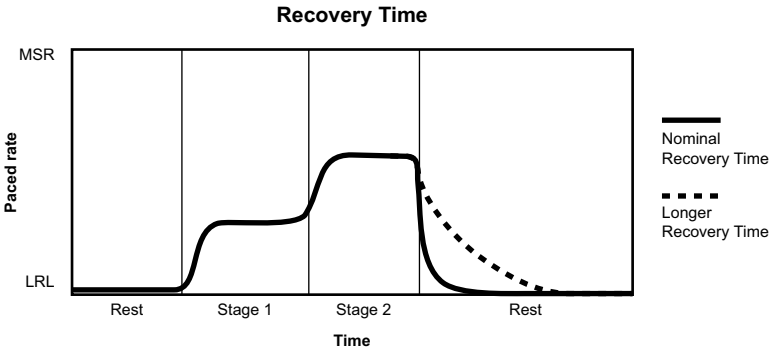


The figure shows the effect of higher and lower settings during a theoretical two-stage exercise test.

Figure 5-11. Recovery Time in exercise test

Programming Recovery Time for Normal Settings also changes the corresponding selection for Post-Therapy Settings.

ATRIAL TACHY RESPONSE

ATR Mode Switch

ATR limits the amount of time that the ventricular paced rate is at the MTR or exhibits upper-rate behavior (2:1 block or Wenckebach) in response to a pathological atrial arrhythmia.

In the presence of detected atrial activity that exceeds the Atrial Arrhythmia Rate Threshold, ATR switches the pacing mode from a tracking mode to a nontracking mode as follows:

- From DDD(R) to DDI(R) or VDI(R)
- From VDD(R) to VDI(R)

An example of ATR behavior is shown (Figure 5-12 on page 5-20).

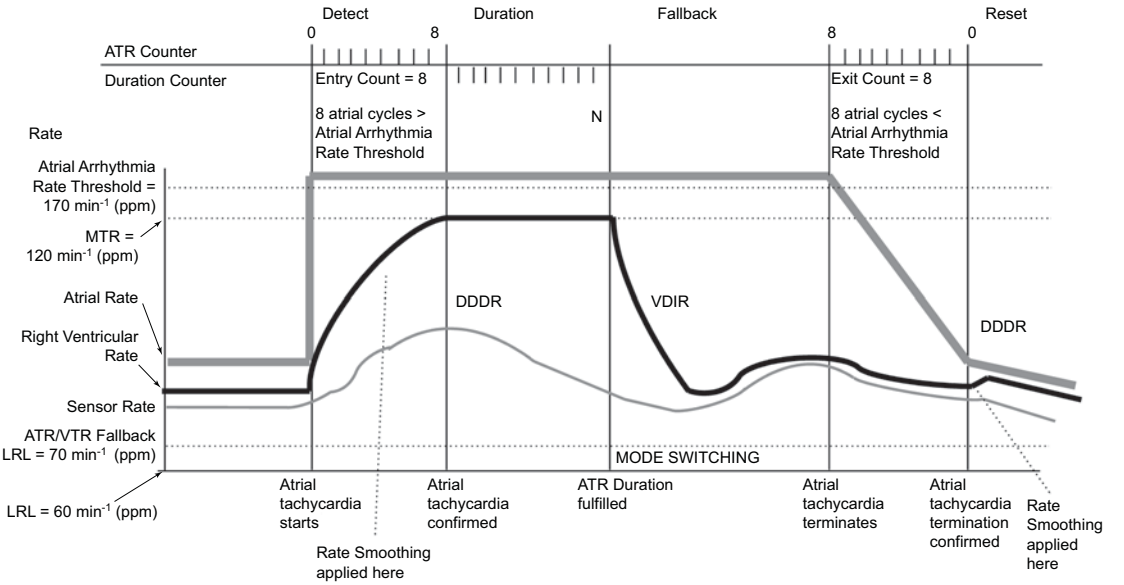


Figure 5-12. ATR behavior

NOTE: *Parameter settings that reduce the atrial sensing window may inhibit ATR therapy.*

Atrial Arrhythmia Rate Threshold

The Atrial Arrhythmia Rate Threshold determines the rate at which the pulse generator begins to detect atrial tachycardias.

The pulse generator monitors atrial events throughout the pacing cycle, except during the atrial blanking period and the noise interrogation intervals. Atrial events faster than the Atrial Arrhythmia Rate Threshold increase the ATR detection counter; atrial events slower than the Atrial Arrhythmia Rate Threshold decrease the counter.

When the ATR detection counter reaches the programmed entry count, the ATR Duration begins. When the ATR detection counter counts down from the programmed Exit Count value to zero at any point in time, ATR Duration and/or fallback are terminated, and the ATR algorithm is reset. An event marker is generated whenever the ATR detection counter is incremented or decremented.

NOTE: *During post-therapy pacing, ATR functions the same as in normal pacing.*

ATR Duration

ATR Duration determines the number of cardiac cycles during which the atrial events continue to be evaluated after initial detection. This feature is intended to avoid mode switching due to short, nonsustained episodes of atrial tachycardia. If the ATR counter reaches zero during ATR Duration, the ATR algorithm will be reset, and no mode switch will occur.

If the atrial tachycardia persists for the programmed ATR Duration, then mode switching occurs and the ventricular rate begins decreasing to the sensor-indicated rate, VRR rate or the ATR/VTR Fallback LRL, depending on the programmed Fallback Mode.

Entry Count

The Entry Count determines how quickly an atrial arrhythmia is initially detected.

The lower the programmable value, the fewer the fast atrial events required to fulfill initial detection. Once the number of fast atrial events detected equals the programmable Entry Count, ATR Duration begins, and the Exit Count is enabled.

CAUTION: Exercise care when programming the Entry Count to low values in conjunction with a short ATR Duration. This combination allows mode switching with very few fast atrial beats. For example, if the Entry Count was programmed to 2 and the ATR Duration to 0, ATR mode switching could occur on 2 fast atrial intervals. In these instances, a short series of premature atrial events could cause the device to mode switch.

Exit Count

The Exit Count determines how quickly the ATR algorithm is terminated once the atrial arrhythmia is no longer detected.

The lower the programmed value, the more quickly the pulse generator will return to an atrial tracking mode. Once the number of slow atrial events detected equals the programmable Exit Count, ATR Duration and/or Fallback will be terminated, and the ATR algorithm will be reset.

CAUTION: Exercise care when programming the Exit Count to low values. For example, if the Exit Count was programmed to 2, a few cycles of atrial undersensing could cause termination of mode switching.

Fallback Mode

Fallback Mode is the nontracking pacing mode that the pulse generator automatically switches to when ATR Duration is fulfilled.

After switching modes, the pulse generator gradually decreases the ventricular paced rate to the ATR/VTR Fallback LRL, VRR rate, if enabled, or the sensor-indicated rate if programmed to an adaptive-rate mode, whichever is higher. The decrease in the ventricular paced rate is controlled by the Fallback Time parameter.

NOTE: *Dual-chamber pacing fallback mode values are only available when the Normal pacing mode is also set to dual chamber.*

Fallback Time

Fallback Time controls how quickly the paced rate will decrease during fallback to the ATR/VTR Fallback LRL, the sensor-indicated rate, or VRR if enabled.

During fallback, the following features are disabled:

- Rate Smoothing—disabled until fallback reaches the ATR/VTR Fallback LRL, the sensor-indicated rate, or VRR; if VRR is enabled, then Rate Smoothing is disabled throughout the mode switch
- Rate Hysteresis
- AV Search +
- PVARP Extension

All sensor parameters must be programmed when the adaptive-rate Fallback Mode is selected. When the pulse generator is permanently programmed to an adaptive-rate mode with an adaptive-rate ATR Fallback Mode, the pulse generator will use the sensor and sensor parameters already in effect at the time of the switch. If the pulse generator is permanently programmed to a nonadaptive rate mode, it is possible to program the ATR Fallback Mode to an adaptive-rate ATR Fallback Mode using the accelerometer sensor. In this case, the Accelerometer field displays ATR Only.

Fallback LRL

The ATR/VTR Fallback LRL is the programmed lower rate to which the rate decreases during mode switching.

Consider the following interactions when programming the ATR/VTR Fallback LRL:

- If an adaptive-rate mode is programmed and the sensor-indicated rate is greater than the ATR/VTR Fallback LRL, the rate decreases to the sensor-indicated rate
- If VRR is enabled and the VRR rate is greater than the ATR/VTR fallback LRL, the rate decreases to the VRR rate
- If an adaptive-rate mode is programmed and VRR is enabled, the rate will decrease to the faster of the sensor-indicated rate, VRR rate, and the ATR/VTR Fallback LRL
- The ATR/VTR Fallback LRL is also the Backup VVI pacing rate during backup pacing in the presence of detected ventricular arrhythmias

End of ATR Episode

The End of ATR Episode identifies the point when the pulse generator reverts to AV synchronous pacing because the atrial arrhythmia is no longer detected.

The pulse generator continues to pace in the Fallback Mode at the sensor-indicated rate, the VRR-calculated rate, or the ATR Fallback LRL until the atrial arrhythmia terminates. With the termination of the arrhythmia, the ATR Exit Count decrements from its programmed value until it reaches 0. The ATR Exit Count is decremented by atrial events slower than the ATR Trigger Rate or any ventricular event that occurs more than two seconds after the last atrial event. When the ATR Exit Count reaches 0, the pacing mode automatically switches to the programmed tracking mode, and AV-synchronous pacing is restored.

Ventricular Tachy Response (VTR)

VTR serves as an automatic mode switch for backup VVI pacing in the presence of detected ventricular tachyarrhythmias.

When detection is satisfied in a ventricular tachycardia zone, the pacing mode switches to VVI (RV) or to Off if the current mode is AAI(R) or Off.

When the mode switches, backup pacing occurs at the programmed ATR/VTR Fallback LRL and uses the programmed ATP ventricular Pulse Width and Amplitude values.

Ventricular Rate Regulation (VRR)

VRR is designed to reduce the V–V cycle length variability during partially conducted atrial arrhythmias by modestly increasing the ventricular pacing rate.

The VRR algorithm calculates a VRR-indicated pacing interval based on a weighted sum of the current V–V cycle length and the previous VRR-indicated pacing intervals.

- Paced intervals have more influence than sensed intervals such that paced events cause a decrease in the VRR-indicated rate.
- For sensed intervals, the VRR-indicated rate may be increased; however, the influence is tempered by the previous history.
- The VRR-indicated rate is further bound by the LRL and the VRR MPR.

When VRR is programmed on in tracking modes, it is only active when an ATR mode switch has occurred. Once the tracking mode operation resumes at the termination of the atrial arrhythmia, VRR becomes inactive. In tracking modes where both Rate Smoothing and VRR are programmed on, whenever VRR is active, the pulse generator automatically disables Rate Smoothing, then reactivates it once the ATR terminates.

When programmed to On in single-chamber modes, VRR is continually active and updates the following on each cardiac cycle:

- VRR-indicated pacing rate
- Smoothed average

Ventricular Rate Regulation Maximum Pacing Rate (VRR MPR)

The VRR MPR limits the maximum pacing rate for VRR.

VRR operates between the LRL and the MPR.

Atrial Flutter Response (AFR)

Atrial Flutter Response is designed to:

- Prevent pacing into the atrial vulnerable period
- Provide immediate fallback for atrial rates higher than the AFR programmable rate

The fallback is maintained for as long as atrial events continually exceed the AFR programmable rate.

Example: When AFR is programmed to 170 ppm, a detected atrial event inside the PVARP or a previously triggered AFR interval starts an AFR window of 353 ms (170 ppm). Atrial detection inside the AFR is classified as refractory senses and is not tracked. Tracking starts only after both the AFR and the PVARP expire. Paced atrial events scheduled inside an AFR window are delayed until the AFR window expires. If there are fewer than 50 ms remaining before a ventricular pace, the atrial pace is inhibited for the cycle.

Ventricular pacing is not affected by AFR and will take place as scheduled. The wide programmable range for AFR rates allows for appropriate sensing of slow atrial flutters. High-rate atrial sensing may continuously retrigger the AFR window, effectively resulting in fallback to the VDI(R) mode.

NOTE: *When both AFR and ATR are active and in the presence of atrial arrhythmias, nontracking ventricular paced behavior may occur sooner, but the ATR mode switch may take longer.*

NOTE: *For atrial arrhythmias that meet the programmed AFR rate criteria, using the AFR feature will result in slower ventricular pacing rates.*

PMT Termination

PMT Termination detects and attempts to interrupt pacemaker-mediated tachycardia (PMT) conditions.

In the DDD(R) and VDD(R) pacing modes, any device may detect and track retrograde conducted P-waves that fall outside of PVARP, causing triggered ventricular pacing rates as high as the MTR (i.e., PMT). When PMT Termination is programmed to On, a PMT condition is detected when 16 successive ventricular paces are counted at the MTR following atrial sensed events.

During the 16 intervals, the V–A interval is monitored to determine if:

- A PMT is occurring
- The intrinsic atrial rate is simply meeting the MTR or exceeding it

The V–A intervals are compared to the second V–A interval measured during the 16 ventricular paced events.

- If any of the successive intervals is more than 32 ms shorter or longer than this second interval, the algorithm continues to monitor successive ventricular paces for the presence of a PMT
- If the V–A intervals are all within this 32 ms criteria, the rhythm is declared a PMT

When PMT Termination is programmed to On, the pulse generator stores PMT episodes in the Arrhythmia Logbook.

When a PMT condition is detected at the MTR, the pulse generator sets the PVARP setting to a fixed setting of 500 ms for one cardiac cycle in an attempt to break the PMT. Programming the PVARP After PVC option and/or Rate Smoothing can also be useful in controlling the pulse generator's response to retrograde conduction.

RATE ENHANCEMENTS

Rate Enhancements includes the parameters as described.

Rate Hysteresis

Rate Hysteresis can improve device longevity by reducing the number of pacing stimuli. In dual-chamber models, this feature is available in DDD, DDI, VVI, and AAI modes. In single-chamber models, this feature is available in VVI mode. In DDD, DDI, and AAI modes, rate hysteresis is activated by a single nonrefractory sensed atrial event. In VVI mode, rate hysteresis is activated by a single nonrefractory, sensed ventricular event.

Hysteresis is deactivated by the following:

- A single atrial pace at the hysteresis rate

- In DDD mode:
  - A single atrial pace during a cardiac cycle when an RV pace is scheduled at the hysteresis LRL
  - An atrial rate that rises above the MTR

NOTE: *In VVI mode, hysteresis is deactivated by a single ventricular pace at the hysteresis rate.*

When Rate Smoothing Down is enabled, Rate Hysteresis remains in effect until pacing occurs at the hysteresis rate. This allows Rate Smoothing to control the transition to the hysteresis rate.

Hysteresis Offset

Hysteresis Offset is used to lower the escape rate below the LRL when the pulse generator senses intrinsic atrial activity.

If intrinsic activity below the rate limit occurs, then Hysteresis Offset allows inhibition of pacing until the LRL minus Hysteresis Offset is reached. As a result, the patient might benefit from longer periods of sinus rhythm.

Search Hysteresis

When Search Hysteresis is enabled, the pulse generator periodically lowers the escape rate by the programmed Hysteresis Offset in order to reveal potential intrinsic atrial activity below the LRL.

During Search Hysteresis, the pacing rate is lowered by the Hysteresis Offset for up to 8 cardiac cycles. When the search ends, hysteresis remains active if intrinsic atrial activity is sensed during that period. If there is no intrinsic atrial activity during the 8-cycle search, pacing resumes at the LRL. If Rate Smoothing Up is enabled, pacing will rate smooth up to the LRL.

Example: At a rate of 70 ppm and a search interval of 256 cycles, a search for intrinsic atrial activity would occur approximately every 3.7 minutes (256 ÷ 70 = 3.7).

Rate Smoothing is disabled during the search cycles. If no intrinsic atrial activity is detected during the search, the pacing rate is brought up to the LRL. If Rate Smoothing Up is enabled, the pacing will rate smooth up to the LRL.

NOTE: *In VVI mode, the intrinsic activity would be a sensed ventricular event instead of a sensed atrial event.*

Rate Smoothing

Rate Smoothing controls the pulse generator's response to atrial and/or ventricular rate fluctuations that cause sudden changes in pacing intervals. Rate Smoothing is an important enhancement to ATR because it can significantly reduce the rate fluctuations associated with the onset and cessation of atrial arrhythmias.

Patients who experience large variations in their ventricular paced rate can feel symptomatic during these episodes. Rate Smoothing can prevent these sudden rate changes in patients along with the accompanying symptoms (such as palpitations, dyspnea, and dizziness).

In a normal conduction system, limited cycle-to-cycle rate variations occur. However, the paced rate can change dramatically from one beat to the next in the presence of any of the following:

- Sinoatrial disease such as sinus pause or arrest, sinoatrial block, and brady-tachy syndrome
- PACs and/or PVCs
- Pacemaker Wenckebach
- Intermittent, brief, self-terminating SVTs, and atrial flutter/fibrillation
- Retrogradely conducted P-waves
- Pulse generator sensing of myopotential signals, EMI, crosstalk, etc.

In single-chamber models, Rate Smoothing operates between the LRL and the MPR when programmed to VVI.

In dual-chamber models, Rate Smoothing operates between the LRL and the MTR when programmed to DDD or VDD and it operates between the LRL and MPR when programmed to DDI, VVI, or AAI.

In single-chamber models, when the sensor is enabled, the operational range is from LRL to MSR. Rate Smoothing is also applicable between the hysteresis rate and LRL when hysteresis is active, except during Search Hysteresis.

In dual-chamber models, when the sensor is enabled and MSR is higher than MTR, the operational range is from LRL to MSR. Rate Smoothing is also

applicable between the hysteresis rate and LRL when hysteresis is active, except during Search Hysteresis.

When Rate Smoothing is programmed to On, the following information applies.

- Programmable Rate Smoothing values are a percentage of the RV R–R interval (3% to 25% in 3% increments) and can be independently programmed for:
  - Increase—Rate Smoothing Up
  - Decrease—Rate Smoothing Down
  - Off
- The pulse generator stores the most recent R–R interval in memory. R-waves may be either intrinsic or paced. Based on this R–R interval and the programmed Rate Smoothing value, the device sets up two synchronization windows for the next cycle: one for the atrium and one for the right ventricle.

NOTE: *Single-chamber pulse generators set up a ventricular window.*

- Rate Smoothing is functional except:
  - During the 8 cycles of rate Search Hysteresis
  - During ATR Fallback until fallback reaches the ATR LRL, the sensor-indicated rate, or the VRR interval
  - During VRR when active
  - Upon triggering PMT Termination
  - Immediately following programmed LRL increases
  - When above the MTR

Rate Smoothing Example Based on a Dual-Chamber Tracking Mode

Based on the most recent R–R interval stored in memory and the programmed Rate Smoothing value, the pulse generator sets up the two synchronization windows for the next cycle: one for the atrium and one for the ventricle. The synchronization windows are defined below:

Ventricular synchronization window: previous R–R interval ± Rate Smoothing value

Atrial synchronization window: (previous R–R interval ± Rate Smoothing value) - AV Delay

The following example explains how these windows are calculated (Figure 5-13 on page 5-30):

- Previous R–R interval = 800 ms
- AV Delay = 150 ms
- Rate Smoothing Up = 9%
- Rate Smoothing Down = 6%

The windows would be calculated as follows:

Ventricular Synchronization Window = 800 - 9% to 800 + 6% = 800 ms - 72 ms to 800 ms + 48 ms = 728 ms to 848 ms

Atrial Synchronization Window = Ventricular Synchronization Window - AV Delay = 728 ms - 150 ms to 848 ms - 150 ms = 578 ms to 698 ms

The timing for both windows is initiated at the end of every ventricular event (R-R interval).

If paced activity is to occur, it must occur within the appropriate synchronization window.

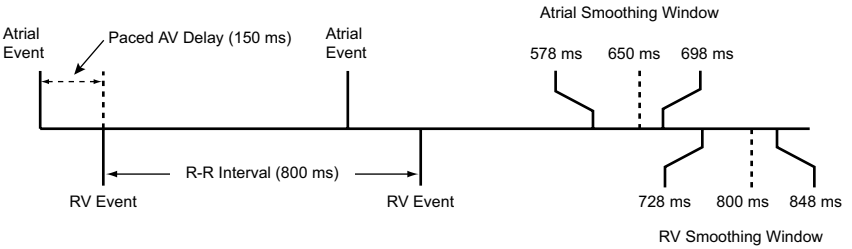


Figure 5-13. Rate smoothing synchronization window

It is important to ascertain the patient's physiologic cycle-to-cycle variation and program the Rate Smoothing parameter to a value that protects against pathologic interval changes, yet allows physiologic interval changes in response to increases in activity or exercise.

NOTE: *Without Rate Smoothing, a sudden, large atrial rate increase (e.g., PAT) will cause a simultaneous sudden increase in the paced ventricular rate as high as the programmed MTR. With Rate Smoothing, the ventricular paced rate in response to such a change might not reach the programmed MTR.*

Rate Smoothing Up

Rate Smoothing Up controls the largest pacing rate increase allowed when the intrinsic or sensor rate is increasing.

Rate Smoothing Down

Rate Smoothing Down controls the largest pacing rate decrease allowed when the intrinsic or sensor rate is decreasing.

NOTE: *When Rate Smoothing Down is programmed on and Rate Smoothing Up is programmed off, the pulse generator will automatically prevent fast intrinsic beats (e.g., PVCs) from resetting the Rate Smoothing Down escape rate any faster than 12% per cycle.*

Rate Smoothing Maximum Pacing Rate (MPR)

The Rate Smoothing Maximum Pacing Rate places a limit on the maximum pacing rate that Rate Smoothing can reach.

The Rate Smoothing Down parameter requires a programmed MPR when in AAI, VVI, or DDI. Rate Smoothing will then be used only between the MPR and the LRL or the hysteresis rate (if applicable).

When both VRR and Rate Smoothing are programmed on in the VVI(R) or DDI(R) mode, VRR will have priority; Rate Smoothing will be suspended.

LEAD CONFIGURATION

The pulse generator has independent outputs for the following:

- Atrium (in dual-chamber models)
- Right Ventricle

The atrial and RV leads are set to Bipolar pacing and sensing. The atrial lead has the option of being programmed Off.

AV DELAY

AV Delay is the programmable time period from the occurrence of either a paced or sensed right atrial event to a paced RV event.

AV Delay helps preserve the heart's AV synchrony. If a sensed ventricular event does not occur during the AV delay following an atrial event, the pulse generator delivers a ventricular pacing pulse when AV Delay expires.

AV Delay can be programmed to the following operations:

- Paced AV Delay
- Sensed AV Delay

This behavior occurs under the following conditions:

- Pacing state: Normal, Post-Therapy, or Temporary
- Pacing mode: DDD(R), DDI(R), or VDD(R)

Paced AV Delay

Paced AV Delay corresponds to the AV Delay following an atrial pace.

When the minimum value is less than the maximum value, then the Paced AV Delay is scaled dynamically according to the current pacing rate. Dynamic AV Delay provides a more physiologic response to rate changes by automatically shortening the Paced AV Delay or Sensed AV Delay with each interval during an increase in atrial rate. This helps minimize the occurrence of large rate changes at the upper rate limit and allows one-to-one tracking at higher rates.

The pulse generator automatically calculates a linear relationship based on the interval length of the previous A–A cycle and the programmed values for the following:

- Minimum AV Delay
- Maximum AV Delay
- LRL
- MTR
- MSR

The dynamic AV Delay is not adjusted following a PVC or when the previous cardiac cycle was limited by the MTR.

When the atrial rate is between the LRL and the higher of the MTR and the MSR, the pulse generator calculates the linear relationship to determine the Dynamic AV Delay (Figure 5-14 on page 5-33).

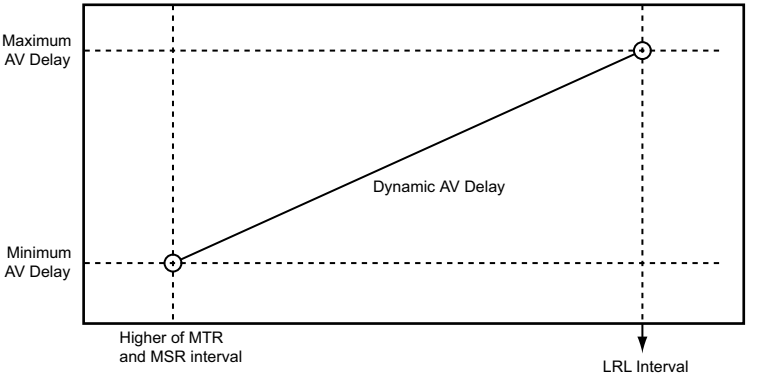


Figure 5-14. Dynamic AV Delay linear relationship

Dynamic AV Delay is activated during Paced AV Delay programming. The AV delay may be programmed to either a fixed or dynamic value as follows:

- Fixed AV Delay—occurs when Paced AV Delay minimum and maximum values are equal
- Dynamic AV Delay—occurs when Paced AV Delay minimum and maximum values are not equal

Sensed AV Delay

Sensed AV Delay corresponds to the AV Delay after a sensed atrial event.

Sensed AV Delay may be programmed to a value shorter than or equal to the Paced AV Delay. A shorter value is intended to compensate for the difference in timing between paced atrial events and sensed atrial events (Figure 5-15 on page 5-34).

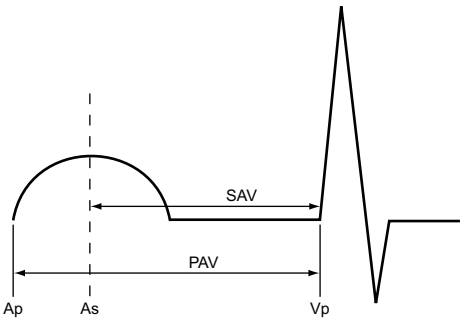


Figure 5-15. Sensed AV Delay

The hemodynamic impact of the Sensed AV Delay depends on the appropriateness of the timing between the atrial and ventricular contractions. An atrial pace starts the atrial contraction, whereas the atrial sense occurs during the contraction. As a result, when Sensed AV Delay is programmed to the same value as Paced AV Delay, the hemodynamic AV interval will differ between paced and sensed atrial events.

Using Sensed AV Delay with Paced AV Delay—*Fixed*

When Paced AV Delay is programmed to a fixed value (i.e., the minimum and maximum Paced AV Delay values are the same), then the Sensed AV Delay will be fixed at the programmed Sensed AV Delay value.

Using Sensed AV Delay with Paced AV Delay—*Dynamic*

When Paced AV Delay is programmed as dynamic (i.e., the minimum Paced AV Delay value is programmed at less than the maximum Paced AV Delay value), then the Sensed AV Delay will also be dynamic.

Dynamic Sensed AV Delay and Paced AV Delay are based on the atrial rate. To reflect the shortening of the PR interval during periods of increased metabolic demand, the AV Delay shortens linearly from the programmed (maximum) value at the LRL to a value determined by the ratio of minimum and maximum AV Delay at the higher of the MTR or MSR (Figure 5-16 on page 5-35). When Dynamic AV Delay is used, if the Sensed AV Delay value is programmed as shorter than the maximum Paced AV Delay value, then the Sensed AV Delay value will also be shorter than the minimum Paced AV Delay value at upper rates.

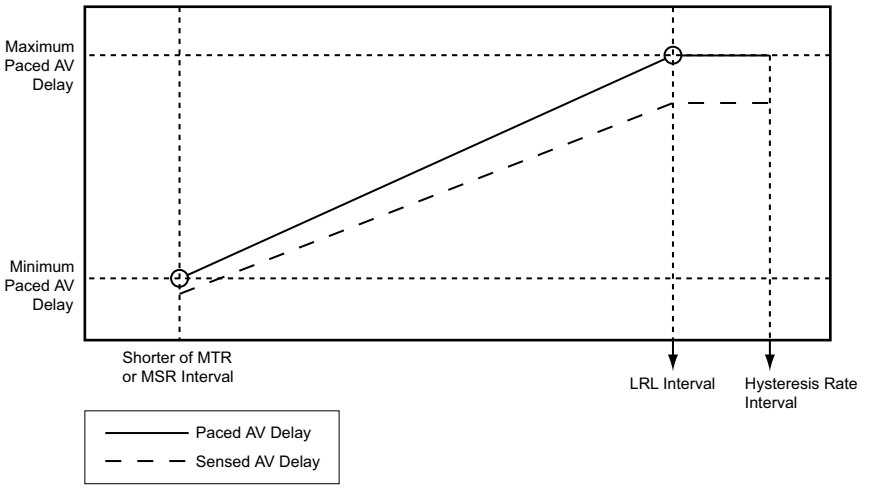


Figure 5-16. Dynamic and Sensed AV Delay as a function of the escape interval

NOTE: *The minimum value is programmable only in VDD(R) mode.*

AV Search+

AV Search+ is designed to promote intrinsic A–V conduction if present; AV Search + will watch for intrinsic AV conduction to occur beyond the programmed AV Delay. In patients with exercise-dependent or intermittent AV nodal block, this intrinsic AV conduction can improve hemodynamic performance and increase device longevity by reducing the amount of ventricular pacing pulses.

When AV Search+ is enabled, the AV Delay is lengthened periodically (according to the programmed value) for up to 8 consecutive paced or sensed cardiac cycles. The AV Search+ AV delay remains active as long as the intrinsic PR intervals are shorter than the maximum programmed Search AV Delay value.

The pulse generator reverts to the programmed AV Delay at the following points:

- When the 8-cycle search expires without sensing intrinsic ventricular activity
- When two ventricular paced events occur within the 10-cycle window.

Search AV Delay

The Search AV Delay parameter determines the length of the sensed and paced AV delays during the search cycles and during the AV hysteresis period.

NOTE: *The Search AV Delay value must be programmed to longer than the maximum Paced AV Delay.*

Search Interval

The Search Interval controls the frequency at which AV Search+ will attempt a search.

REFRACTORY

Refractory includes the features as described.

A-Refractory (PVARP)

PVARP is defined according to the pacing mode:

Single-chamber atrial modes: AAI(R)—the time period after a sensed or paced atrial event when an atrial sense event does not inhibit an atrial pace.

Dual-chamber modes: DDD(R), DDI(R), VDD(R)—the time period after a sensed or paced RV event when an atrial event does not inhibit an atrial pace or trigger a ventricular pace. The atrial refractory period prevents atrial sensing and tracking of retrograde atrial activity initiated in the ventricle.

A long atrial refractory period shortens the brady atrial sensing window. Programming long atrial refractory periods in combination with certain AV Delay periods can cause 2:1 block to occur abruptly at the programmed MTR.

In DDD(R) and VDD(R) pacing modes, the pulse generator may detect retrograde conduction in the atrium, causing triggered ventricular pacing rates as high as the MTR (i.e., PMT). Retrograde conduction times may vary over a patient's lifetime as a function of changing autonomic tone. If testing does not reveal retrograde conduction at implantation, it may still occur at a later time. This problem can usually be avoided by increasing the atrial refractory period to a value that exceeds the retrograde conduction time. In controlling the pulse generator's response to retrograde conduction, it may also be useful to program the following:

- PVARP after PVC
- PMT Termination
- Rate Smoothing

PVARP after PVC

PVARP after PVC is designed to help prevent PMT due to retrograde conduction, which is typically associated with PVCs.

When the pulse generator detects a sensed RV event without a preceding sensed or paced atrial event, including sensed events in refractory (i.e., a PVC), the atrial refractory period automatically extends to the programmed PVARP after PVC value for one cardiac cycle. After a PVC is detected, the timing cycles reset automatically. PVARP extends no more frequently than every other cardiac cycle.

RV-Refractory (RVRP)

The RVRP provides an interval following an RV pace event during which RV sensed events do not impact the timing of therapy delivery.

The use of a long RVRP shortens the RV sensing window for ventricular tachy detection.

RVRP is available in any mode where ventricular sensing is enabled, and RVRP can be programmed to a fixed or dynamic interval (Figure 5-17 on page 5-38):

- Fixed—RVRP remains at the programmed, fixed RVRP value between the LRL and the applicable upper rate limit (MPR, MTR or MSR).
- Dynamic—RVRP shortens as ventricular pacing increases from the LRL to the applicable upper rate limit, allowing more time for RV sensing.
  - Maximum—if the pacing rate is less than or equal to the LRL (i.e., hysteresis), the programmed Maximum VRP is used as the RVRP.
  - Minimum—if the pacing rate is greater than or equal to the applicable upper rate limit, the programmed Minimum VRP us used as the RVRP.

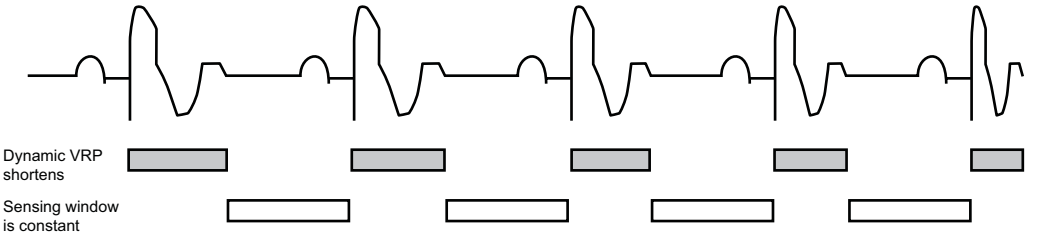


Figure 5-17. Relationship between ventricular rate and refractory interval

To provide an adequate sensing window, the following refractory value programming is strongly recommended:

- Single-chamber modes—less than or equal to one-half the LRL in ms
- Dual-chamber modes—less than or equal to one-half the applicable upper rate limit

Blanking and Noise Rejection

Blanking is the first part of the refractory period where sense amplifiers are completely disabled. It is used to prevent cross-chamber sensing and inhibition.

During a blanking interval, the sensing circuit in one chamber ignores sensed electrical activity generated by a pulse generator pulse in the other chamber (crosstalk).

- If ventricular pacing were sensed in the atrium, it would initiate an inappropriately high ventricular pacing rate in any pulse generator attempting to maintain AV synchrony. Therefore, in DDD(R), DDI(R), and VDD modes, a ventricular pace initiates a programmable atrial blanking interval.
- If atrial pacing were sensed in the ventricle, it would inhibit ventricular pulses and thereby cause an inappropriate decrease in paced rate. Therefore, in DDD(R) and DDI(R) modes, an atrial pace initiates a programmable ventricular blanking interval.

RV-Blank after A-Pace

RV-Blank after A-Pace, a cross-chamber blanking period, inhibits RV sensing following an atrial pace.

If the value is programmed to Smart, the pulse generator automatically adjusts the sensitivity value in order to reject far-field atrial events. This allows for sensing of true ventricular events that had previously fallen in the cross-chamber blanking period.

A-Blank after V-Pace

A-Blank after V-Pace, a cross-chamber blanking period, inhibits atrial sensing following a ventricular pace.

If the value is programmed to Smart, the pulse generator automatically adjusts the sensitivity value in order to reject far-field ventricular events. This allows for sensing of true atrial events that had previously fallen in the cross-chamber blanking period.

A-Blank after RV-Sense

A-Blank after RV-Sense, a cross-chamber blanking period, inhibits atrial sensing following an RV sensed event.

If the value is programmed to Smart, the pulse generator automatically adjusts the sensitivity value in order to reject far-field ventricular events. This allows for sensing of true atrial events that had previously fallen in the cross-chamber blanking period.

Refer to the following illustrations:

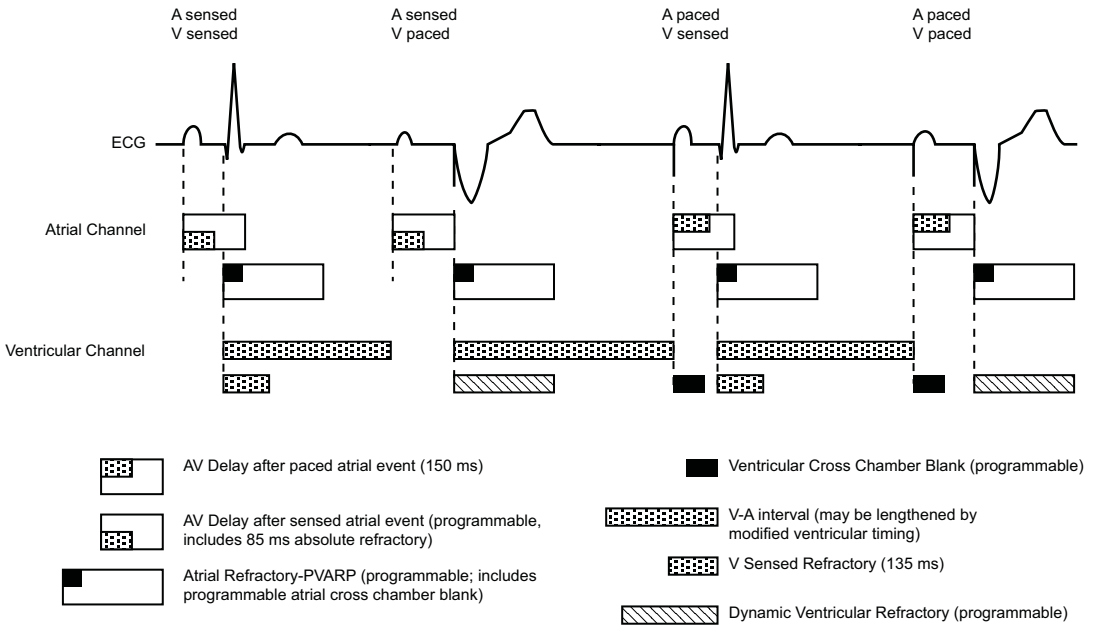


Figure 5-18. Refractory periods, dual-chamber pacing modes

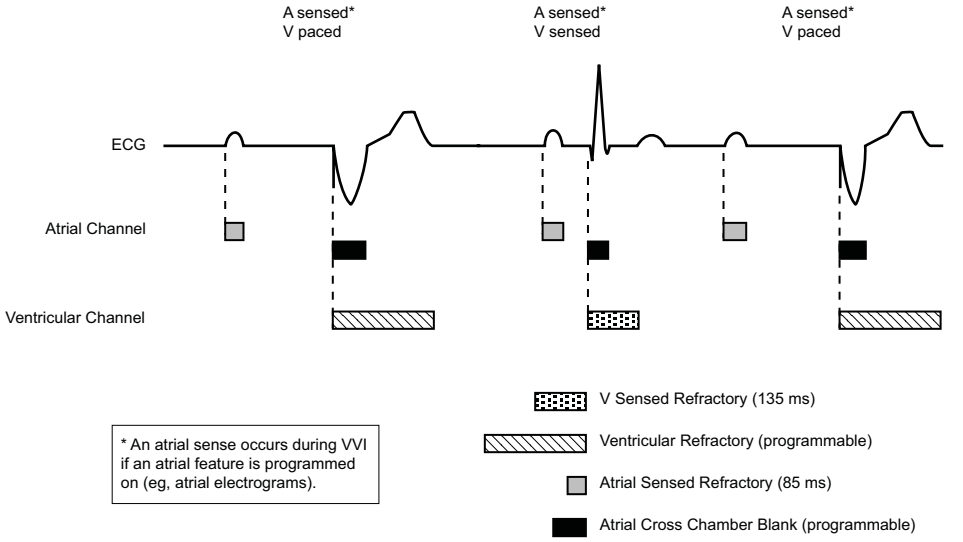


Figure 5-19. Refractory periods, VVI pacing mode

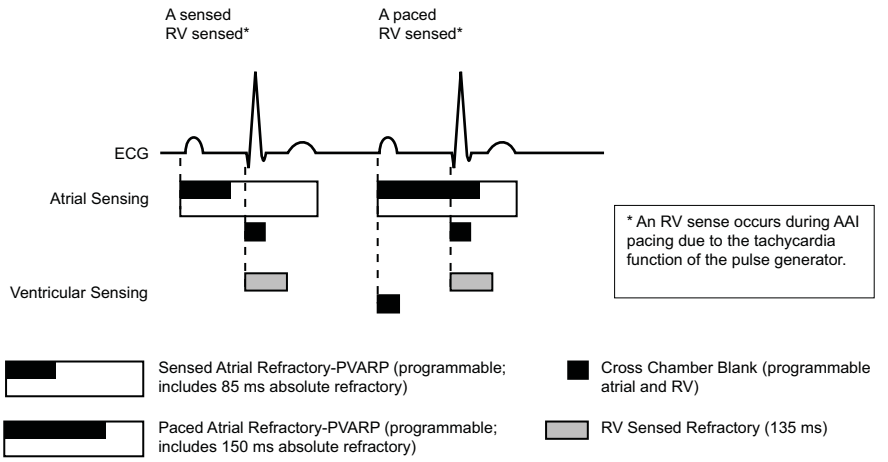


Figure 5-20. Refractory periods, AAI pacing mode

If the value is programmed to Smart, the pulse generator automatically adjusts the sensitivity value in order to reject far-field ventricular events. This allows for sensing of true atrial events that had previously fallen in the cross-chamber blanking period.

NOISE RESPONSE

Noise Response allows you to choose whether to pace or inhibit pacing in the presence of noise.

A retriggerable, 40-ms noise window exists within each refractory and cross-chamber blanking period. The window is initiated by either a sensed or paced event. Both the noise window and the refractory period must be completed for each cardiac cycle in one chamber before the next sensed event restarts the timing in the same chamber. Recurrent noise activity may cause the noise window to restart, extending the noise window and possibly the effective refractory period or blanking period.

The Inhibit mode is intended for patients whose arrhythmias may be triggered by asynchronous pacing. If Noise Response is programmed to an asynchronous mode and the noise persists so that the noise window is extended longer than the programmed pacing escape interval, the pulse generator paces asynchronously at the programmed pacing rate until the noise ceases.

Refer to Figure 5-21 on page 5-42.

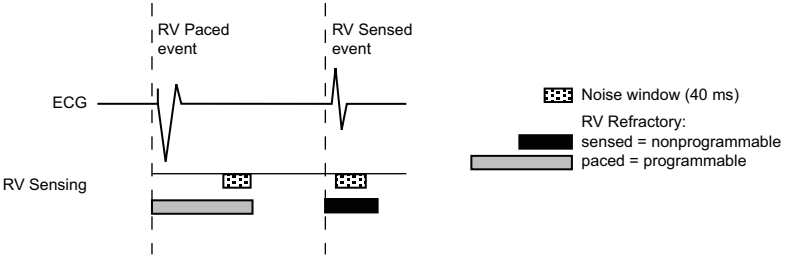


Figure 5-21. Refractory periods and noise windows, RV

If Noise Response is programmed to Inhibit, and the sensed noise extends the noise window beyond the programmed paced or sensed interval, the pace escape interval timing will reset and the pulse generator will not pace until one escape interval after the noise ceases. The pulse generator will continue to use a retriggerable noise window. In addition, a Dynamic Noise algorithm is intended to automatically adjust the maximum sensitivity to avoid noise detection. This algorithm is active in all rate channels.

If event markers are being transmitted:

Single-Chamber

- The marker [VS] occurs when the noise window is initially triggered following a V pace
- If retriggered for 340 ms, the marker [VN] occurs
- With continuous retriggers, the marker [VN] occurs frequently

Dual-Chamber

- Depending on the chamber where noise is occurring, the marker [AS] or [VS] occurs when the noise window is initially triggered following a pace
- If retriggered for 340 ms, the marker [AN] or [VN] occurs
- With continuous retriggers, the marker [AN] or [VN] occurs frequently

NOTE: *In pacer-dependent patients, use care when considering setting Noise Response to Inhibit as pacing will not occur.*

VENTRICULAR TACHY SENSING INTERACTIONS

Refractory periods and blanking intervals are an integral part of the pulse generator sensing system. They are used to efficiently suppress detection of pulse generator artifacts (e.g., a pace or shock) and certain intrinsic signal artifacts (e.g., a T-wave or far-field R-wave). The pulse generator does not discriminate between events that occur during refractory periods and blanking intervals. As a result, all events (pulse generator artifacts, intrinsic artifacts, and intrinsic events) that occur during a refractory period or blanking interval are ignored for purposes of pacing timing cycles and ventricular tachy detection.

Certain programmed combinations of pacing parameters are known to interfere with ventricular tachy detection. When an intrinsic beat from a VT occurs during a pulse generator refractory period, the VT beat will not be detected. As a result, detection and therapy of the arrhythmia may be delayed until enough VT beats are detected to satisfy the tachy detection criteria ("Ventricular Detection Windows" on page 3-13).

Pacing Parameter Combination Examples

The following examples illustrate the effects of certain pacing parameter combinations on ventricular sensing. When programming pulse generator pacing and tachy detection parameters, consider the possible interactions of these features in light of the expected arrhythmias. In general, the PRM screen displays Parameter Interaction Attentions and advisory messages to inform you about programming combinations that could interact to cause these scenarios; the interactions can be resolved by reprogramming the pacing rate, AV Delay and/or refractory/blanking periods.

Example 1: Ventricular Undersensing Due to Ventricular Refractory Period

If the pulse generator is programmed as follows, a VT that occurs synchronous with the pacing will not be detected:

- Brady Mode = VVI
- LRL = 75 ppm (800 ms)
- VRP = 500 ms
- VT Zone = 150 bpm (400 ms)

In this scenario, the pulse generator is VVI pacing at LRL (800 ms). A 500 ms VRP follows each ventricular pace. VT beats that occur during VRP are ignored for purposes of pacemaker timing and ventricular tachy detection/therapy. If a stable VT of 400 ms starts simultaneously with a ventricular pace, the VT

will not be detected because every beat will occur during the 500 ms VRP, either concurrent with a ventricular pace or 400 ms after a pace (Figure 5-22 on page 5-44).

NOTE: *It is not required for the VT to start concurrently with a pace for undersensing to occur. In this example, all pacing will be inhibited and tachy detection will subsequently occur, as soon as a single VT beat is detected.*

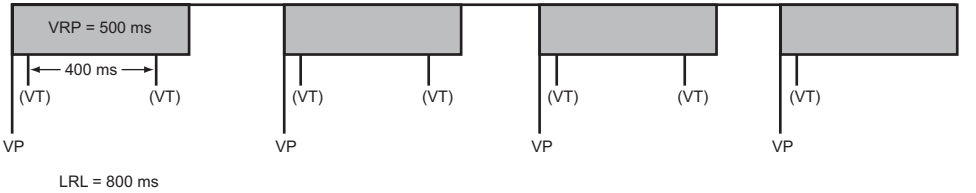


Figure 5-22. Ventricular undersensing due to VRP

When the programming interaction described in this scenario is present, a message will describe the interaction of VRP with LRL. In rate-responsive or tracking modes (e.g., DDDR), similar messages may describe the interaction of VRP with MTR, MSR, or MPR. 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.

Example 2: Ventricular Undersensing Due To V-Blank After A-Pace

Certain programmed combinations of dual-chamber pacing parameters may also interfere with ventricular tachy detection. When dual-chamber pacing occurs, pulse generator refractory periods are initiated by both atrial and ventricular paces. The ventricular refractory period following a ventricular pace is controlled by the VRP parameter; the ventricular refractory period following an atrial pace is controlled by the V-Blank After A-Pace parameter.

Undersensing of a VT due to the pulse generator refractory periods may occur when the pulse generator is pacing at or above LRL. For example, if the pulse generator is rate-adaptive pacing at 100 ppm (600 ms) and is programmed as follows, then a VT that occurs synchronous with the pacing may not be detected:

- LRL = 90 ppm (667 ms), MTR/MSR = 130 ppm (460 ms)
- Brady Mode = DDDR, fixed AV delay = 300 ms
- VRP = 230 ms
- V-Blank After A-Pace = 65 ms

- VT zone = 150 bpm (400 ms)

In this scenario, the pulse generator is DDDR pacing at 600 ms. A VRP of 230 ms follows each ventricular pace; a ventricular refractory period of 65 ms (V-Blank After A-Pace) follows each atrial pace; an atrial pace occurs 300 ms after each ventricular pace. VT beats that occur during either refractory period are ignored for purposes of pacemaker timing and ventricular tachy detection/therapy. If a stable VT of 350 ms starts, then the VT will not be detected because most beats will occur during a ventricular refractory period, either V-Blank After A-Pace or VRP. Some VT beats will be detected, but not enough to satisfy the 8 of 10 tachy detection criteria ("Ventricular Detection Windows" on page 3-13).

NOTE: *It is not required for the VT to start concurrently with a refractory period or blanking interval for undersensing to occur. In this example, it is likely that the VT will not be detected until either the VT accelerates to faster than 350 ms or the sensor-driven pacing rate changes from 600 ms.*

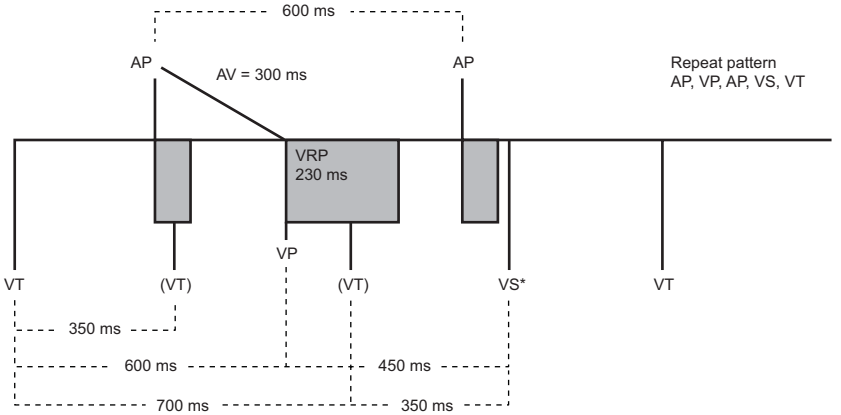


Figure 5-23. Ventricular undersensing due to V-Blank after A-Pace

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
  - Reduce the percent AV Search Hysteresis
  - 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

  – 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.

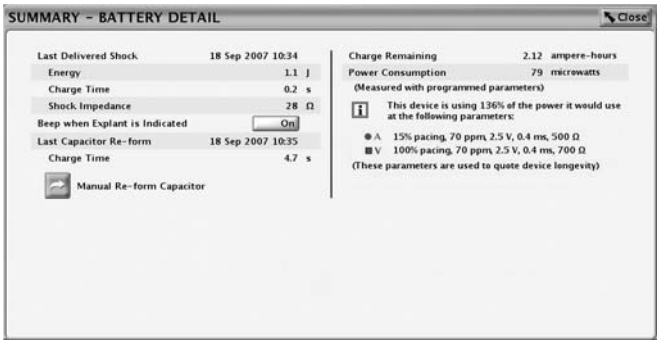


Figure 6-1. Battery Detail summary screen

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

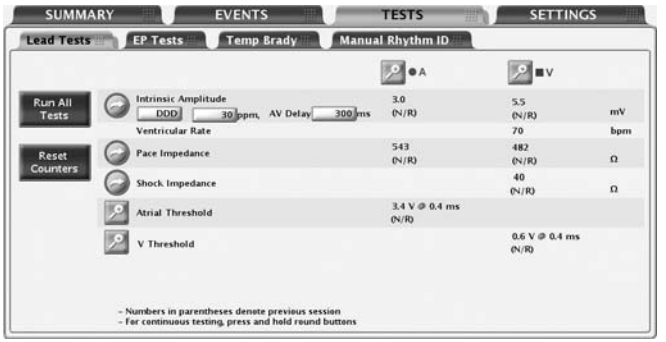


Figure 6-2. Lead Tests screen

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.*

NOTE: *When DDD mode and a ventricular test are selected, only the pacing output of the ventricular chamber decreases; the atrium is paced at a continuous amplitude.*

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
   - Amplitude
   - Pulse Width
   - Cycles per Step

   For DDD mode, the normal Brady MTR is used.

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[a]	4	1	3
PMT[a]	4	1	3

a. Not available in VR models.

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 Heart Rate Trend 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.
- 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:

    - 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.
- 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.

Heart Rate Trend Collection Criteria

Only valid sinus rhythm intervals are used in the heart Rate Trend data calculations. For Heart Rate Trend, valid intervals are those which include only valid Heart Rate Trend events. Heart Rate Trend event validation criteria are listed below:

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 7-5):

- 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
- 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 7-9).

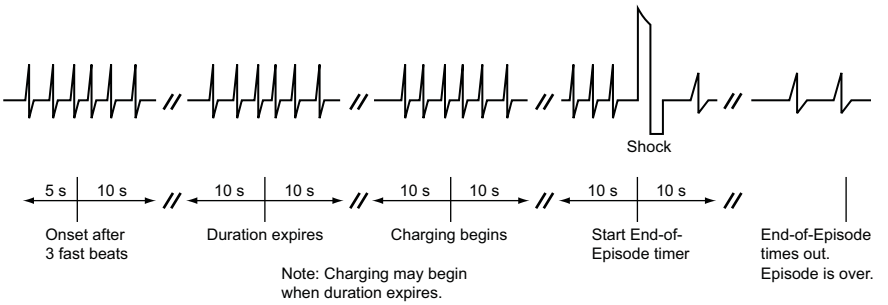


Figure 7-2. Relationship between ventricular tachy episode EGM storage and surface ECG strip chart recording

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

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.

Counters

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

- Ventricular Tachy
- Brady

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 Counters

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

- Percent of atrial paced
- Percent of RV paced

- Intrinsic Promotion—includes Rate Hystereses % successful and AV Search+ % 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):

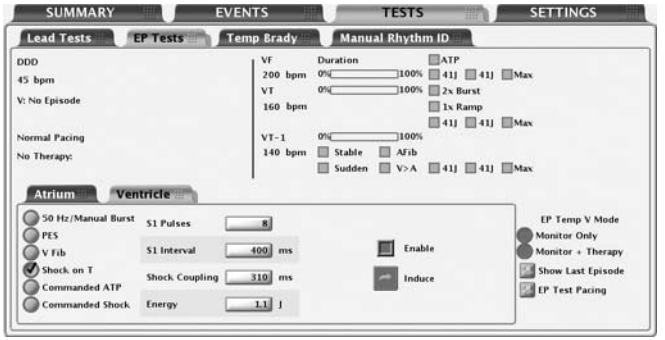


Figure 8-1. EP Test Screen

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:

- 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).

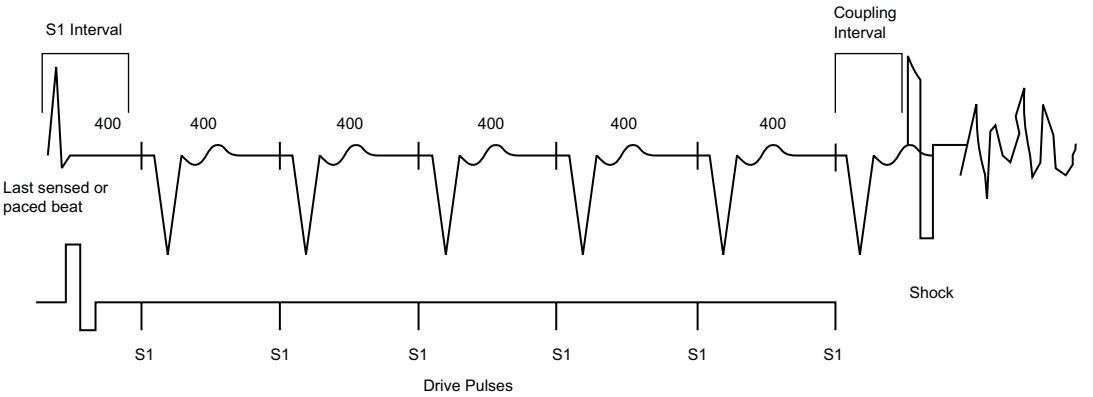


Figure 8-2. Shock on T induction drive train

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.

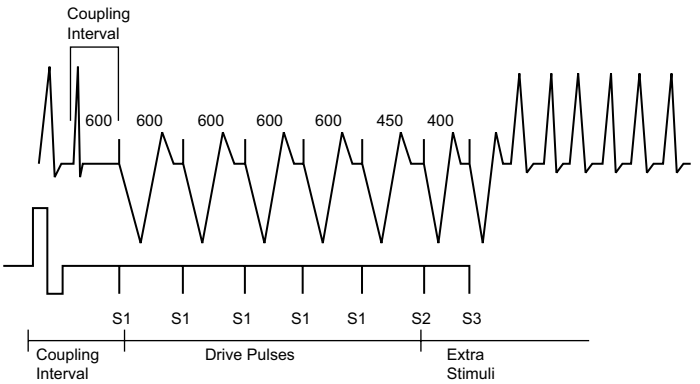


Figure 8-3. PES induction drive train

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.

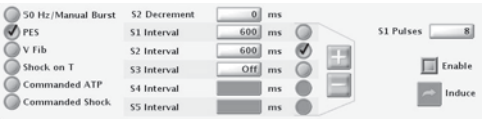


Figure 8-4. PES induction options

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
- 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

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 (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

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.

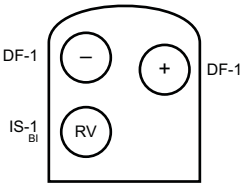


Figure 9-1. Lead connections, single chamber

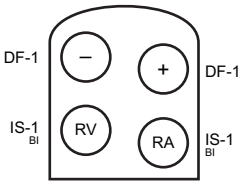


Figure 9-2. Lead connections, dual chamber

Setscrew locations are illustrated below.

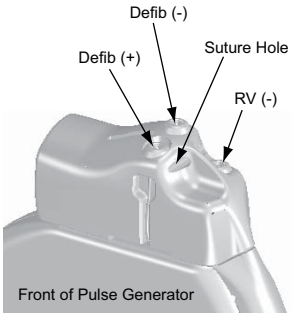


Figure 9-3. Setscrew and suture hole locations, single chamber

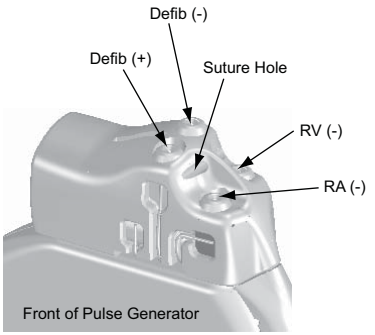


Figure 9-4. Setscrew and suture hole locations, dual chamber

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. 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.

5. 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.

- 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: For dual-chamber models, 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.

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.

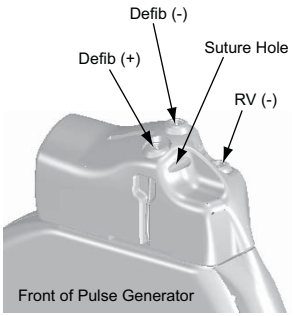


Figure 9-5. Setscrew and suture hole locations, single chamber

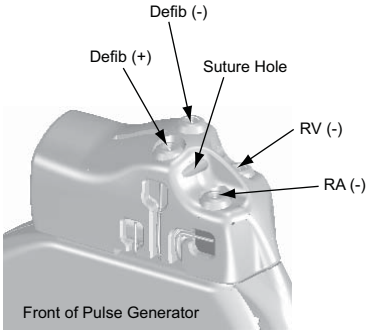


Figure 9-6. Setscrew and suture hole locations, dual chamber

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.

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).

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).

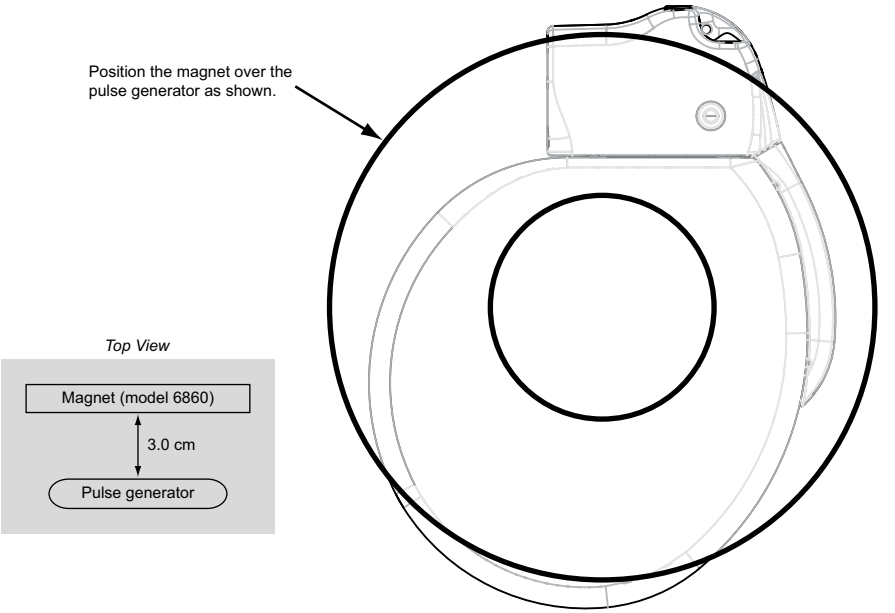


Figure 10-1. Proper position of magnet Model 6860 to activate the pulse generator magnet feature

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 7-13 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	Rhythm ID

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 (DR); 30 (VR) (Tolerance ± 5 ms)
Stability (ms) 2 zones	– –	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	– –	20 (DR); 30 (VR) (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	– –	On
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[a] (one value for all zones)	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	– –	20 (DR); 30 (VR) (Tolerance ± 5 ms)
Stability (ms) 2 zones[a] (one value for all zones)	– –	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	– –	20 (DR); 30 (VR) (Tolerance ± 5 ms)

a. The Stability parameter only applies in Post-shock for VR devices.

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 (DR); 30 (VR) (Tolerance ± 5 ms)
Post-shock Stability (ms) 2 zones	– –	Off, 6, 8, ..., 32, 35, 40, ..., 60, 70, 80, ..., 120	– –	20 (DR); 30 (VR) (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
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)
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 k]	DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off; Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off	DDD (DR); VVI (VR)
Lower Rate Limit (LRL)[a c] (ppm)	30, 35, ..., 185	60 (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
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)
V-Blank After A-Pace[a h] (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-Pace[a h] (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-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 (DR); 250 (VR) (Tolerance ± 5 ms)
Maximum Paced AV Delay[a g] (ms)	30, 40, ..., 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay[a g] (ms)	30, 40, ..., 400	80 (Tolerance ± 5 ms)

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

Parameter	Programmable Values	Nominal
Maximum Sensed AV Delay[a g] (ms)	30, 40, ..., 400	150 (Tolerance ± 5 ms)
Minimum Sensed AV Delay[a g] (ms)	30, 40, ..., 400	65 (Tolerance ± 5 ms)
AV Search +[g j]	Off, On	Off
AV Search + Search Interval[g j] (cycles)	32, 64, 128, 256, 512, 1024	32 (Tolerance ± 1 cycle)
AV Search + Search AV Delay[g j] (ms)	30,40 ..., 400	300 (Tolerance ± 5 ms)
Respiratory Sensor[a g]	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 l]	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
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.
k. The programmable values for VR devices only include VVI(R), Off; Temporary: VVI, VOO, Off
l. The programmable values for VR devices only includes VOO and Inhibit Pacing and as such the nominal is VOO.

Table A-13. 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)

Table A-13. Atrial Tachy Parameters (continued)

Parameter	Programmable Values	Nominal
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, On	On
ATR Maximum Pacing Rate[a] [b] (ppm)	30, 35, ..., 185	130
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, On	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-14. 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-15. 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-16. 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
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

Table A-17. 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-18. 50 Hz/Manual Burst Pacing

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

Table A-18. 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-19. 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-20. VFib (Ventricular Fibrillation) Induction

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

Table A-21. 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-22. 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-22. 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.

PACEMAKER INTERACTION

APPENDIX B

There may be instances where patients may have a separate temporary or permanent pacemaker. Temporary or permanent pacemakers can interact with an ICD and can interfere with the identification of tachyarrhythmias in the following ways:

- During a tachyarrhythmia, if the pacemaker does not sense the arrhythmia and paces, and the pacing pulse detected from the ICD rate-sensing electrode is large enough, it could cause the ICD to interpret the pacing as a normal rhythm at the rate of the pacemaker. The ICD would neither detect the arrhythmia nor deliver therapy.

- The pacemaker could present signals to the ICD resulting from the following events:

  – Inappropriate sensing
  – Lead dislodgment
  – Failure to capture

  This could cause the ICD's rate measurement to be faster than the patient's actual heart rate. As a result, the ICD could deliver inappropriate therapy.

- Conduction delay could cause the ICD to count both pacemaker artifact and ventricular depolarization. This could result in inappropriate ICD therapy.

For these reasons, the use of a pacemaker that results in pacemaker and ICD interaction is not recommended. Unipolar pacemakers are contraindicated for use with an ICD.

Consider the following actions if a separate pacemaker is used:

- Always deactivate a patient's ICD when:

  – Using temporary bipolar or temporary AV sequential pacing
  – Reprogramming a separate implanted pacemaker

  If cardioversion or defibrillation is needed at such times, use an external defibrillator.

- The ICD rate-sensing electrodes should be as far from the pacing electrodes as possible.

- After implanting the pacing leads, examine the signals from the ICD rate-sensing electrodes to ensure that minimal pacemaker artifacts are present.

- Since it is difficult to predict the relative magnitudes of pacemaker artifacts and various tachyarrhythmia electrograms that may occur chronically or during EP testing, it is important to reduce artifacts to a minimum.

- All of the patient's rhythms should be induced while the ICD is activated and the separate pacemaker is programmed to an asynchronous mode at maximum output. This should provide the greatest opportunity for inhibition of arrhythmia detection due to pacemaker artifacts. Leads may have to be repositioned to eliminate artifacts.

- To reduce the possibility of pacemaker interaction, consider testing the separate pacemaker by programming it to the following settings:

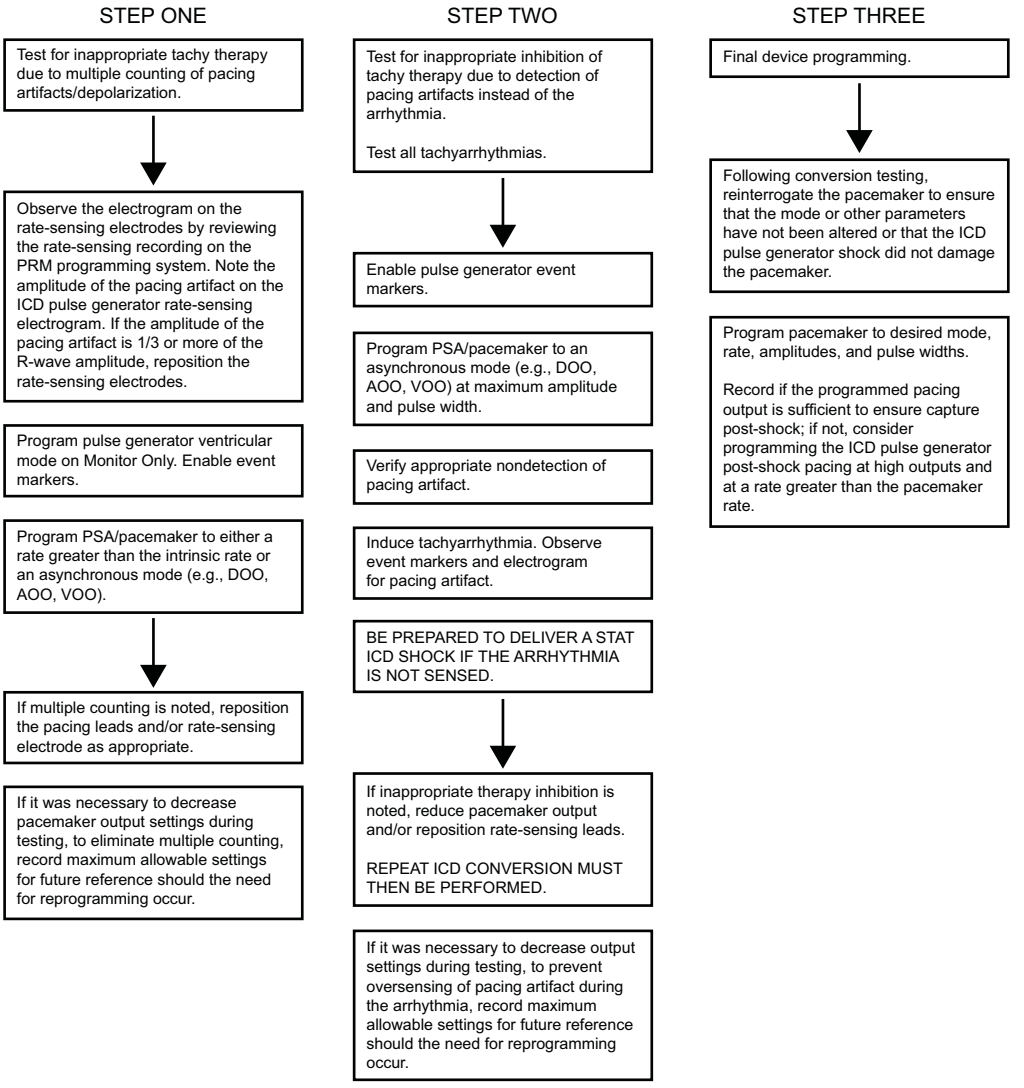
  – The lowest amplitude allowable for safe capture in the chronic state
  – The maximum sensitivity to ensure that pacing is inhibited during VF
  – The minimum cardiac rate acceptable for the patient

  Also consider using rate-sensing and pacemaker leads with close intraelectrode spacing (e.g., 11 mm).

- Consider turning off the bradycardia pacing function of the ICD or programming that function to a rate less than the separate pacemaker rate.

- For pacing control following any shock therapy, consider whether to use the ICD's post-therapy bradycardia pacing feature at higher rates and outputs or the separate pacemaker.

The following test procedure aids in determining the potential for pacemaker/ICD interaction (Figure B-1 on page B-3).



NOTE: The Guidant Model 6860 Magnet also can be used to assess pacemaker interaction if the magnet function is enabled. Placing the magnet over a device in a ventricular Monitor + Therapy mode should produce tones.

Figure B-1. Test procedure for pacemaker-ICD interaction

CLINICAL STUDY - MADIT II

APPENDIX C

SUMMARY

Guidant Cardiac Rhythm Management has received FDA approval for the following expanded indications for patients identified by the Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) to be at high risk for sudden cardiac death.

The Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) was designed to determine if implantation of an ICD in high-risk cardiac patients with advanced left ventricular dysfunction could improve overall survival. The previous MADIT I trial demonstrated improved overall survival with an ICD in high-risk patients with coronary heart disease, left ventricular dysfunction, asymptomatic nonsustained ventricular tachyarrhythmias and an inducible nonsuppressible ventricular tachycardia at EP study.

INDICATIONS FOR USE

Guidant implantable cardioverter defibrillators (ICDs) are indicated in patients who have had spontaneous and/or inducible life-threatening ventricular arrhythmias and those who are at high risk for developing such arrhythmias. In addition, this device is indicated for prophylactic treatment of patients with a prior myocardial infarction and an ejection fraction (EF) ≤ 30%.

OBSERVED ADVERSE EVENTS

The Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) was a prospective, randomized, controlled, multicenter, unblinded study conducted at 76 sites (71 in the United States and 5 in Europe) and enrolled a total of 1,232 patients. Patients were randomly assigned in a 3:2 ratio to receive an ICD (742 patients) or conventional medical therapy (490 patients). There were a total of 22 conventional therapy patients that were crossed over to the ICD group and a total of 32 patients randomized to the ICD arm that were considered crossovers. Of these 32 crossovers, 11 were due to subsequent device explants.

There were no unanticipated adverse events reported in the MADIT II study as of December 7, 2001. There were no patient deaths that occurred during implantation. Table C-1 on page C-2 provides information on all adverse events reported from implant through the randomization period in patients attempted or implanted with the MADIT II criteria. The table includes a total of 3,161 events

reported for a total of 1,206 patients as of the data cutoff date of January 16, 2002. The number of patients is less than the total enrolled 1,232 patients because not all patients had reached the point of the one-month follow-up. The observed adverse events do not reflect an intention-to-treat analysis.

Table C-1. Adverse events through the randomization period

Adverse Event	# Of Events (# of pts)[a]	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
Total of All Adverse Events (AE)	3161 (813[a])	49.7 (599)	7.9 (1761)	46.9 (566)	6.3 (1400)
ICD Therapy (Total AEs–treatment group)	2105 (503)	51.5 (376)	8.4 (1172)	49.9 (364)	6.7 (933)
Conventional Therapy (Total AEs–control group)	1056 (310)	46.8 (223)	7.0 (589)	42.4 (202)	5.5 (476)
TOTAL CARDIOVASCULAR RELATED ADVERSE EVENTS					
Device-Related Events[b]					
Prophylactic replacement	7 (7)	0.6 (7)	0.0 (7)	0.0 (0)	0.0 (0)
Lead related problem	14 (13)	0.8 (10)	0.0 (10)	0.3 (3)	0.0 (4)
Battery depletion – normal (at EOL)	2 (2)	0.2 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Electromagnetic interference (EMI)	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Nonconversion of arrhythmia	3 (3)	0.2 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Sense time prolonged / inappropriate	5 (5)	0.2 (3)	0.0 (3)	0.2 (2)	0.0 (2)
Generator manufacturing problem	2 (2)	0.2 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Pacemaker mediated tachycardia	79 (47)	0.0 (0)	0.0 (0)	3.9 (47)	0.4 (79)
Individual events that occurred one time	18 (18)	1.0 (10)	0.0 (10)	0.8 (8)	0.0 (8)

Table C-1. Adverse events through the randomization period (continued)

Adverse Event	# Of Events (# of pts)[a]	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
Subtotal Device Related Events	132 (91[a])	2.9 (35)	0.2 (37)	4.9 (59)	0.4 (95)
Procedure Related Events[b]					
Infection	13 (13)	0.8 (9)	0.0 (9)	0.3 (4)	0.0 (4)
Lead problem	2 (2)	0.1 (1)	0.0 (1)	0.1 (1)	0.0 (1)
Patient bleeding	2 (2)	0.1 (1)	0.0 (1)	0.1 (1)	0.0 (1)
Pulse generator flipped (Twiddler)	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Pocket inflammation/hematoma	15 (15)	0.9 (11)	0.0 (11)	0.3 (4)	0.0 (4)
Pain	10 (10)	0.1 (1)	0.0 (1)	0.7 (9)	0.0 (9)
Fibrillation, atrial	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Deep Vein Thrombosis	3 (3)	0.1 (1)	0.0 (1)	0.2 (2)	0.0 (2)
Anxiety	2 (2)	0.0 (0)	0.0 (0)	0.2 (2)	0.0 (2)
Individual events that occurred one time	17 (17)	0.8 (8)	0.0 (8)	0.9 (9)	0.0 (9)
Subtotal Procedure Related Events	68 (59[a])	2.2 (26)	0.1 (32)	3.0 (36)	0.2 (36)
Cardiovascular Related Events (n=730 pts): ICD Therapy (treatment group)					
Arrhythmia, atrial	78 (66)	4.2 (31)	0.2 (34)	5.3 (39)	5.3 (39)
Arrhythmia, ventricular	64 (49)	5.3 (39)	0.4 (53)	1.4 (10)	0.1 (11)
Mitral valve regurgitation	1 (1)	0.1 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Congestive heart failure	444 (227)	22.9 (167)	2.2 (304)	14.1 (103)	1.0 (140)
Palpitation, pounding heart	21 (18)	1.0 (7)	0.1 (7)	1.5 (11)	0.1 (14)
Syncope	62 (50)	4.7 (34)	0.3 (40)	2.5 (18)	0.2 (22)
Infarction, myocardial	34 (28)	3.8 (28)	0.2 (34)	0.0 (0)	0.0 (0)

Table C-1. Adverse events through the randomization period (continued)

Adverse Event	# Of Events (# of pts)[a]	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
Angina pectoris	166 (110)	10.0 (73)	0.8 (112)	6.0 (44)	0.4 (54)
Bradycardia, sinus	8 (8)	1.0 (7)	0.1 (7)	0.1 (1)	0.0 (1)
Tachycardia	7 (7)	0.3 (2)	0.0 (2)	0.7 (5)	0.0 (5)
AV Block, Complete	1 (1)	0.1 (1)	0.1 (1)	0.0 (0)	0.0 (0)
Cardiac allograft rejection	2 (2)	0.3 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Hypotension	28 (26)	1.4 (10)	0.1 (10)	2.2 (16)	0.1 (18)
Hypertension	6 (6)	0.1 (1)	0.0 (1)	0.7 (5)	0.0 (5)
Claudication	10 (7)	0.8 (6)	0.1 (9)	0.1 (1)	0.0 (1)
Carotid stenosis	5 (5)	0.5 (4)	0.0 (4)	0.1 (1)	0.0 (1)
Aneurysm	1 (1)	0.1 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Deep vein thrombosis	9 (9)	1.0 (7)	0.1 (7)	0.3 (2)	0.0 (2)
Pulmonary Embolus	4 (4)	0.5 (4)	0.0 (4)	0.0 (0)	0.0 (0)
Individual events that occurred one time	5 (5)	0.5 (4)	0.0 (4)	0.1 (1)	0.0 (1)
Subtotal Cardiovascular Related Events: ICD Therapy (treatment group)	956 (354)	36.8 (269)	4.6 (637)	26.8 (196)	2.3 (319)
Cardiovascular Related Events (n=476 pts): Conventional Therapy (control group)					
Arrhythmia, atrial	31 (29)	3.2 (15)	0.2 (16)	3.2 (15)	0.2 (15)
Arrhythmia, ventricular	33 (26)	4.6 (22)	0.3 (27)	1.1 (5)	0.1 (6)
Arrhythmia, general report	3 (3)	0.4 (2)	0.0 (2)	0.2 (1)	0.0 (1)
Mitral valve regurgitation	1 (1)	0.2 (1)	0.0 (1)	0.0 (0)	0.0 (0)
Congestive heart failure	212 (128)	16.6 (79)	1.5 (126)	14.3 (68)	1.0 (86)

Table C-1. Adverse events through the randomization period (continued)

Adverse Event	# Of Events (# of pts)[a]	% Complications (Patients)	Complications per 100 Device Months (Events)	% Observations (Patients)	Observations per 100 Device Months (Events)
Palpitation, pounding heart	6 (5)	0.4 (2)	0.0 (3)	0.6 (3)	0.0 (3)
Syncope	35 (31)	4.8 (23)	0.3 (24)	2.1 (10)	0.1 (11)
Infarction, myocardial	19 (17)	3.6 (17)	0.2 (19)	0.0 (0)	0.0 (0)
Angina pectoris	93 (71)	10.7 (51)	0.8 (64)	5.5 (26)	0.3 (29)
Bradycardia, sinus	8 (8)	1.7 (8)	0.1 (8)	0.0 (0)	0.0 (0)
AV Block, Complete	4 (2)	0.4 (2)	0.0 (3)	0.2 (1)	0.0 (1)
Bundle branch block	4 (4)	0.4 (2)	0.0 (2)	0.4 (2)	0.0 (2)
Hypotension	17 (13)	1.9 (9)	0.1 (12)	1.1 (5)	0.1 (5)
Hypertension	2 (2)	0.0 (0)	0.0 (0)	0.4 (2)	0.0 (2)
Claudication	6 (4)	0.6 (3)	0.1 (5)	0.2 (1)	0.0 (1)
Carotid stenosis	5 (5)	1.1 (5)	0.1 (5)	0.0 (0)	0.0 (0)
Aneurysm	3 (3)	0.6 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Deep vein thrombosis	3 (3)	0.6 (3)	0.0 (3)	0.0 (0)	0.0 (0)
Pulmonary Embolus	2 (2)	0.4 (2)	0.0 (2)	0.0 (0)	0.0 (0)
Tachycardia	2 (2)	0.2 (1)	0.0 (1)	0.2 (1)	0.0 (1)
Individual events that occurred one time	7 (7)	1.1 (5)	0.1 (5)	0.4 (2)	0.0 (2)
Subtotal Cardiovascular Related Events: Conventional Therapy (control group)	496 (222)	34.7 (165)	3.9 (329)	25.0 (119)	2.0 (165)
Subtotal Cardiovascular Related Events: Both groups	1452 (576[a])	36.0 (434)	4.3 (968)	26.1 (315)	2.2 (484)

a. Identifies number of unique patients. Patients may have one or more adverse events.
b. Events include only patients in the ICD treatment group.

MORTALITY

There were a total of 202 deaths that occurred during the trial and recorded as of the stop date, November 20, 2001. These deaths occurred during the study periods as shown in Table C-2 on page C-6 along with the cause of death as adjudicated by an independent events committee.

Table C-2. Cause of death during the treatment period

Cause of Death (as a percent of total pts)	ICD Therapy (N=742) Patients (%)	Conventional Therapy (N=490) Patients (%)	Total (N=202)
Noncardiac	25 (3.4%)	21 (4.3%)	46 (3.7%)
Cardiac: Arrhythmic	28 (3.8%)	48 (9.8%)	76 (6.2%)
Cardiac: Nonarrhythmic	45 (6.1%)	22 (4.5%)	67 (5.4%)
Cardiac: Undetermined cause	1 (0.1%)	2 (0.4%)	3 (0.2%)
Unknown	6 (0.8%)	4 (0.8%)	10 (0.8%)
Total Deaths	105 (14.2%)	97 (19.8%)	202 (16.3%)

SUMMARY OF CLINICAL STUDY

Guidant supported the MADIT II Clinical Study as conducted by the University of Rochester to evaluate the potential survival benefit of a prophylactically implanted ICD in patients with a prior myocardial infarction and a left ventricular ejection of ≤ 30 percent. Unlike MADIT I[1], patients enrolled in MADIT II were not required to undergo electrophysiologic testing to induce arrhythmias prior to implant. Patients were randomized to either ICD or conventional therapy. All cause mortality was the primary endpoint of the study.

The MADIT II trial was monitored using a sequential design and on November 20, 2001, after review of the data by the Data and Safety Monitoring Board, the study was stopped. Results of the trial data indicated a 31percent decrease in the mortality rate in patients implanted with an ICD device compared to patients randomized to the conventional therapy group, thus meeting its effectiveness endpoint.

The trial began July 11, 1997 and was conducted over a period of four years at 76 investigational centers both within and outside the United States.

1. Moss AJ, Hall WJ, Cannom DS, et al. Improved survival with an implanted defibrillator in patients with coronary disease at high risk for ventricular arrhythmia. NEJM 1996;335:1993-40

STUDY DESIGN

MADIT II was a prospective, randomized (3:2 ICD to conventional non-ICD therapy), controlled, unblinded, multicenter trial. Randomization to the ICD group consisted of implantation of a legally marketed Guidant ICD device. Randomization to the conventional therapy group consisted of beta-adrenergic blocking drugs and angiotensin-converting enzyme (ACE) inhibitors when indicated.

Patients provided written informed consent and received a baseline reference examination that included prior clinical history, physical examination and a 12-lead ECG. Following completion of the baseline evaluation, patients were randomized by the Coordination and Data Center (CDC) in a 3:2 fashion to receive either an ICD or conventional medical therapy; randomization was done separately for each center, with blocking, to assure proper balance between the two 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.

Patients randomized to the ICD arm were implanted with Guidant transvenous defibrillator devices by MADIT II investigators. All Guidant ICD systems used during the trial were legally approved devices and the use of investigational devices was strictly prohibited. Following randomization, patients were seen at a 1-month follow-up visit in the clinic and at 3-month intervals thereafter until termination of the study.

Primary Endpoint

The primary endpoint for MADIT II was all cause mortality.

Primary Objective

The primary objective of the trial was to determine if implantation of ICDs in moderately high-risk coronary patients would result in significant reduction in death when compared to patients treated without an ICD.

Secondary Objectives

The secondary objectives of the trial were as follows:

- Determine if (electrophysiology study) EPS inducibility at ICD implantation in the ICD group was associated with a higher appropriate ICD discharge rate during follow-up than noninducibility.

- Determine if Holter-recorded noninvasive electrocardiologic parameters (SAECG, heart rate variability, temporal dispersion of refractoriness, T-wave alternans, and T-wave lability) can identify patients with an increased mortality rate in the non-ICD group.

- Evaluate the cost-effectiveness of ICDs in saving lives.

- Determine if ICD therapy is associated with an improved quality of life.

The results of these secondary objectives are pending and were not included as part of the approval for this expanded indication.

INCLUSION/EXCLUSION CRITERIA

Study inclusion criteria were as follows:

- Patients must have an ejection fraction ≤ 0.30 obtained ≤ 3 months prior to enrollment by angiographic, radionuclide, or echocardiographic methods. This ejection fraction must be obtained at least 30 days following the most recent myocardial infarction, coronary artery bypass graft surgery, or coronary revascularization procedure.

- Patients must have had at least one or more documented Q-wave or other enzyme positive infarctions. If enzyme information is not available, then there must be clear evidence of an infarct identified as a Q-wave on an ECG, fixed defect (scar) on a thallium scan, or infarcted area on a coronary angiogram or echocardiography.

- Patients must be men or women greater than 21 years of age (no upper cut-off).

Study exclusion criteria were as follows:

- Previous cardiac arrest or syncopal ventricular tachycardia unassociated with an acute myocardial infarction (existing ICD indication)

- Patients meeting MADIT I criteria with EF ≤ 0.35, nonsustained VT, and inducible-nonsuppressible VT at electrophysiologic study (existing ICD indication)

- Cardiogenic shock, symptomatic hypotension while in a stable baseline rhythm

- NYHA functional Class IV
- Current use of antiarrhythmic agents except when indicated for atrial arrhythmias
- Coronary artery bypass graft surgery or PTCA within the past 3 months
- Enzyme-positive myocardial infarction ≤ 30 days prior to enrollment
- Patients with angiographic evidence of coronary disease who are candidates for coronary revascularization and are likely to undergo coronary artery bypass graft surgery or PTCA in the foreseeable future
- Patients with irreversible brain damage from preexisting cerebral disease
- Women of childbearing potential not using medically prescribed contraceptive measures
- Presence of any disease, other than the patient's cardiac disease, associated with a reduced likelihood of survival for the duration of the trial, e.g., cancer, uremia (BUN ≥ 70 mg% and/or creatinine ≥ 30 mg%)
- Patients participating in other clinical heart disease trials
- Patients unwilling or unable to cooperate with the study due to dementia, psychological, or other related reasons
- Patients who were unable to participate due to one or more logistical considerations
- Patient's primary care physician refuses to allow patient to participate
- Patients who are on the heart transplant list. If the patient is pending evaluation for the heart transplant list, the patient cannot be enrolled in MADIT II until it is definitively determined that the patient will NOT be placed on the transplant list
- ICD cannot be implanted due to anatomical abnormality or other medical problem

PATIENT STATUS

There were a total of 1,232 patients with a prior myocardial infarction and a left ventricular ejection fraction of ≤ 0.30 enrolled in the MADIT II trial. A total of 742 patients were randomized to receive an ICD and 490 patients were randomized to conventional therapy. Figure C-1 on page C-10 provides an overview of the patient enrollment.

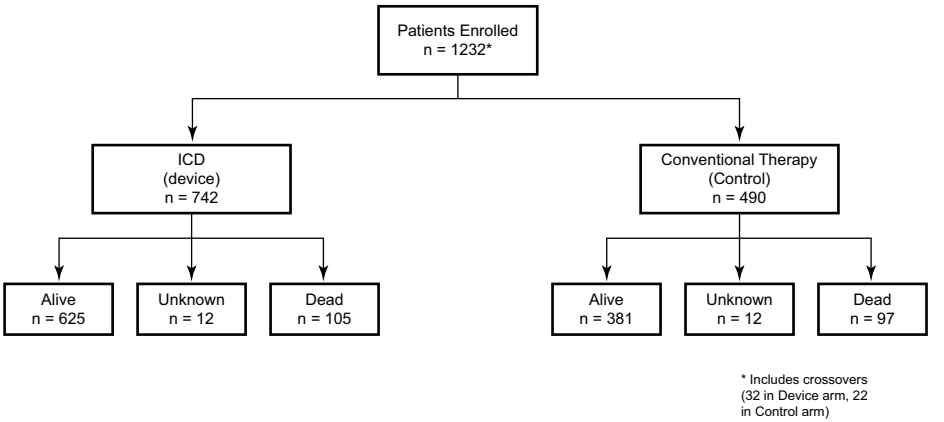


Figure C-1. Patient enrollment cascade primary endpoint

PRIMARY ENDPOINT

The primary endpoint for MADIT II was death from any cause. Analysis was performed according to the intention-to-treat principle. The trial was designed to have 95 percent power to detect a 38 percent reduction in the two-year mortality rate among the patients in the ICD group, given a postulated two-year mortality rate of 19 percent among patients assigned to conventional therapy, with a two-sided significance level of 5 percent. For proportional-hazards modeling, power was maintained for a true hazard ratio of 0.63, after allowance for crossovers. A triangular sequential design was used, which was modified for two-sided alternatives. The data was corrected to account for any lag in obtaining data accrued (during weekly monitoring), but not reported before the termination of the trial with preset boundaries to permit termination of the trial if the ICD therapy was found to be superior to, inferior to, or equal to conventional medical therapy.

Secondary analyses were performed with use of the Cox proportional hazards regression model. Survival curves were determined according to the Kaplan and Meier method, with comparisons of cumulative mortality based on

logarithmic transformation. The p-values were termed nominal when they were not adjusted for sequential monitoring. All p-values were two-tailed.

At the recommendation of the Data and Safety Monitoring Board (DSMB), the trial was stopped on November 20, 2001, when it was revealed that the difference in mortality between the two groups had reached the prespecified efficacy boundary (p=0.027) (Figure C-2 on page C-11).

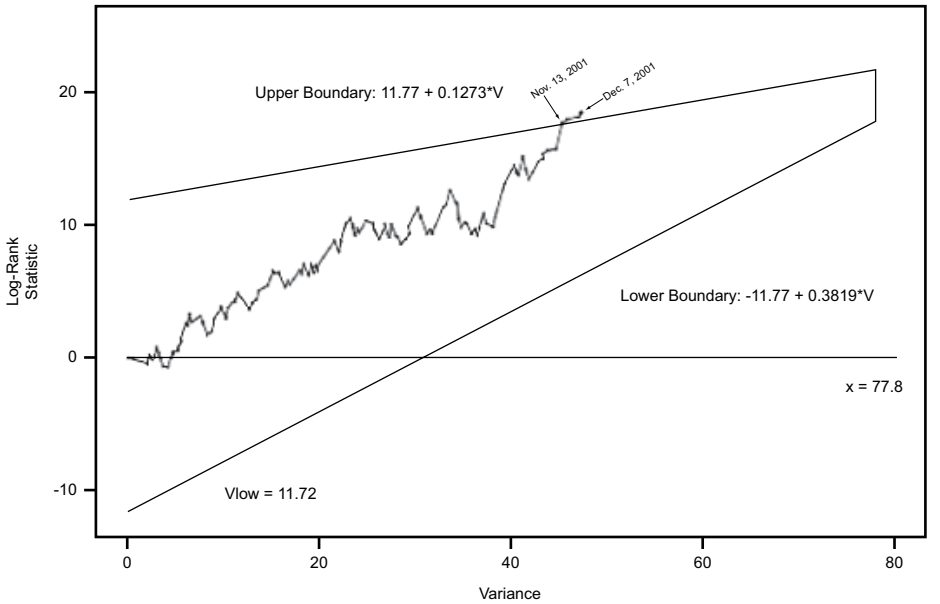


Figure C-2. Sequential monitoring in the triangular design

FOLLOW-UP SCHEDULE

Following randomization, patients were seen at a 1-month follow-up visit in the clinic and at 3-month intervals thereafter until termination of the study. During each clinic visit, an appropriate clinical evaluation was completed. Patients with an ICD device underwent device testing according to an agreed-upon protocol at the investigational center. Patients were followed from between 6 days and 53 months averaging 20 months.

STUDY RESULTS

Study Duration

Study duration, measured in months, is displayed in Table C-3 on page C-12. The mean duration was similar between the ICD group and the conventional therapy group. As expected, the ICD group accumulated >15,000 months of follow-up.

Table C-3. Study duration in months

Therapy	No.	Mean	±SD	Minimum	Maximum	Cumulative
ICD Therapy	742	20.5	12.9	0.2	51.7	15,190
Conventional Therapy	490	19.6	12.6	0.2	52.3	9,624

Demographic Data

Table C-4 on page C-12 provides a summary of the general characteristics of the enrolled MADIT II patient population. Characteristics were balanced across therapy groups and no statistical differences were found during data analysis as indicated by the p-values in the table.

Table C-4. Patient population characteristics

Characteristic	ICD Patients (n=742)	Conventional Therapy Patients (n=490)	p-value
Age at Enrollment			
> 65 years (patients, %) Mean ± Standard Deviation (years)	397 (53.5%) 64.4 ± 10.4	262 (53.5%) 64.6 ± 10.3	0.99
Gender (patients, %)			
Male	623 (83.9%)	417 (85.1%)	0.59
LVEF (%)			
Mean ± Standard Deviation	23.1 ± 5.4	23.2 ± 5.6	0.93
LVEF[a]			
≤ 25% (patients, %)	502 (76.7%)	330 (67.3%)	0.91
New York Heart Association Classification 3 months before enrollment (patients, %)			

Table C-4. Patient population characteristics (continued)

Characteristic	ICD Patients (n=742)	Conventional Therapy Patients (n=490)	p-value
No CHF	179 (24.1%)	129 (26.3%)	0.64
Class I	75 (10.1%)	58 (11.8%)	
Class II	258 (34.8%)	162 (33.1%)	
Class III	187 (25.2%)	111 (22.7%)	
Class IV	33 (4.5%)	20 (4.1%)	
Unknown	10 (1.4%)	10 (2.0%)	
Canadian Heart Association Classification			
Class I	126 (16.9%)	81 (16.5%)	0.62
Class II, III, IV	168 (23.1%)	120 (24.4%)	
Angina Decubitus	35 (4.7%)	15 (3.1%)	
No Angina Pectoris	402 (54.1%)	268 (54.7%)	
Unknown	11 (1.4%)	6 (1.2%)	
Other			
Ventricular arrhythmias requiring treatment (patients, %)	74 (10.0%)	64 (13.1%)	0.24
Atrial Arrhythmias requiring treatment (patients, %)	201 (27.1%)	120 (24.4%)	0.56
History of Hypertension (patients, %)	411 (55.3%)	277 (56.5%)	0.71
Blood Urea Nitrogen (patients, %) > 25 mg %	213 (28.7%)	153 (31.2%)	0.52
Diabetes Mellitus (patients, %)	246 (33.2%)	184 (37.6%)	0.45
Non-CABG Revascularization Procedures (patients, %)	331 (44.6%)	205 (41.8%)	0.56
CABG Surgery (patients, %)	428 (57.7%)	274 (55.9%)	0.53
Permanent Pacemaker (patients, %)	62 (8.4%)	30 (6.1%)	0.22
EP Study prior to enrollment (262 patients)	n=150 (20.2%)	n=112 (22.8%)	0.27
Inducible	8 (5.3%)	2 (1.8%)	0.25

a. Two patients enrolled with EF > 30%.

Medications

Table C-5 on page C-14 provides a summary of the medication utilization for the patients enrolled. The two treatment groups were balanced and appropriately treated with standard cardiac therapy. There were no differences in ACE

inhibitors, beta blockers, or digitalis therapy between the ICD therapy group and the conventional therapy patients.

Table C-5. Patient population medication therapy

Medication	ICD Patients (n = 742)	Conventional Therapy Patients (n = 490)	p-value
ACE inhibitor use (patients, %)			
Baseline/Enrollment	574 (77.4%)	377 (76.9%)	0.47
Last Follow-up	533 (71.8%)	363 (74.1%)	0.31
Amiodarone use (patients, %)			
Baseline/Enrollment	49 (6.6%)	36 (7.3%)	0.41
Last Follow-up	94 (12.7)	51 (10.4%)	0.23
Antiarrhythmic use (patients, %)			
Baseline/Enrollment	18 (2.4%)	15 (3.1%)	0.37
Last Follow-up	21 (2.8%)	12 (2.4%)	0.43
Aspirin use (patients, %)			
Baseline/Enrollment	503 (67.8%)	344 (70.2%)	0.30
Last Follow-up	477 (64.3%)	332 (67.8%)	0.20
Beta blocker use (patients, %)			
Baseline/Enrollment	469 (63.2%)	295 (60.2%)	0.28
Last Follow-up	529 (71.3%)	351 (71.6%)	0.46
Digitalis use (patients, %)			
Baseline/Enrollment	441 (59.4%)	277 (56.5%)	0.29
Last Follow-up	451 (60.8%)	290 (59.2%)	0.41
Diuretics use (patients, %)			
Baseline/Enrollment	541 (72.9%)	379 (77.3%)	0.09
Last Follow-up	562 (75.7%)	396 (80.8%)	0.04
Lipid Lowering use (patients, %)			
Baseline/Enrollment	492 (66.3%)	315 (64.3%)	0.37
Last Follow-up	556 (74.9%)	339 (69.2%)	0.04
Sotalol use (patients, %)			

Table C-5. Patient population medication therapy (continued)

Medication	ICD Patients (n = 742)	Conventional Therapy Patients (n = 490)	p-value
Baseline/Enrollment	7 (0.9%)	3 (0.6%)	0.38
Last Follow-up	18 (2.4%)	4 (0.8%)	0.05

All Cause Mortality

The Kaplan Meier mortality curves depicting mortality for the two groups are shown in Figure C-3 on page C-15. Although the conventional and ICD survival curves remain close during the first nine months, they progressively separate thereafter. Table C-6 on page C-15 presents information derived from these curves, with the conclusion that 3-year cumulative all-cause mortality is estimated to be reduced by 29 percent in those with an ICD.

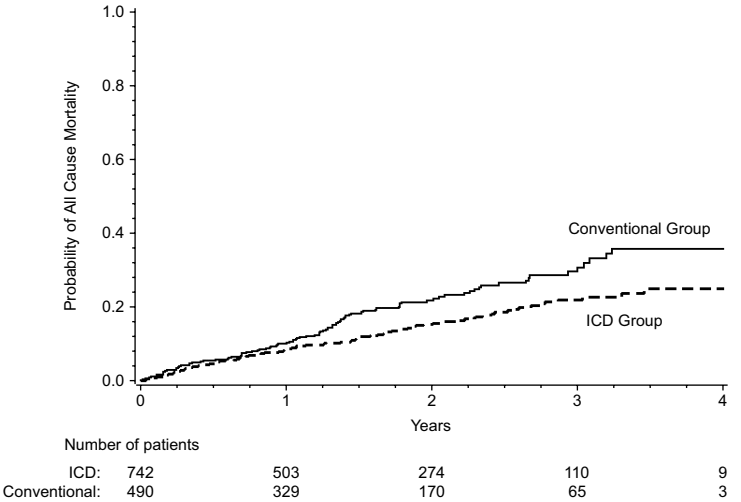


Figure C-3. Kaplan-Meier Mortality Curve: Conventional vs. ICD groups

Table C-6. Cumulative mortality and percentage reduction

Year	Conventional Arm	ICD Arm	Difference	Reduction	CI[a]%	p-value[b]
1 Year	9.9	8.8	1.1	11%	-29, 39	0.53

Table C-6. Cumulative mortality and percentage reduction (continued)

Year	Conventional Arm	ICD Arm	Difference	Reduction	CI[a]%	p-value[b]
2 Years	21.5	15.5	6.0	28%	5, 46	0.02
3 Years	30.4	21.6	8.8	29%	6, 46	0.02

a. Indicates Confidence Interval for the percentage reduction in cumulative mortality. The cumulative mortality (and associated standard errors) is taken from the Kaplan-Meier analyses; percentage reduction analyses are based on a log transform method.
b. For null hypothesis that the percentage (%) reduction is zero.

The pre-specified primary analysis of the trial was based on computation of a hazard ratio, based on an assumption that the two survival curves satisfy a proportional hazards condition (one is a power —the 'hazard ratio'— of the other), and recognizing the sequential stopping rule of the trial. The hazard ratio is interpreted as the ratio of instantaneous risks of dying, at each point in time, in the two treatment groups. The hazard ratio for the ICD group relative to the conventional therapy group was found to be 0.69, indicating a 31percent reduction in instantaneous risk (95 percent confidence interval, 0.51 to 0.93; p=0.016, reduced from p=0.027 when reaching the stopping boundary, by incorporation of lagged data). The Cox regression analyses used for this purpose were stratified by enrollment centers, thus allowing for somewhat different patient pools at differing locations.

The proportional hazards assumption was evaluated by several standard statistical methods, all providing support. One method is derived from finding parallelism in so-called log (-log) plots of the cumulative hazards. Another is from fitting models that allow for differing hazard ratios in differing intervals of time, and demonstrating that any apparent differences among the period-specific hazard ratios can be attributed to chance. One such analysis is summarized in Table C-7 on page C-16.

Table C-7. Year-specific hazard ratio (HR)

Year	Estimate	CI
1 Year	0.87	0.59, 1.29
2 Years	0.56	0.29, 1.07
3+ Years	0.61	0.28, 1.34
Overall	0.69	0.51, 0.93

The p-value = 0.16 for differences among the 3 HRs, and the p-value = 0.016 for the overall HR. The exponential mortality curves fit the data very well, with risks of mortality of 0.0100 each month for patients in the conventional

therapy group and 0.0069 each month in the ICD group, with the ratio, 0.69, in agreement with that reported above.

Verification of ICD Shock Therapy Treatment

Of the 710 patients that were implanted with an ICD, 134 received appropriate therapy for ventricular tachycardia/ventricular fibrillation (VT/VF) and the probability of therapy increased over time. There was a 34 percent cumulative probability that ICD patients received therapy from the device for VT/VF within three years (Figure C-4 on page C-17). The probability of first appropriate shock for VF only at one year was 4 percent and increased to 10 percent after four years. These percentages are closely related to the survival probability differences observed between the ICD and conventional therapy groups (1 percent and 11 percent, respectively) as shown in Figure C-3 on page C-15.

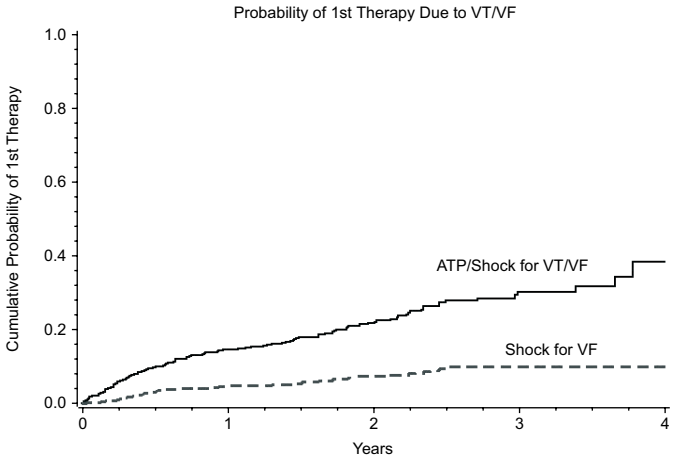


Figure C-4. Probability of first therapy due to VT/VF

The probability of appropriate ICD shocks for ventricular fibrillation (Figure C-4 on page C-17) correlates closely to the difference in the cumulative number of deaths between the ICD and conventional groups (Figure C-3 on page C-15).

Hospitalization Results

The rate of occurrence of patients requiring hospitalization due to adverse events was 0.29 per year of observation in both the conventional therapy patients and in the ICD patients. Table C-8 on page C-18 provides the summary of all hospitalizations that occurred as a result of adverse events. Adverse events that resulted in hospitalizations do not differ significantly between groups.

Table C-8. Adverse events requiring hospitalizations (Rate/Year)

Treatment Group	Cumulative Years of Observation	Total Number of Individuals with Adverse Events	Rate per Year of Individuals with Adverse Events	p-value
Conventional (n=490)	703.6	201 (41%)	0.29	0.85
ICD Therapy Group (n=742)	1155.97	337 (45%)	0.29	

Table C-9 on page C-18 provides a summary of hospitalizations that were required as a result of congestive heart failure (CHF) related adverse events. There were 78 of the 490 patients in the conventional group and 161 of the 742 ICD patients who had one or more hospitalizations that did not result in death. The annual rate of hospitalization for CHF for each treatment group was calculated by dividing the number of patients with one or more hospitalizations for new or worsening CHF by the cumulative years of observation. The rate of hospitalization for CHF per year was somewhat higher in the ICD group (161/115.97 = 0.14) compared to the conventional therapy group (78/703.6 = 0.11); however, this difference in the rate of hospitalization for CHF was not statistically significant (p=0.11).

Table C-9. Heart failure adverse events requiring hospitalization (Rate/Year)

Treatment Group	Cumulative Years of Observation	Total Number of Individuals with Adverse Events	Rate per Year of Individuals with Adverse Events	p-value
Conventional (n=490)	703.6	78 (16%)	0.11	0.11
ICD Therapy Group (n=742)	1155.97	161 (22%)	0.14	

Reasons for Crossover

The MADIT II study was an intention-to-treat analysis, therefore, any patient receiving therapy outside of their randomized therapy group was counted as a crossover. Table C-10 on page C-18 details crossovers by treatment group.

Table C-10. Reasons for crossovers by treatment group

Description	ICD Therapy (n=742)	Conventional Therapy (n=490)
Refusal of therapy	21	0
Met ICD implant criteria	N/A	21
Heart transplant	9	0
Sepsis related to CABG surgery	1	0

Table C-10. Reasons for crossovers by treatment group (continued)

Description	ICD Therapy (n=742)	Conventional Therapy (n=490)
Nonconversion of arrhythmia	1	0
Physician Discretion	0	1
Total Crossovers (54)	32	22

A crossover patient was defined as a patient who, at the time of a specified data cutoff date, was receiving treatment that was different than their originally randomized assignment. Crossovers from the conventional therapy group to the ICD group were strongly discouraged unless a patient was determined to have a strong clinical justification such as positive inducibility during EP testing or spontaneous ventricular arrhythmia event(s) requiring hospitalization that would be an approved indication for receiving an ICD.

Follow-up Compliance

The compliance rate is calculated by dividing the number of successful visits by the sum of the visits expected for the designated month sequence. Table C-11 on page C-19 details reported visit compliance in six-month intervals. Compliance to follow-up was ≥ 88 percent at the majority of required visits. There was no difference in the follow-up rates between the two groups.

Table C-11. Follow-up compliance

Follow-up Sequence Month	% Compliant ICD Group	% Compliant Conventional Therapy Group
1–6 months	98	96
7–12 months	97	95
13–18 months	96	93
19–24 months	95	93
25–30 months	93	89
31–36 months	97	90
37–42 months	95	85

Table C-11. Follow-up compliance (continued)

Follow-up Sequence Month	% Compliant ICD Group	% Compliant Conventional Therapy Group
43–51 months	96	100
Total Average	96	94

Subgroup Analysis of MADIT II Patient Population

Figure C-5 on page C-20 provides the hazard ratios and 95 percent confidence intervals for death from any cause in the ICD group as compared to the conventional therapy group according to selected clinical characteristics.

The hazard ratios in the various subgroups were similar, with no statistically significant interactions. The dotted vertical line represents the results for the entire study (nominal hazard ratio, 0.66, without adjustment for the stopping rule). The horizontal lines indicate nominal 95 percent confidence intervals.

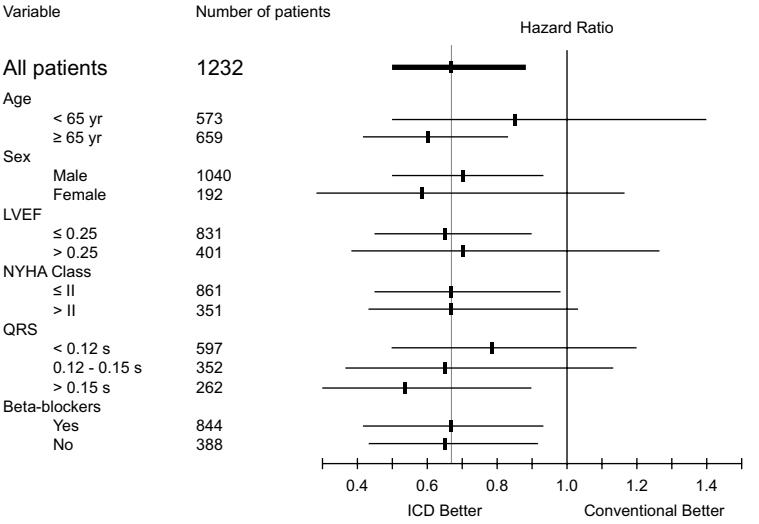


Figure C-5. Hazard ratios and 95 percent confidence intervals

Analysis of Inducibility as a Risk Factor

There were 583 patients enrolled in MADIT II who had EP testing performed either prior to or during ICD implant. The definition for inducibility was the same one used for the MADIT I study. Of these 583 patients, 373 (63 percent) were not inducible and the remaining 210 (36 percent) were inducible. Of the 210 patients who were inducible, 180 (88 percent) had EP testing performed

at implant using a catheter method and 24 (12 percent) using the ICD for induction; there was no data on the method of induction for 6 patients.

The Occurrence of ICD Therapy for VT, VF, or VT/VF Combined

Therapy for VT was defined as antitachycardia pacing (ATP) or ICD shock delivered by the device in an attempt to stop an arrhythmia as reported by the enrolling center. Therapy for VF was defined as the delivery of ICD shock therapy. The endpoint for VT/VF was defined by the occurrence of either VT or VF therapy. The occurrence of therapy for each of these groups is provided in Table C-12 on page C-21. All analyses were Cox regression analyses, stratified by enrollment center, with time to VT, time to VF or time to VT/VF therapy as the respective endpoint.

Table C-12. ICD patients receiving one or more therapies

Type of ICD Therapy[a]	Number of Patients	Percent of Patients with Therapy Episodes
VT (ATP or shock)	89	15.4%
VF (Shock only)	36	6.2%
VT/VF VF (ATP + shock)	114	19.7%

a. Some patients received both types of therapy.

Predictions of VT and VF Therapy in ICD Patients

A statistical analysis was performed to evaluate whether inducibility at EP testing provides predictability of the potential effectiveness of an ICD. To this end, the occurrence of each of the three endpoints defined above (VT, VF and VT/VF), in ICD patients with EP testing were evaluated. Analyses were done by Cox proportional hazards regression, stratified by enrollment center. (Table C-13 on page C-22)

A list of potential risk factors was considered for these endpoints, such as age, gender, and standard cardiological variables like NYHA class, EF, etc., and developed a parsimonious regression model in the 583 ICD patients identified above. GENDER and BUN (dichotomized at up to 25 versus 26 and over) were observed as potential risk factors for these endpoints, with males and elevated BUN associated with increased occurrence of these endpoints. Further analysis investigated whether inducibility added any additional, independent predictive power for each of these endpoints.

The conclusion was that inducibility increases the risk of VT events by perhaps 60 percent (p=0.07) and decreases the risk of VF events by perhaps 50

percent (p=0.08). As a consequence of these opposite directional effects of similar magnitudes, there was no reliable evidence that inducibility affects the frequency of VT/VF events (p=0.26); it may be associated with a slight increase since VT events occur more frequently than VF.

Table C-13. Therapy predictability based on induced arrhythmia

Therapy Delivered for the Following Type of Arrhythmia	Inducible	
	Yes	No
VF		
Yes	7	29
No	202	341
VT		
Yes	43	46
No	166	324
VT/VF		
Yes	48	66
No	161	304

CLINICAL STUDY - VENTAK AV II DR

APPENDIX D

CLINICAL STUDY POPULATIONS

Guidant ICDs have been demonstrated to be safe and effective in patient populations including, but not limited to, those with:

- Prior myocardial infarction and an ejection fraction (EF) ≤ 30%, based on the Guidant sponsored MADIT II clinical study. (Guidant devices were the only devices studied in the MADIT II clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT II population.)

- Prior myocardial infarction, left ventricular ejection fraction of ≤ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia, based on the Guidant sponsored MADIT clinical study. (Guidant devices were the only devices studied in the MADIT clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT population.)

CHRONIC IMPLANT STUDY - VENTAK AV II DR

Since this pulse generator system has many of the same therapies, diagnostics, and electrophysiology testing features as the VENTAK AV III DR system, the VENTAK AV II DR implant study, which was used to support the VENTAK AV III DR system, was used also to support this pulse generator system.

The purpose of the implant study was to confirm that the VENTAK AV II DR could sense, detect, and deliver ventricular tachyarrhythmia therapy. In addition, the adaptive-rate pacing function was evaluated by exercise testing. Fifty-two patients were enrolled and implanted in 18 centers outside the U.S. between June 27 and October 21, 1997. A total of 53 devices were used throughout the duration of the study and consisted of VENTAK AV II DR, models 1821 and 1826. The VENTAK AV II was approved for commercial distribution in the U.S. on March 13, 1998.

This clinical data remains applicable to these pulse generator systems since there are no significant differences between tachyarrhythmia therapy and adaptive-rate pacing capabilities.

Patients Studied

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

Methods

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

Results

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

Forty patients had the sensor programmed "ON" and performed an exercise test. The remaining patients were not tested for the following reasons: patient had sinus rhythm and did not require adaptive-rate pacing, patient could not tolerate exercise testing, and patient death. Nominal settings were appropriate

for 80% of patients tested; in all cases, the physician was able to program appropriate adaptive-rate settings to accommodate patient need (Table D-1 on page D-3).

Table D-1. Implant study results

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

CLINICAL STUDY - VITALITY

APPENDIX E

CLINICAL STUDY POPULATIONS

Guidant ICDs have been demonstrated to be safe and effective in patient populations including, but not limited to, those with:

- Prior myocardial infarction and an ejection fraction (EF) ≤ 30%, based on the Guidant sponsored MADIT II clinical study. (Guidant devices were the only devices studied in the MADIT II clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT II population.)

- Prior myocardial infarction, left ventricular ejection fraction of ≤ 35%, and a documented episode of nonsustained VT, with an inducible ventricular tachyarrhythmia, based on the Guidant sponsored MADIT clinical study. (Guidant devices were the only devices studied in the MADIT clinical trial. The trial demonstrated these devices to be safe and effective in the MADIT population.)

CHRONIC IMPLANT STUDY - VITALITY

The purpose of this study was to evaluate the safety and effectiveness of Guidant VITALITY family devices with Automatic Intrinsic Rhythm ID. This clinical study was a single-arm, prospective, multi-center study. There were a total of 100 patients enrolled at 21 US investigational centers between December 3, 2002 and January 10, 2003.

Patient Population

One hundred patients were enrolled in this study and 96 patients received investigational devices. The mean age of the patients implanted with the VITALITY device was 67.3 ± 10.8 years old. The mean left ventricular ejection fraction was 30.4% (range 11.0% - 71.0%). Seventy-eight (78) patients (81.3%) were male. The primary cardiovascular disease (42.1%) was coronary artery disease (CAD) and the primary tachyarrhythmia (38.5%) was monomorphic ventricular tachycardia (MVT).

Methods

A prospective, multi-center, nonrandomized clinical study evaluated the safety and effectiveness of the VITALITY device in humans. Ninety-six patients

selected from the investigator's general patient population who met the indications for use of the VITALITY device were followed through pre-discharge, 2-week and 1-month follow-ups and continued every 3 months thereafter until study closure.

Results

A total of 100 patients were enrolled in this study. Of these, 96 patients were successfully implanted, with 4 intents. Ninety-three (93) patients finished their 1-month follow-up per the study protocol. All primary and secondary endpoints of this study were met. The results from this study provide evidence of the safety and effectiveness of the VITALITY with Automatic Intrinsic Rhythm ID algorithm (Table E-1 on page E-2).

Table E-1. VITALITY Chronic Study Results

Safety Endpoints			
VT/VF Detection Time			3.43 seconds
Primary Endpoints			
Sensitivity			
Induced VT/VF			100%
Spontaneous VT/VF			100%
Specificity—Induced			
Rhythm	**Physician/Annotation**	**Device Decision–SVT**	**Specificity**
Atrial Fibrillation	71	68	95.8%
Atrial Flutter	94	88	93.6%
Sinus Tachycardia	7	5	71.4%
Total Induced	172	161	93.6%
Specificity–Spontaneous			
Rhythm	**Physician/Annotation**	**Device Decision–SVT**	**Specificity**
Atrial Fibrillation	65	65	100%
Atrial Flutter	31	28	90.3%
Sinus Tachycardia	37	32	86.5%
Other	7	7	100%
Total Spontaneous	140	132	94.3%[a]
Combined Specificity[b]	**312**	**293**	**93.9%**

Table E-1. VITALITY Chronic Study Results (continued)

Secondary Endpoints	
Acute Automatic Rhythm ID Accuracy (2 weeks)	100%
Automatic Rhythm ID Accuracy (1 month)	97.7%
Manual Rhythm ID Accuracy (1 month)	100%

a. GEE adjusted specificity = 93.7%
b. Combined specificity includes both Induced and Spontaneous data.

ACUTE STUDY - VITALITY

The VITALITY ICD was compared to a commercially available ICD (VENTAK PRIZM, or VENTAK PRIZM 2 ICD) in an acute (nonimplant) paired study of 50 patients enrolled at nine investigating centers between March 8, 2001 and July 24, 2001. A total of 47 patients were tested with the study device, followed by a control device at the time of a Guidant commercially approved (VENTAK PRIZM, model 1851 or VENTAK PRIZM 2, model 1861) implantation.

The purpose of the acute study was to demonstrate that the addition of an SVT detection enhancement and brady features did not adversely impact normal ICD sensing and detection functionality. A total of 50 patients were tested in nine U.S. centers.

Patients studied

The patients (38 M/9 F) had a mean age of 66 years (range 37 to 90) and a left ventricular ejection fraction of 32% (range 10% to 62%). Most (40%) presented with monomorphic ventricular tachycardia (MVT) and nonsustained VT as their primary arrhythmia. Of the patients studied, 87 percent presented with coronary artery disease or ischemic cardiomyopathy.

Methods and statistics

The acute study was done in the operating room or electrophysiology laboratory without implantation of the study device. The primary endpoint was to determine that VT/VF detection time for induced episodes is within two seconds of the VENTAK PRIZM or VENTAK PRIZM 2 detection time.

Results

A total of 50 patients were enrolled in the acute study. Of those, 47 patients were successfully tested with the system per study protocol; there were two attempted procedures and one intent. There was one clinical

complication and two observations reported in the acute study, all of which were non-investigational device related. No patient deaths were reported. The VT/VF detection time of the VITALITY ICD was found to be within two seconds of the VENTAK PRIZM 2 detection time, leading to the conclusion that activating the additional VITALITY features does not have a negative effect on the existing ICD sensing and detection functionality (Table E-2 on page E-4).

Table E-2. Acute study results

Study Endpoint	VITALITY (Mean ± std) N	VENTAK PRIZM 2 DR (Mean ± std) N
VT/VF Detection Time (seconds)	3.60 ± 0.60 N = 47	3.52 ± .057 N = 47
p-value: <0.001		

CLINICAL STUDY - SUMMARY OF GDT1000 SENSING ACUTE STUDY

APPENDIX F

CLINICAL STUDY POPULATIONS

GDT1000 study included patients indicated for a CRT-D device. Excluded from the study were patients meeting any of the following criteria:

- Having no intrinsic P and/or R waves at implant
- Having a pre-existing unipolar pacemaker that was not to be explanted/abandoned
- Enrolled in a concurrent study that would confound the study results
- Having ventricular tachyarrhythmias associated with a reversible cause (e.g., digitalis toxicity, hypoxia, sepsis, transient electrolyte imbalance, acute myocardial infarction, electrocution, or drowning)
- Women who were pregnant or planned to become pregnant
- Having a prosthetic mechanical tricuspid heart valve

STUDY METHODS

This clinical investigation was a 50 patient, multi-center, acute study conducted at seven (7) centers in the United States. The main purpose of this clinical investigation was to characterize the performance of the new Automatic Gain Control (AGC) sensing platform, with the Dynamic Noise Adjustment (DNA) feature, that is used in both COGNIS and TELIGEN devices. The AGC sensing platform was studied using a Guidant Acute Sensing Device (GASD) system, a non-implantable device containing the COGNIS/TELIGEN system board, hardware, and firmware required for sensing intracardiac signals. The study enrolled a total of 50 patients and was conducted in two phases. In the first phase, 28 of 30 patients completed protocol testing. The algorithm was modified after the first phase, and it was re-evaluated in the second phase, in which 17 of 20 patients completed protocol testing. Of the five patients who did not complete testing in the two phases, three were attempts, and two were intents.

Protocol Testing

Four scenarios were tested, including different combinations of sensed atrial signals (AS), paced atrial signals (AP), sensed ventricular signals (VS), and paced ventricular signals (VP), i.e., AS/VS, AS/VP, AP/VS, and AP/VP. Sensing algorithm performance was analyzed from patients' real-time electrograms (EGM) and electronic signals. Primary analysis was performed by visually reviewing the EGM and markers of the printed strips for proper sensing, as well as for instances of undersensing and oversensing.

Additional analysis included tabulating the sensed and paced events stored in the patient data files from the patient CD-ROM. During this tabulation, unexpected events were noted. An example of an unexpected event is a sensed event during an AP/VP testing scenario. The sensed event could be a real event, such as a PVC, or an oversensed event. These unexpected events were evaluated by viewing the electronic signals stored in the patient data files and correlating these signals to the printed strips.

Statistical Analysis

The sensitivity, specificity, positive predictive value, rate of oversensing, and rate of undersensing of the sensing algorithm were analyzed for each chamber. A true positive (TP) is the number of intrinsic/paced signals appropriately sensed, a false positive (FP) is the number of intrinsic/paced signals from the opposite chamber oversensed, a false negative (FN) is the number of intrinsic/paced signals undersensed, and a true negative (TN) is the number of intrinsic/paced signals from the opposite chamber appropriately not sensed. The sensing sensitivity was calculated as TP/(TP+FN), specificity as TN/(TN+FP), positive predictive value (PPV) as TP/(TP+FP), rate of oversensing as FP/(TP+FP), and rate of undersensing as FN/(TP+FN).

The sensing performance results from the first phase of the study are provided and compared to the results from the second phase in order to demonstrate the improvement in the operation of the updated sensing algorithm following the between-phase changes. Results from the second phase of the study are the most clinically relevant, as they reflect the performance of the final sensing algorithm implemented in the COGNIS/TELIGEN devices.

The GDT1000 protocol did not pre-specify acceptable sensitivities, specificities, PPV, rates of oversensing, or rates of undersensing for the RA, RV, and LV channels.

STUDY RESULTS

Patient Characteristics

The table below shows the characteristics of the patients implanted or attempted (Table F-1 on page F-3).

Table F-1. All patients implanted or attempted, Phase 1 and Phase 2

Characteristic	Measurement	Phase 1 Result (N=29)	Phase 2 Result (N=19)
Age at implant	Mean ± SD	65.8 ± 12.2	68.1 ± 9.6
	Range	[44.6, 85.5]	[51.3, 81.8]
Gender [N (%)]	Female	14 (48.0)	14 (74.0)
	Male	15 (52.0)	5 (26.0)
NYHA Class [N (%)]	III	27 (93)	19 (100)
	IV	2 (7)	0 (0)
LVEF (%)	Mean ± SD	22.4 ± 7.7	23.5 ± 6.4
	Range	[10.0, 35.0]	[15.0, 35.0]
QRS Duration	Mean ± SD	161± 29	149± 30
	Range	[124, 248]	[106, 220]
Cardiac Disease [N (%)]	Nonischemic Cardiomyopathy	14 (48)	7 (37)
	Ischemic Cardiomyopathy, CAD	10 (34)	9 (47)
	Hypertension	3 (10)	0 (0)
	Coronary Artery Disease (CAD)	1 (3)	0 (0)
	Ischemic Cardiomyopathy, no CAD	1 (3)	3 (16)
	Valvular Heart Disease	0 (0)	1 (5)
	Other	0 (0)	1 (5)

Lead Position

In this study, the position of each lead was per physician's discretion. A majority of the atrial leads in the first/second phase of the study were placed in the right atrial appendage (19/12) with the remaining placed in the lateral wall (5/2), septal wall (2/3), and unspecified location (1/0). A majority of the right ventricular leads were implanted in the right ventricular apex, with the remaining

placed in the septal wall (0/1) and unspecified location (1/0). A majority of the left ventricular leads were implanted in the lateral, postero-lateral, or posterior wall (21/15), with the remaining placed in an antero-lateral, anterior, or postero-septal location (4/3).

Lead Configurations

In this study, both RA and RV leads used a bipolar configuration, which was not programmable. The LV lead configuration programming was per physician's discretion. In the first phase, 20 patients had LV sensing programmed to the LVtip>>LVring configuration, four to LVtip>>RVcoil, and one to LVtip>>Can. In the second phase, 13 patients had LV sensing programmed to the LVtip>>LVring configuration, and four to LVtip>>RVcoil.

Lead Performance

The lead performance, including pacing threshold, pacing impedance and sensing amplitude, were measured at implant by a commercially available Pacing System Analyzer (PSA). The results are provided in the table below (Table F-2 on page F-4).

Table F-2. Lead performance

Measurement	Lead Location	Number of Leads: Phase 1	Mean ± SD: Phase 1	Number of Leads: Phase 2	Mean ± SD: Phase 2
Pacing Impedance (Ω)	Left Ventricle	25	1034 ± 394	18	779 ± 227
	Right Atrium	28	520 ± 161	17	519 ± 112
	Right Ventricle	29	816 ± 263	18	649 ± 206
Pacing Threshold (V)	Left Ventricle	25	1.9 ± 1.4	18	1.3 ± 1.0
	Right Atrium	28	1.1 ± 0.7	16	1.2 ± 0.6
	Right Ventricle	29	1.0 ± 0.4	18	0.8 ± 0.3
Sensing Amplitude (mV)	Left Ventricle	25	14.1 ± 7.6	18	13.2 ± 7.3
	Right Atrium	28	2.9 ± 1.5	16	3.7 ± 3.3
	Right Ventricle	29	12.3 ± 6.2	18	13.4 ± 7.0

Sensing Performance

In the first phase of the study, a total of 55,207 signals were recorded, including 54,151 appropriate sensed intrinsic and paced beats and 1,056 inappropriate

sensed events (223 undersense and 833 oversense events). The sensing algorithm used in the first phase achieved the sensitivities, specificities, positive predictive values (PPV), rates of undersensing (1-sensitivity), and rates of oversensing (1-PPV) are summarized in the table below (Table F-3 on page F-5).

Table F-3. Summary of Sensing Performance - First Phase

	Sensitivity (Rate of Undersensing)	Specificity	Positive Predictive Value (Rate of Oversensing)	Appropriate Sensed Beats	Inappropriate Sensed Beats: Undersense	Inappropriate Sensed Beats: Oversense
Right Atrial Channel	100% (0%)	96.81%	97.03% (2.97%)	19,478	0	615
Right Ventricular Channel	100% (0%)	98.94%	98.86% (1.14%)	18,439	0	216
Left Ventricular Channel	98.63% (1.37%)	99.99%	99.99% (0.01%)	16,054	223	2
Totals				54,151	223	833

In the second phase of the study, a total of 35,998 signals were recorded including 35,831 appropriate sensed intrinsic and paced beats and 171 inappropriate sensed events (2 undersense and 169 oversense events). The upgraded sensing algorithm used in the second phase achieved the sensitivities, specificities, positive predictive values (PPV), rates of undersensing (1-sensitivity), and rates of oversensing (1-PPV) summarized in the table below; the table also summarizes the results of the analysis from the second phase (Table F-4 on page F-5).

Table F-4. Summary of Sensing Performance - Second Phase

	Sensitivity (Rate of Undersensing)	Specificity	Positive Predictive Value (Rate of Oversensing)	Appropriate Sensed Beats	Inappropriate Sensed Beats: Undersense	Inappropriate Sensed Beats: Oversense
Right Atrial Channel	100% (0%)	98.64%	98.54% (1.46%)	11,372	0	168
Right Ventricular Channel	100% (0%)	100%	100% (0%)	12,230	0	0

Table F-4. Summary of Sensing Performance - Second Phase (continued)

	Sensitivity (Rate of Undersensing)	Specificity	Positive Predictive Value (Rate of Oversensing)	Appropriate Sensed Beats	Inappropriate Sensed Beats: Undersense	Inappropriate Sensed Beats: Oversense
Left Ventricular Channel	99.98% (0.016%)	99.99%	99.99% (0.008%)	12,227	2	1
Totals				35,831	2	169

Comparing the performance between the two phases, there were 1,056 inappropriate sensing events out of 55,027 signals (1.919%) in the first phase of the study, and a total of 171 inappropriate sensing events out of 35,998 signals (0.475%) in the second phase of the study, reflecting a 75.2% reduction in inappropriate sensing events from phase one to two.

Oversense Events

During the analysis of the first phase data, some unexpected oversense events were identified. There were a total of 831 oversense events in the RA (615) and RV (216) channels in phase one. The majority of the RA and RV oversense events were attributed to an artificial event introduced while pacing. This type of oversense was observed in 6 patients in the RA channel and 7 patients in the RV channel. The results for the second phase of the study demonstrated that oversensing artificial events observed in the first phase of the study were successfully eliminated by using the upgraded GASD system. There were no artificial events introduced in the second phase of the study.

In the second phase, a total of 168 oversense events in the RA channel were observed in one patient. This patient had an intrinsic P-R interval greater than 300 ms. In order to complete the AP/VS test scenario, the device was programmed with a LRL = 80 bpm and AV Delay = 300 ms, which is the maximum allowable AV Delay in a CRT-D device. At the end of the AV Delay, no intrinsic activity occurred and the device paced both ventricles. These paced beats were oversensed by the atrial channel. If the atrial blanking period were programmed to a larger value, atrial oversensing would have been eliminated. Therefore, excluding this patient's AP/VS test scenario from the analysis, there were no undersensing or oversensing events in the RA channel.

In one patient, the single oversense event in the LV channel was caused by noise.

Undersense Events

LV undersense events (223) in the first phase of the study primarily occurred in one patient whose LV intrinsic amplitude was less than 1.0 mV, which is much smaller than the clinically acceptable threshold. This small LV intrinsic amplitude resulted in undersensing some LV events.

Two LV undersense events occurred in the second phase of the study. A potential cause for the LV undersense events was premature ventricular contractions while atrial pacing.

CONCLUSIONS

This acute study demonstrated excellent sensitivity (100% in the RA, 100% in the RV, and 99.98% in the LV channels), specificity (98.64% in the RA, 100% in the RV, and 99.99% in the LV channels), and positive predictive values (98.54% in the RA, 100% in the RV, and 99.99% in the LV channels). In conclusion, the new sensing platform evaluated in the GDT1000 study will be implemented in COGNIS/TELIGEN devices.

By excluding one patient's oversensed events that could be eliminated by programming a longer atrial blanking period, the modified specificity and positive predictive values in the RA channel are 100% and 100% (oversensing eliminated). While the GDT1000 protocol did not pre-specify acceptable sensitivities, specificities, or PPV values, a Sensing Tape Testing DAT report for COGNIS/TELIGEN on file at Boston Scientific CRM[1] reported a 99.96% sensitivity (0.04% Undersensing) and a 99.97% positive predictive value (0.03% Oversensing) for the RV channel in normal sinus rhythm. Using the RV values as a benchmark (RA and LV values were not calculated), the results of this study compare favorably.

1. Sensing Tape Testing Design Analysis Test report 100019-687 Revision A describes testing performed in which the COGNIS/TELIGEN sensing platform is modeled and compared to a previous Guidant device, CONTAK RENEWAL TR. The analysis was performed using 219 patient rhythms from the Gold Development Database, including normal sinus rhythm and atrial and ventricular arrhythmias.

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