blocker, ACE inhibitor or ARB, diuretic, and aldosterone antagonist. A stable dose was defined as 30 days for all drugs except beta-blocker, which required 90 days stabilization from last up titration prior to randomization. Diuretic dosage could be adjusted any time by the investigator using medical discretion.

Patients enrolled in the study were required to meet the following inclusion criteria:

- Moderate or severe heart failure, defined as symptomatic heart failure for at least six months with NYHA class III or IV symptoms at the time of enrollment, and at least one of the following events in the previous 12 months:
  - Hospitalization for heart failure management
  - Outpatient visit in which intravenous (IV) inotropes or vasoactive infusion were administered continuously for at least 4 hours
  - Emergency room visit of at least twelve hours duration in which IV heart failure medications were administered (including diuretics)
- QRS ≥ 120 ms and PR interval > 150 ms from any two leads of a 12–lead ECG
- Left ventricular ejection fraction ≤ 35%
- Left ventricular end diastolic dimension ≥ 60 mm (required only if LVEF measured by echo) or > 3.0 cm/m^2 (The cm/m^2 is calculated by LVEDD [in cm] divided by BSA [body surface area])
- Age ≥ 18 years
- Optimal pharmacologic therapy for heart failure (beta blocker, ACE inhibitor, diuretics, and spironolactone)

Additional eligibility criteria for the Exercise Performance sub-study:

- Understand the nature of the sub-study and provide informed consent
- Have been enrolled at a participating sub-study investigational center
- Have no neuromuscular or vascular disability that prevents normal walking (e.g., intermittent claudication, arthritis, residual stroke weakness)
- Have no history of angina during previous exercise testing
- $FEV_1/FVC \geq 50\%$
- 150 m ≤ Six-minute walk distance ≤ 425 m
- Baseline Peak $VO_2 < 22$ ml/kg/min
- Have no cardiac disabilities that would ordinarily contraindicate exercise testing:
  - Changing pattern on the ECG
  - Changing pattern of chest discomfort
  - Decompensated heart failure
  - Uncontrolled arrhythmias

Patients were excluded from the investigation if they met any of the following criteria:

- Unable or unwilling to undergo device implant and follow-up testing
- Patients with a hypersensitivity to 0.7 mg nominal dose of dexamethasone acetate
- Meet the general indications for an implantable cardioverter defibrillator
- Surgically uncorrected primary valvular disease
- Meet the general indications for antibradycardia pacing
- Coronary artery disease (CAD) in which surgical or percutaneous correction is recent (within 60 days of randomization)

- Expected to receive a heart transplant in the next six months
- Women who are pregnant or not using medically acceptable birth control
- Chronic, medically refractory atrial tachyarrhythmias
- Hypertrophic obstructive cardiomyopathy
- Unexplained syncope
- Amyloid disease
- Myocardial infarction within 60 days of randomization
- Hospitalization for heart failure or IV inotropic or vasoactive therapy in excess of 4 hours in the 30 days prior to enrollment
- History of non-compliance with oral heart failure therapy
- Involved in any other investigational studies
- Progressive or unstable angina
- Life expectancy < 6 months due to any other medical conditions
- Uncontrolled blood pressure: Systolic BP > 160 mm Hg or < 85 mm Hg or diastolic BP > 90 mm Hg

ENDPOINTS

This summary focuses on the CRT-D vs. OPT contrast, providing evidence of safety and effectiveness for Guidant CRT-Ds in the COMPANION patient population.[3] The clinical data and analyses herein address the following study endpoints for all patients randomized to CRT-D and OPT only, unless otherwise stated as a sub-study measurement (where CRT-D and CRT-P data were pooled for exercise performance).

Primary Endpoint

The primary endpoint was a composite consisting of all-cause mortality or first hospitalization (time to first event) as analyzed from the date of randomization

3. Guidant CRT-Ps are already approved for use in the COMPANION patient population, P030005, approved 01/26/04.

on an intention-to-treat basis. The study was designed to demonstrate a 25% relative reduction with CRT-D when compared to an estimated 40% annual rate in the OPT cohort. All-cause mortality was defined as death from any cause. Hospitalization is defined below:

Qualifying Duration for Hospitalization—the intent behind hospitalization was to capture hospitalizations that were of sufficient duration to enter into a composite with all-cause mortality. Thus, hospitalization was defined as care provided at a hospital in which hospital admission and discharge occurred on separate dates. Patients excluded from this definition were those who received care at a hospital, but were discharged on the same day as admission. In addition to hospitalizations, the use of intravenous inotropes or vasoactive agents for a duration of greater than four hours was also considered to be of significant importance to be treated as an instance of hospitalization.

Hospitalizations Related to the Implant Procedure—hospitalizations associated with device implant (initial and reattempted for unsuccessful initial implant) were not considered to be an event for evaluating the primary endpoint. Similarly, hospitalizations associated with elective implant of devices (i.e., absence of an electrophysiological indication or an ongoing hospitalization requiring intravenous therapy) in the OPT cohort also were not considered to be a primary endpoint event. Surgical revisions of a previous implanted system did count as a primary endpoint event if the revision was of a sufficient duration to result in different admission and discharge dates. Table B-4 on page B-13 summarizes the criteria for determining which hospitalization events were considered as a primary endpoint event.

Table B-4. Hospitalizations contributing to primary endpoint

Event Description	CRT-D	OPT
Initial implant/reattempts	No	No
Surgical revisions of system	Yes[a]	Yes[a]
Hospitalization with no calendar date change	No	No
Hospitalization with a calendar date change	Yes	Yes
IV inotrope and/or vasoactive drug use > 4 hours	Yes	Yes

a. If calendar date change.

Secondary Endpoints

All-cause mortality—the all-cause mortality (death from any cause) endpoint was designed to show a 25% reduction in mortality in the CRT-D arm from an OPT annual mortality rate of 24%. Difference in mortality was determined by

contrasting patients randomized to CRT-D in addition to OPT versus patients randomized to OPT alone.

Cardiac morbidity—the hospitalization component of the primary endpoint included non-cardiac events that may not be impacted by CRT-D. The cardiac morbidity endpoint was unique to the COMPANION study. It is a more specific outcome measure intended to determine whether CRT-D when compared to OPT would reduce the type of events that are pertinent to a hospitalization for heart failure.

Cardiac morbidity was defined as the occurrence of one or more of the following events:

- Worsening heart failure resulting in use of intravenous vasoactive or inotropic therapy exceeding four hours
- Mechanical respiratory or cardiac support
- Any cardiac surgery, including heart transplant
- Resuscitated cardiac arrest or sustained ventricular tachycardia requiring intervention (e.g., chest thump, external cardioversion, or external defibrillation)
- Hospitalization for acute decompensation of heart failure
- Hospitalization that results in death from cardiac causes
- Significant device-related events resulting in:
  - Permanent disability
  - Hospitalization for pending death or permanent disability

Safety—CRT-D system-related complication-free rate is determined by measuring complications related to any of the implanted components or their associated implant procedure in those patients who were successfully implanted with the CRT-D system.

NOTE: *During the course of the COMPANION clinical study, the EASYTRAK Coronary Venous pace/sense lead was established as safe and effective in a separate clinical study and was approved for commercial distribution (P010012, 05/02/02). Refer to the commercially available EASYTRAK Coronary Venous pace/sense lead labeling for clinical safety and performance characteristics.*