When a detection window becomes satisfied, the pulse generator begins calculating for sudden Onset in a two-stage sequence.

- Stage 1 measures the ventricular intervals prior to the start of the episode and locates the pair of adjacent intervals (pivot point) where the cycle length decreased the most. If the decrease in cycle length is equal to or greater than the programmed Onset value, stage 1 declares sudden Onset.

- Stage 2 then compares additional intervals. If the difference between the average interval before the pivot point and 3 out of the first 4 intervals following the pivot point is equal to or greater than the programmed Onset Threshold, stage 2 declares sudden Onset.

If both stages declare the rhythm sudden, therapy will be initiated. If either stage indicates a gradual onset, initial ventricular therapy will be inhibited in the lowest zone. Therapy will not be inhibited by Onset if:

- The rate accelerates to a higher ventricular zone

- Information from the atrial lead determines that the RV rate is faster than the atrial rate (V Rate > A Rate programmed to On)

- The SRD timer expires

Onset is measured using RV intervals only. It can be programmed as a percentage of cycle length or as an interval length (in ms). It is limited to the lowest therapy zone of a multi-zone configuration. The selected Onset value represents the minimum difference that must exist between intervals that are above and below the lowest programmed rate threshold. The pulse generator performs Onset calculations (even when the feature is programmed to Off) for all episodes except induced or commanded episodes. The measured Onset results from a two-stage calculation are stored in therapy history. This stored data may be used to program an appropriate Onset value.

Sustained Rate Duration (SRD)

Sustained Rate Duration allows delivery of the programmed ventricular therapy when a tachycardia is sustained for a programmed period beyond Duration, but the programmed therapy inhibitors (Vector Timing and Correlation, AFib Rate Threshold, Onset, and/or Stability) indicate to withhold therapy (Figure 3-21 on page 3-36).

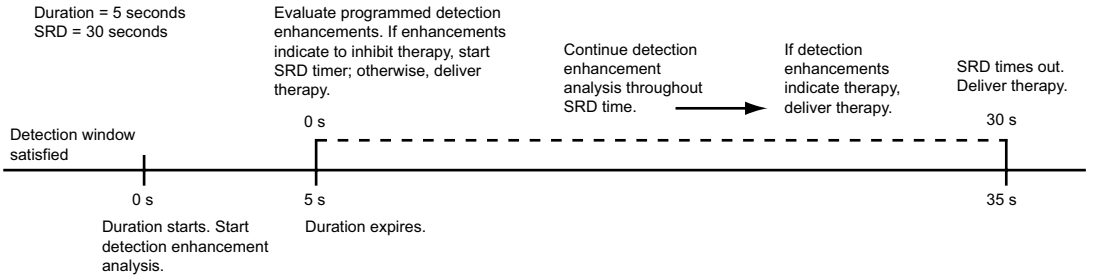


Figure 3-21. Combination of Onset OR Stability, SRD programmed on

SRD is available in a zone only when an inhibitor enhancement is programmed on in that zone. When the Rhythm ID detection enhancement suite is enabled, SRD may be programmed separately for the VT and VT-1 zones.

- If an inhibitor is withholding ventricular therapy delivery and the Rate criterion in the lowest zone is maintained, the programmed SRD timer begins at the end of the first zone's completed Duration.

- If the detection window in the lowest zone is maintained for the programmed SRD period, the programmed ventricular therapy will be delivered at the end of the VT-1 SRD period if VT-1 SRD is programmed and the rhythm is in the VT-1 zone. Therapy will be delivered at the end of the VT SRD period if VT SRD is programmed and the rhythm is in the VT zone.

- If the rate accelerates to a higher ventricular zone, detection enhancements are not programmed to On in the higher zone, and the Duration for the higher zone expires, therapy is initiated in that zone without waiting for SRD time-out in a lower ventricular zone. If SRD is programmed to Off, an SRD timer will not start when Duration expires, thus allowing detection enhancements to potentially inhibit therapy indefinitely.

An independent Post-Shock SRD value may be programmed.

Combinations of AFib Rate Threshold, Stability, and Vector Timing and Correlation

The combination of AFib Rate Threshold, Stability, and Vector Timing and Correlation add specificity to ventricular detection beyond rate and duration. In addition to using AFib Rate Threshold and Stability to identify AF, this combination of enhancements uses Vector Timing and Correlation analysis to differentiate SVT rhythms from VT rhythms based on conduction patterns within the heart.

The AFib Rate Threshold, Stability, and Vector Timing and Correlation detection enhancement combination also includes V Rate > A Rate; both AFib Rate Threshold and V Rate > A Rate are enabled when Atrial Tachyarrhythmia Discrimination is programmed to On. This combination is only available when the Rhythm ID detection enhancement suite is enabled, and only for Initial Detection (Table 3-11 on page 3-37).

If V Rate > A Rate is programmed to On (by programming Atrial Tachyarrhythmia Discrimination to On) and is True, it will take precedence over all inhibitor enhancements.

Table 3-11. AFib Rate Threshold, Stability, and Vector Timing and Correlation combinations and resulting therapy decision if Atrial Tachyarrhythmia Discrimination is programmed to On

Detected Ventricular Rhythm[a b c]	Therapy Decision[d]
Correlated, Unstable, A > AFib Rate Threshold	Inhibit
Correlated, Unstable, A < AFib Rate Threshold	Inhibit
Uncorrelated, Unstable, A > AFib Rate Threshold	Inhibit
Uncorrelated, Unstable, A < AFib Rate Threshold	Treat
Correlated, Stable, A > AFib Rate Threshold	Inhibit
Correlated, Stable, A < AFib Rate Threshold	Inhibit
Uncorrelated, Stable, A > AFib Rate Threshold	Treat
Uncorrelated, Stable, A < AFib Rate Threshold	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. If a Rhythm ID reference template is not available, the detected ventricular rhythm is considered to be Uncorrelated.
c. For post shock detection (if enabled), Vector Timing and Correlation is considered to be Uncorrelated.
d. Decisions to inhibit can be overridden by V > A or expiration of SRD.

When Atrial Tachyarrhythmia Discrimination is programmed to Off, then Vector Timing and Correlation is used for Initial Detection and Stability is used for Post-shock detection. V Rate > A Rate and AFib Rate Threshold are no longer used (Table 3-12 on page 3-37).

Table 3-12. Vector Timing and Correlation and Stability combinations with resulting therapy decision if Atrial Tachyarrythmia Discrimination is programmed to Off

Detection[a b]	Dectected Ventricular Rhythm[a c]	Therapy Decision
Initial	Correlated	Inhibit[d]
Initial	Uncorrelated	Treat

Table 3-12. Vector Timing and Correlation and Stability combinations with resulting therapy decision if Atrial Tachyarrythmia Discrimination is programmed to Off (continued)

Detection[a] [b]	Dectected Ventricular Rhythm[a] [c]	Therapy Decision
Post-shock	Unstable	Inhibit[d]
Post-shock	Stable	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. If Atrial Tachyarrhythmia Discrimination is programmed to Off, then Vector Timing and Correlation is used for Initial Detection, and Stability is used for Postshock Detection.
c. If a Rhythm ID reference template is not available, the detected ventricular rhythm is considered to be Uncorrelated.
d. Decision to inhibit can be overridden by expiration of SRD.

Combinations of AFib Rate Threshold, Stability, and Onset

The combination of AFib Rate Threshold, Stability, and Onset add specificity to ventricular detection beyond rate and duration. This combination of detection enhancements is available only when the Onset/Stability detection enhancement suite is enabled and is available only for Initial Detection. When detection enhancements are enabled, they will act to recommend or inhibit therapy for a specific zone.

If AFib Rate Threshold, Stability, and Onset parameters are all programmed to On, ventricular therapy will be initiated if the rhythm has a sudden onset provided that either the ventricular rate is stable or the atrial rate is less than the AFib Rate Threshold (Table 3-13 on page 3-38).

Table 3-13. AFib Rate Threshold, Stability, and Onset combinations and resulting ventricular therapy

Detected Ventricular Rhythm[a]	Therapy Decision[b]
Gradual, Unstable, A > AFib Rate Threshold	Inhibit
Gradual, Unstable, A < AFib Rate Threshold	Inhibit
Sudden, Unstable, A > AFib Rate Threshold	Inhibit
Sudden, Unstable, A < AFib Rate Threshold	Treat[c]
Gradual, Stable, A > AFib Rate Threshold	Treat
Gradual, Stable, A < AFib Rate Threshold	Inhibit
Sudden, Stable, A > A Fib Rate Threshold	Treat
Sudden, Stable, A < AFib Rate Threshold	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. Decisions to inhibit can be overridden by V > A or expiration of SRD.
c. If V Rate > A Rate is programmed to On and is False, ventricular therapy will be inhibited because the rhythm is unstable.

If V Rate > A Rate is programmed to On and is True, it will take precedence over all inhibitor enhancements.

Combinations of Onset and Stability

When Stability is programmed to inhibit, it may be combined with Onset to provide even greater specificity in classifying arrhythmias.

This combination of detection enhancements is available only when the Onset/Stability detection enhancement suite is enabled and is available only for Initial Detection. The enhancements can be programmed to initiate ventricular therapy if the following options are selected (Table 3-14 on page 3-39):

- Both Onset And Stability indicate to treat
- Either Onset Or Stability indicates to treat

Based on these programming decisions, ventricular therapy is inhibited when any of the following criteria is met:

- If the combination programmed is Onset And Stability, ventricular therapy is inhibited if either parameter indicates that therapy should be withheld; that is, the rhythm is gradual Or unstable (the And condition to treat is not satisfied).
- If the combination programmed is Onset Or Stability, ventricular therapy is inhibited immediately at the end of Duration only if both parameters indicate that therapy should be withheld; that is, the rhythm is gradual and unstable (the Or condition to treat is not satisfied).

In either case, ventricular therapy will be initiated only if the And/Or conditions to treat are satisfied. When these two combinations (And/Or) are used in conjunction with SRD, and the And/Or conditions are not satisfied, ventricular therapy will be inhibited until V Rate > A Rate is True or SRD times out (Table 3-14 on page 3-39).

Table 3-14. Combinations of Onset And Stability and resulting therapy

Detection Rhythm	Onset And Stability Combination[a] [b]	Onset Or Stability Combination[c]
Gradual, unstable	Inhibit	Inhibit
Gradual, stable	Inhibit	Treat

Table 3-14. Combinations of Onset And Stability and resulting therapy (continued)

Detection Rhythm	Onset And Stability Combination[a] [b]	Onset Or Stability Combination[c]
Sudden, unstable	Inhibit	Treat
Sudden, stable	Treat	Treat

a. If the detected ventricular rhythm changes, then the appropriate, corresponding row in the table is evaluated.
b. The And combination is the nominal setting when both are enabled.
c. Decisions to inhibit can be overridden by V > A or expiration of SRD.

TACHYARRHYTHMIA THERAPY

CHAPTER 4

This chapter contains the following topics:

VENTRICULAR THERAPY

The pulse generator can deliver the following types of therapy to terminate VT or VF:

- Antitachycardia pacing (ATP)
- Cardioversion/defibrillation shocks

ATP pacing schemes are bursts of pacing pulses delivered between the ventricular pace/sense electrodes. Shocks are high-voltage biphasic pulses delivered through the shocking electrodes synchronously with detected heart activity.

NOTE: *Tachycardia therapy decisions are based on cardiac cycle length by using RV sensed events only.*

Ventricular Therapy Prescription

A ventricular therapy prescription determines the type of therapy to be delivered in a particular ventricular rate zone. It consists of ventricular ATP and/or shocks. Each ventricular zone may be programmed with independent ventricular therapy prescriptions (Figure 4-1 on page 4-2).

Within each zone, therapy strength must be in ascending order.

Lowest strength → Highest strength

Between zones, therapy strengths are not restricted.

Zone	ATP1[2]	ATP2[2]	QUICK CONVERT ATP	Shock 1[1]	Shock 2[1]	Remaining (Maximum) Shocks[1]
VF	Not available		On/Off	0.1-max J	0.1-max J	max J
VT	All ATP types available	All ATP types available	N/A	0.1-max J	0.1-max J	max J
VT-1	All ATP types available	All ATP types available	N/A	0.1-max J	0.1-max J	max J

[1] In the lowest zone of a multi-zone configuration, some or all of the shocks may be programmed to Off, starting with the maximum shocks first. If the maximum shocks are programmed to Off, then Shock 2 can be programmed to Off. If Shock 2 is programmed to Off, then Shock 1 can be programmed to Off. If the arrhythmia persists in the lowest zone when some or all of the shocks are programmed to Off, no further therapy will be delivered unless the arrhythmia accelerates to a higher zone. A Disable Therapy button is available in the VT or VT-1 zones' therapy window to quickly disable all ATP and Shock therapy in that zone.

[2] Ventricular ATP therapy can be programmed as Off, Burst, Ramp, Scan, or Ramp/Scan in VT-1 and VT zones.

Figure 4-1. Ventricular therapy prescription, 3-zone configuration

The therapies within a ventricular zone must be ordered in ascending therapy strengths. All ventricular ATP therapies are considered to be of equal strength, but are of lower strength than any shock therapy. The strength of the shock therapies is determined by the programmed energy. In a multi-zone

configuration, therapies in a higher ventricular zone may be of lesser, greater, or equal strength to those in a lower ventricular zone; however, within each zone the therapies must be programmed in equal or increasing energy output.

Ventricular Therapy Selection

The pulse generator determines which ventricular therapy to deliver based on the following rules:

- Each successive therapy delivery must be greater than or equal to the strength of the previous therapy in a ventricular episode. Whenever a ventricular shock therapy has been delivered, no further ventricular ATP therapy is allowed in that episode since ATP therapy is of lower strength than shock therapy. Each subsequent ventricular shock delivery must be of equal or greater strength regardless of ventricular zone changes during a ventricular episode.

- Each ventricular ATP scheme (which may consist of multiple bursts) can only be delivered once during a ventricular episode.

- Up to 8 shocks may be delivered in a ventricular episode. The first 2 shocks are programmable. The following maximum-energy, non-programmable shocks are available in each zone:

  – VT-1 zone: 3 maximum-energy shocks
  – VT zone: 4 maximum-energy shocks
  – VF zone: 6 maximum-energy shocks

NOTE: *In the event a shock is diverted with the DIVERT THERAPY programmer command, by magnet application or due to a Diverted-Reconfirm, the diverted shock is not counted as one of the available shocks for that tachyarrhythmia episode. Also, commanded therapies and STAT SHOCK are not counted as one of the available shocks for an episode and do not affect subsequent therapy selection.*

Based on initial ventricular detection criteria, the pulse generator selects the first prescribed therapy in the ventricular zone in which the tachyarrhythmia is detected (i.e., detection is met; see "Ventricular Detection" on page 3-6). After delivering the selected therapy, the pulse generator begins redetection to determine whether the arrhythmia has been converted.

- If the arrhythmia is converted to a rate below the lowest programmed threshold, the pulse generator continues monitoring until the end of the episode is declared. When the episode ends, the pulse generator will again use initial ventricular detection criteria for a new episode. When a new episode is declared, the first prescribed therapy will be delivered again.

- If the arrhythmia is not converted and an arrhythmia is redetected in the same ventricular zone, the next programmed therapy in that zone is selected and delivered (Figure 4-2 on page 4-4), followed again by redetection. If the arrhythmia persists in the same zone, the therapy will progress in that zone.

- If an arrhythmia crosses ventricular zones (accelerates or decelerates) following therapy delivery and is redetected in a higher or lower ventricular zone, a therapy of equal or greater strength than the previously delivered therapy is selected from the detected zone and delivered (Figure 4-3 on page 4-5 through Figure 4-10 on page 4-8). For shock therapy, the pulse generator determines which shock to deliver prior to capacitor charging based on the detected rate threshold. If during capacitor charging, the tachyarrhythmia accelerates or decelerates from the initial detected rate, the predetermined energy will still be delivered.

Redetection is performed after each therapy delivery to determine if further therapy is required.

Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			On/Off	5 J	11 J	max max max max max max
VT	Burst	Scan	N/A	3 J	9 J	max max max max
VT-1	① Burst	② Ramp	N/A	③ 0.1 J	④ 2 J	⑤ ⑥ ⑦ max max max

Figure 4-2. Therapy delivery progression, arrhythmia remains in same zone as initially detected

After each redetection cycle, therapy delivery progresses in the direction indicated by the circled numbers (Figure 4-3 on page 4-5 through Figure 4-10 on page 4-8).

- Upward sloping lines indicate acceleration of the arrhythmia to a higher ventricular zone

- Downward sloping lines indicate deceleration into a lower ventricular zone

The lowest strength therapy is in the ATP columns; the therapy strengths increase as you move to the right in the table.

NOTE: *In the VT-1 zone of a 3-zone configuration or the VT zone of a 2-zone configuration, one or two ATP schemes may be programmed as the only therapy, with all shocks in the lowest zone programmed to Off. If those pacing schemes do not terminate an arrhythmia detected in the VT-1 zone, no further therapy will be delivered in the episode unless the rate is redetected in a higher zone.*

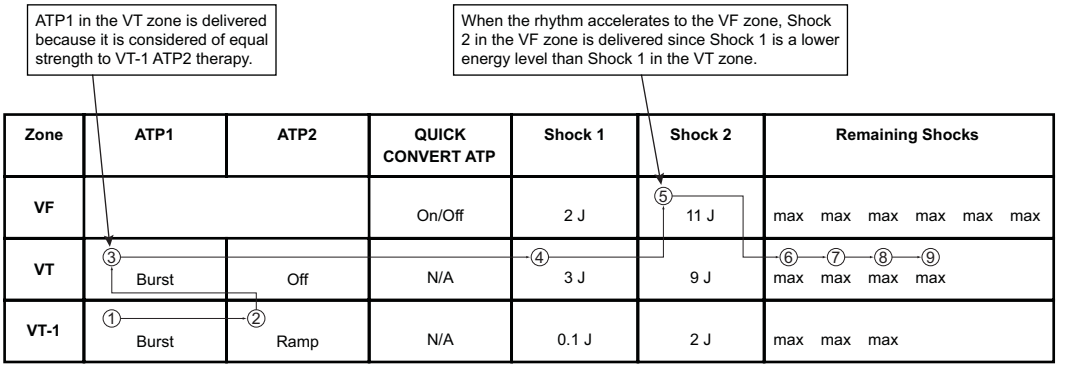


Figure 4-3. Therapy delivery progression, ATP1 in the VT zone and shock 2 in the VF zone

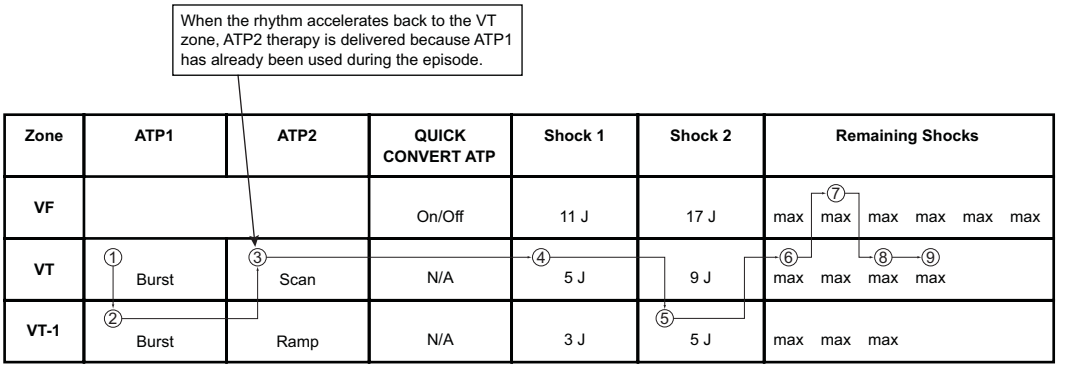


Figure 4-4. Therapy delivery progression, ATP2 therapy

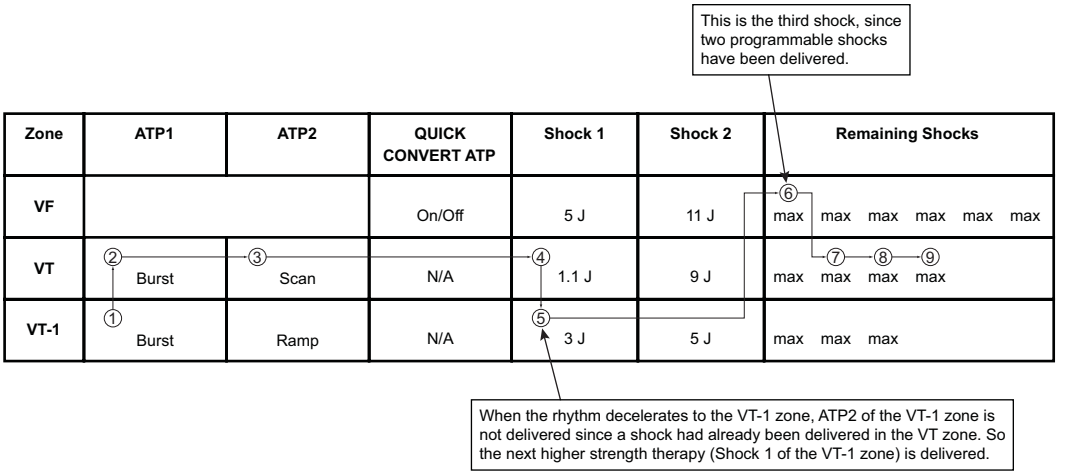


Figure 4-5. Therapy delivery progression, shock 1 in the VT-1 zone

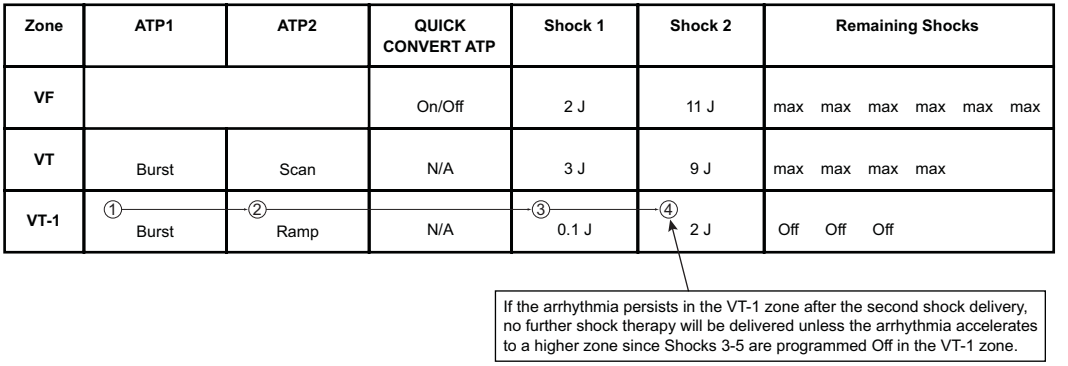
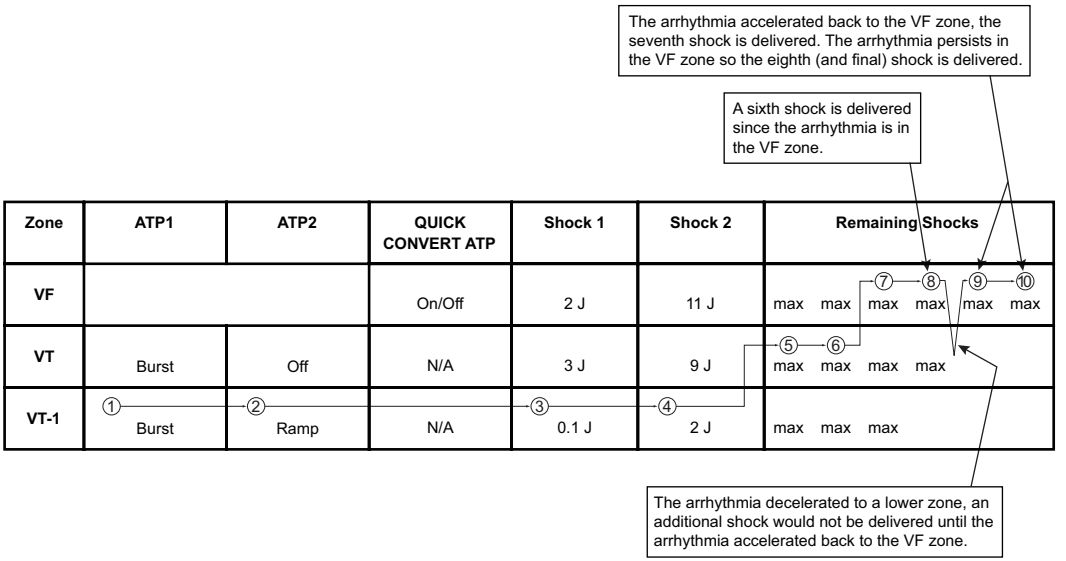
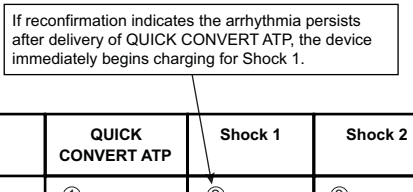


Figure 4-6. Therapy delivery progression, shocks 3 to 5 programmed to Off in the VT-1 zone



Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			On/Off	2 J	11 J	max max max max max max
VT	Burst	Off	N/A	3 J	9 J	max max max max
VT-1	① Burst	② Ramp	N/A	③ 0.1 J	④ 2 J	max max max

Figure 4-7. Therapy delivery progression, sixth shock delivered



Zone	ATP1	ATP2	QUICK CONVERT ATP	Shock 1	Shock 2	Remaining Shocks
VF			① On	② 11 J	③ 21 J	max max max max max max
VT	Burst	Scan	N/A	3 J	9 J	max max max max
VT-1	Burst	Ramp	N/A	0.1 J	2 J	max max max

Figure 4-8. Therapy delivery progression, QUICK CONVERT ATP and shock in the VF zone

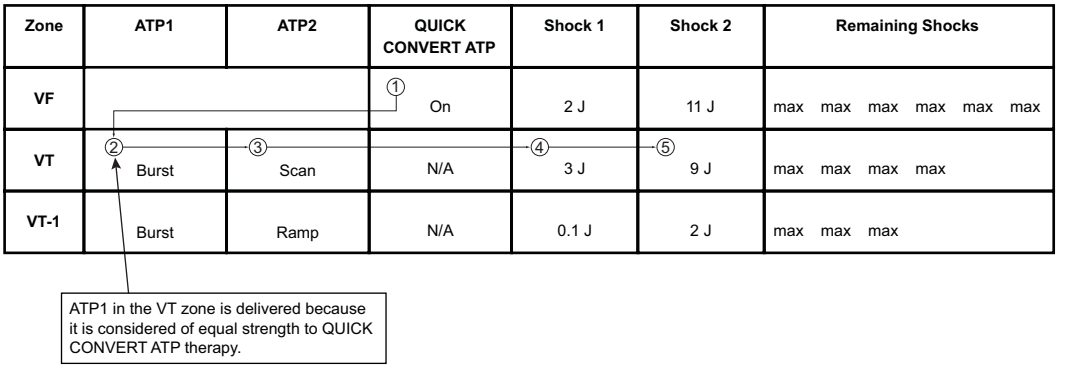


Figure 4-9. Therapy delivery progression, QUICK CONVERT ATP decelerates the rhythm, ATP1 and shock delivered in the VT zone

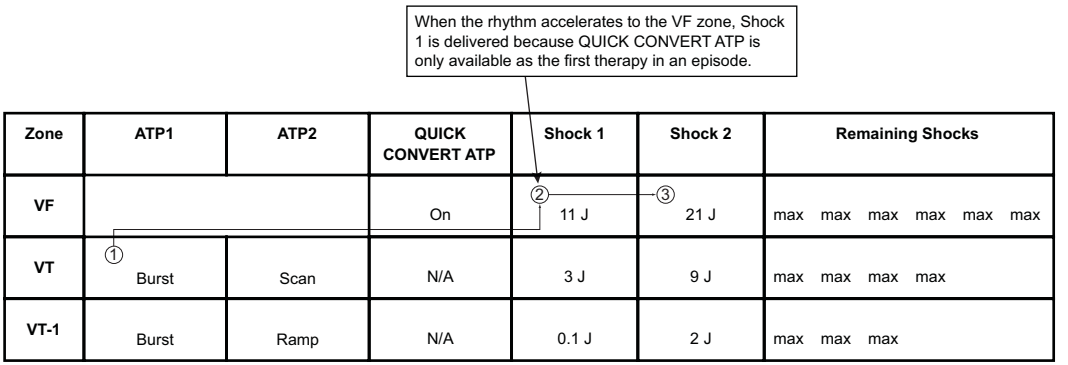


Figure 4-10. Therapy delivery progression, ATP1 in VT zone accelerates the rhythm, QUICK CONVERT ATP is skipped in VF zone

Ventricular Redetection after Ventricular Therapy Delivery

After ventricular therapy delivery, the pulse generator uses redetection criteria to evaluate the rhythm and determine whether more therapy is appropriate. When redetection criteria are satisfied, the rules for therapy selection then determine the type of therapy to deliver.

Ventricular Redetection after Ventricular ATP Therapy

Ventricular Redetection after ventricular ATP therapy determines if an arrhythmia has been terminated.

As a ventricular ATP scheme is delivered, the pulse generator monitors the cardiac rate after each burst and uses ventricular detection windows (looking

for 8 of 10 fast intervals) and the Ventricular Redetection Duration to determine if the arrhythmia has terminated.

The ATP scheme will continue with the next bursts in the sequence until any one of the following conditions is satisfied:

- Redetection declares that the therapy has been successful (end-of-episode)
- The specified number of ATP bursts in the scheme has been delivered
- The ATP Time-out for the ventricular zone has expired
- The detected ventricular arrhythmia rate changes to a different ventricular rate zone, whereby a different therapy is selected
- Shock If Unstable forces the device to skip the remaining ATP therapy and initiate shock therapy
- A DIVERT THERAPY command is received from the PRM during delivery of a burst of a scheme
- A magnet abort occurs during delivery of a scheme
- The temporary Tachy Mode has changed
- A commanded therapy is requested
- The episode ends due to reprogrammed Tachy Mode, reprogrammed ventricular tachy parameters, or attempted induction method or lead test

NOTE: *Aborting an ATP burst terminates the affected ATP scheme. If further therapy is required, the next programmed therapy (either ATP or shocks) in the prescription is initiated.*

Ventricular Redetection after Ventricular Shock Therapy

Ventricular redetection after ventricular shock therapy determines if an arrhythmia has been terminated.

As shock therapy is delivered, the pulse generator monitors the cardiac rate after each shock and uses ventricular detection windows (looking for 8 of 10 fast intervals) and post-shock detection enhancements, if applicable, to

determine if the arrhythmia has been terminated. Shock therapy will continue until one of the following conditions is satisfied:

- Redetection declares the therapy has been successful (end-of-episode)
- All available ventricular shocks have been delivered for an episode
- The rhythm is redetected in either the VT or VT-1 zone, the available number of programmed shock(s) in those zones has been delivered and the arrhythmia stays in one of these lower zones

If all available shocks have been delivered for an episode, no further therapy is available until the pulse generator monitors a rate below the lowest rate threshold for 30 seconds and end-of-episode is declared.

ANTITACHYCARDIA PACING THERAPIES AND PARAMETERS

Antitachycardia Pacing (ATP) therapy and parameters enable the pulse generator to interrupt the following fast rhythms by delivering a series of critically timed pacing pulses:

- Monomorphic ventricular tachycardia
- Supraventricular tachycardias

ATP Therapy is delivered when the last sensed event fulfills the programmed detection criteria (Figure 4-11 on page 4-11).

An ATP scheme may be customized with the following parameters:

- Number of bursts delivered
- Number of pulses within each burst
- Coupling Interval
- Burst Cycle Length
- Minimum pacing interval

These parameters can be programmed to produce the following ATP therapy schemes:

- Burst
- Ramp
- Scan

- Ramp/Scan

The ATP amplitude and pulse width are common to all schemes. They are independently programmable from the normal pacing settings. The ATP amplitude and pulse width share the same programmable value as the post-therapy pacing settings.

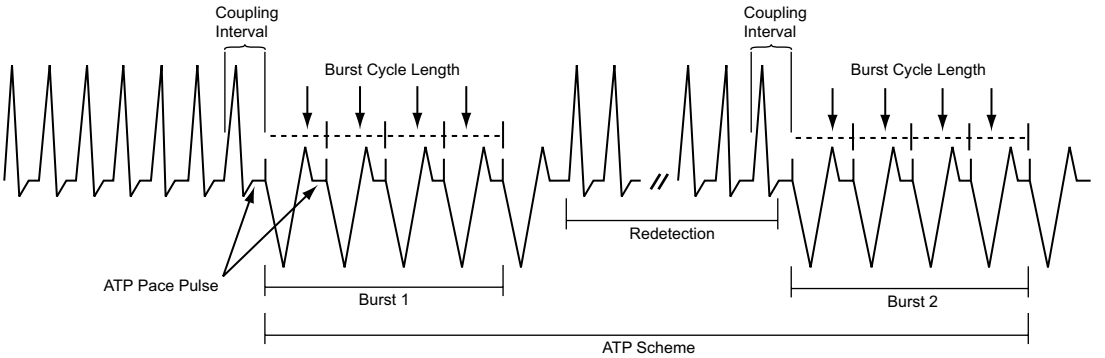


Figure 4-11. ATP therapy basic parameters are Coupling Interval, Burst Cycle Length, Number of Bursts, and Number of Pulses within each burst.

Burst Parameters

A burst is a series of critically timed pacing pulses delivered by the pulse generator during ATP therapy. By programming burst parameters, you can optimize ATP therapy for the patient.

All ATP schemes have several parameters in common. In addition to programming the type of scheme (Off, Burst, Ramp, Scan, Ramp/Scan), the following burst parameters are programmable (Figure 4-12 on page 4-12):

- The Number of Bursts parameter determines the number of bursts used in an ATP scheme and may be programmed independently for each ATP scheme. Programming the parameter to Off will deactivate the ATP scheme.

- The Initial Pulse Count parameter determines the number of pulses delivered in the first burst of a scheme.

- The Pulse Increment parameter determines the number of pulses per burst to be increased for each successive burst in the scheme.

- The Maximum Number of Pulses parameter determines the greatest number of pulses used in an ATP burst and may be programmed independently for each ATP scheme. After the maximum number of pulses is reached in a burst, each additional burst remaining in the scheme contains the programmed Maximum Number of Pulses. The parameter is available only if the Pulse Increment is greater than zero.

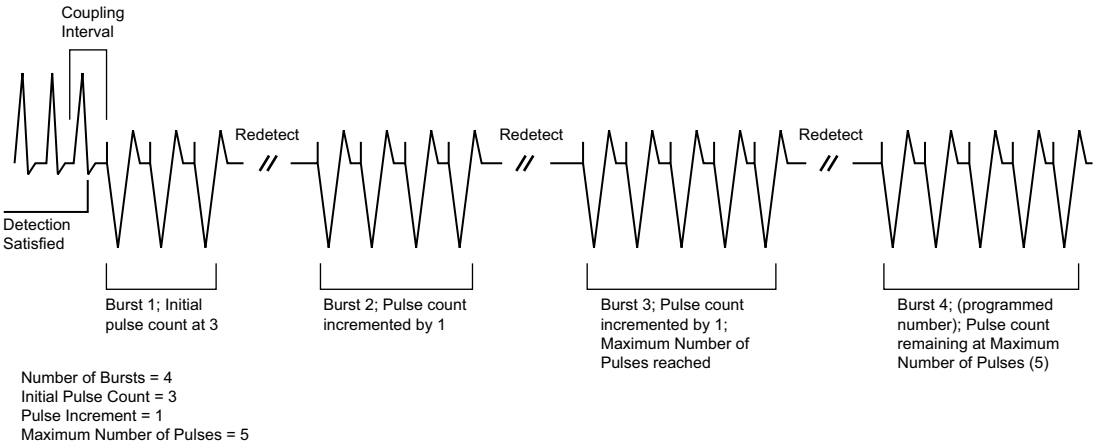


Figure 4-12. Interaction of Maximum Number of Pulses and Number of Bursts

Coupling Interval and Coupling Interval Decrement

The Coupling Interval controls the timing of the first pulse in a burst. It defines the time between the last sensed event that fulfills the detection criteria and delivery of the first pulse in a burst.

The Coupling Interval is programmed independent from the Burst Cycle Length. This allows aggressive ramps and scans to be used without compromising capture of the first pacing pulse in a burst. The Coupling Interval can be programmed as any of the following:

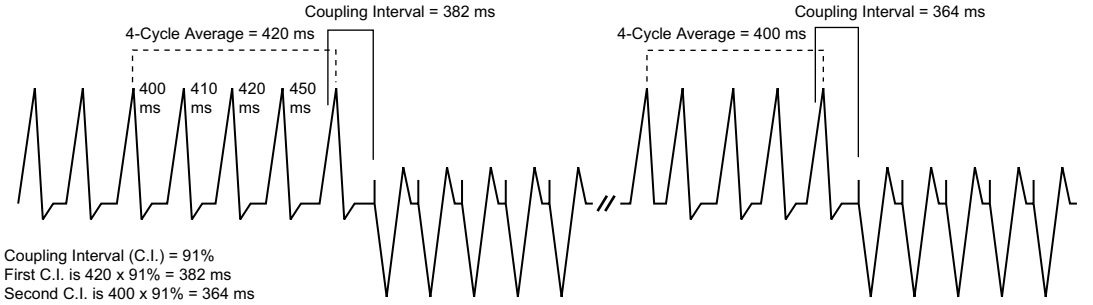
- Adaptive, with timing specified as percentages of the computed average heart rate

- A fixed interval, with timing specified in absolute time (ms) independent of the measured average rate

When programmed as adaptive, the Coupling Interval adjusts to the patient's rhythm based on a four-cycle average (Figure 4-13 on page 4-13). The Coupling Interval Decrement may be programmed such that the Coupling

Interval decreases from one burst to the next within a multiple-burst scheme (Figure 4-14 on page 4-13).

NOTE: *You cannot program an ATP burst that lasts longer than 15 seconds. The length of an adaptive burst is calculated based on the interval of the ventricular zone in which the ATP is programmed, which means it is based on worst-case timing.*



The 4-cycle average is calculated on the four cycles prior to each tachycardia therapy delivery only when no Decrement (Coupling Interval or Scan) is programmed.

Figure 4-13. Adaptive Coupling Interval, Coupling Interval Decrement and Scan Decrement programmed to 0

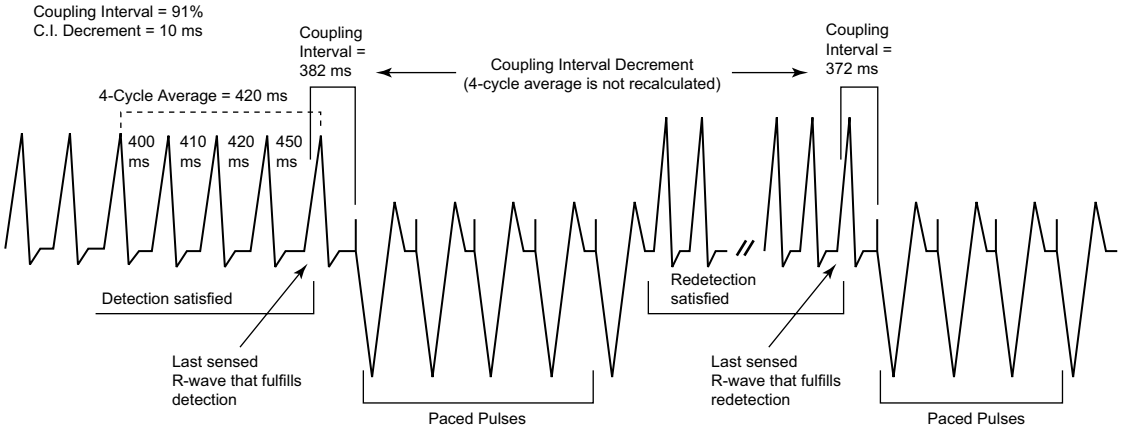


Figure 4-14. Coupling Interval Decrement

The following information should be taken into consideration when programming the Coupling Interval and Coupling Interval Decrement:

- When the Coupling Interval Decrement is programmed to On, the programmed ATP scheme is called a Scan

- When the Coupling Interval is programmed as adaptive, the Coupling Interval will not re-adapt following redetection when the following are programmed to On (greater than zero):
  - Coupling Interval Decrement—the decrement value determines the timing of the first pulse in subsequent bursts
  - Scan Decrement—the decrement value determines the timing of the second pulse in subsequent bursts

Burst Cycle Length (BCL)

The Burst Cycle Length controls the interval between pacing pulses after the Coupling Interval.

This timing is controlled in the same fashion as the Coupling Interval: rate adaptive to the sensed tachycardia or fixed time specified in ms.

NOTE: *An adaptive BCL is affected in the same manner as an adaptive Coupling Interval; the average cycle length is not continually recalculated for subsequent bursts if the Scan Decrement or Coupling Interval Decrement are programmed to On.*

The following parameters may be programmed to decrement the burst cycle length during an ATP scheme:

- Ramp Decrement controls the pulse timing within a given burst
- Scan Decrement controls the pulse timing between bursts

Minimum Interval

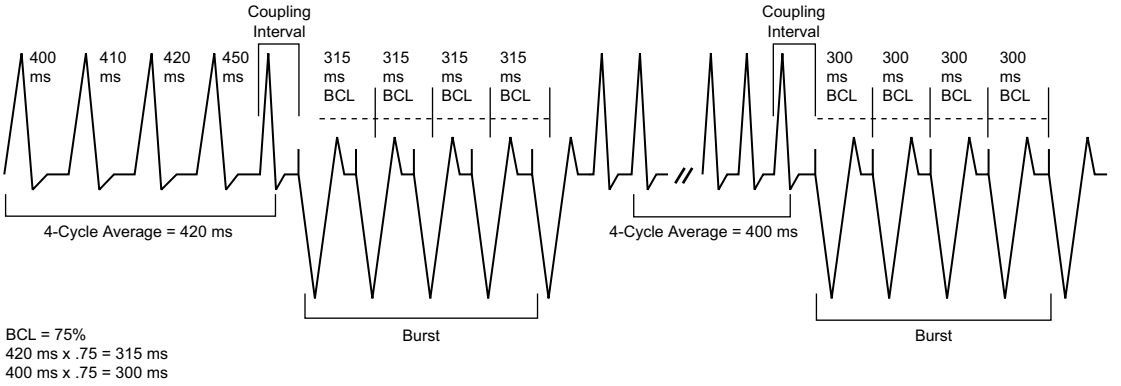
The Minimum Interval limits the Coupling Interval and the BCL in Burst, Ramp, and Scan.

If the Coupling Interval reaches the limit, subsequent Coupling Intervals will remain at the minimum value. Likewise, if the BCL reaches the limit, subsequent BCLs will remain at the minimum value. The Coupling Interval and BCL may reach the limit independently.

Burst Scheme

A Burst scheme is a sequence of critically timed pacing pulses intended to interrupt a reentrant loop, usually delivered at a rate faster than the patient's tachycardia.

An ATP scheme is defined as a Burst (as indicated on the PRM screen) when the timing of all pacing intervals within a burst is the same. The first BCL of each Burst is determined by the programmed BCL. When the number of pulses programmed in a Burst is greater than one, you can use the BCL to control the timing between these paced pulses (Figure 4-15 on page 4-15).



The first BCL of each burst is calculated by multiplying the 4-cycle average prior to delivery of the first pacing pulse of the burst by the BCL percentage.

Figure 4-15. Adaptive-rate Burst scheme

Ramp Scheme

A Ramp scheme is a burst in which each paced-to-paced interval within the burst is shortened (decremented).

To program a Ramp scheme, program (in ms) the Ramp Decrement to specify how much the paced-to-paced interval should be shortened, and the Scan Decrement and Coupling Interval Decrement each to 0 ms. As each additional paced pulse in a burst is delivered, its interval is shortened by the programmed Ramp Decrement until either of the following occur:

- The last paced pulse of the burst is delivered
- The Minimum Interval is reached

If subsequent bursts are required, the programmed Ramp Decrement will be applied based on the calculated BCL of that subsequent burst (Figure 4-16 on page 4-16).

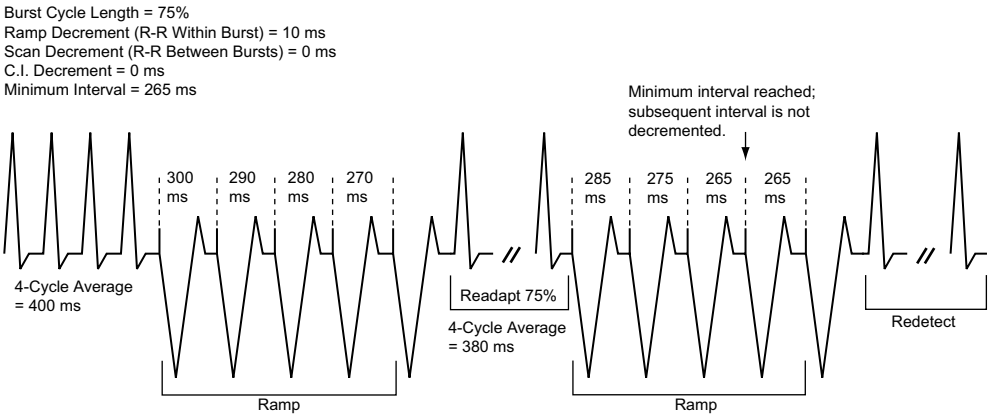
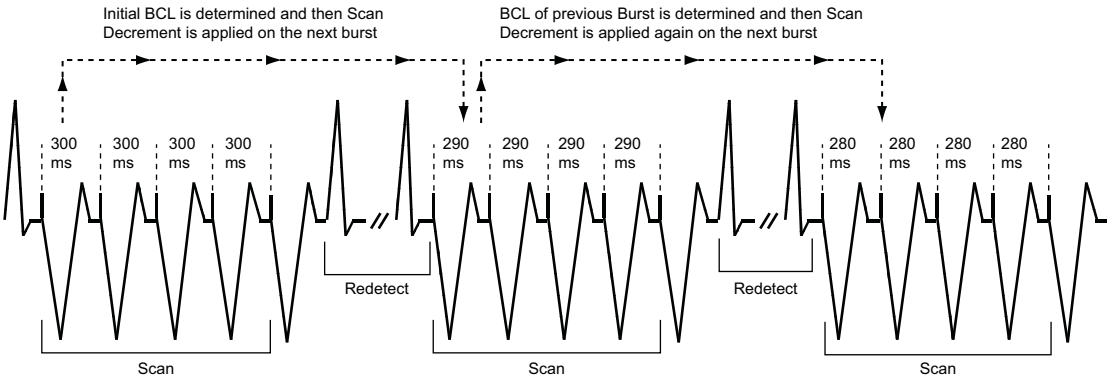


Figure 4-16. Adaptive Ramp Scheme, Coupling Interval Decrement and Scan Decrement programmed to 0

Scan Scheme

A Scan scheme is a burst in which the BCL of each burst in a scheme is systematically shortened (decremented) between successive bursts.

You can program a Scan scheme by programming the Scan Decrement to specify the BCL decrement to a value greater than 0 ms, while the Ramp Decrement is programmed to 0 ms. The BCL of subsequent bursts is determined by subtracting the Scan Decrement from the BCL of the previous burst (Figure 4-17 on page 4-17).

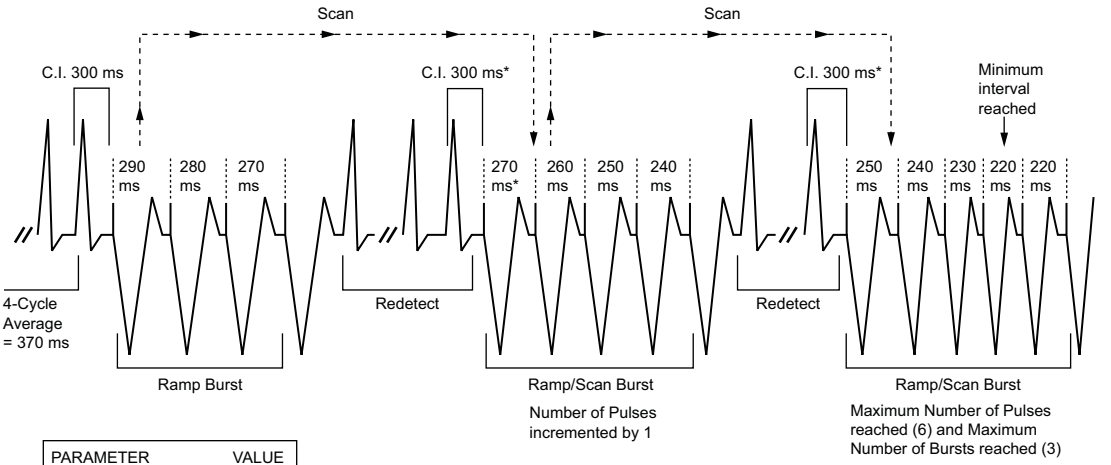


Burst Cycle Length = 300 ms
Scan Decrement = 10 ms
Ramp Decrement = 0 ms
Coupling Interval Decrement = 0 ms

Figure 4-17. Scan scheme, nonadaptive BCL and Scan Decrement programmed on

Ramp/Scan Scheme

A Ramp/Scan scheme is a sequence of bursts. Each scheme contains a Ramp Decrement and a Scan Decrement (Figure 4-18 on page 4-18).



PARAMETER	VALUE
Number of Bursts	3
Pulses per Burst:	
Initial	4
Increment	1
Maximum	6
Coupling Interval	81%
Decrement	0 ms
Burst Cycle Length	78%
Ramp Decrement	10 ms
Scan Decrement	20 ms
Minimum Interval	220 ms

* When a Scan Decrement is programmed to On, the Coupling Interval and BCL, if programmed as a percentage, will not re-adapt following redetection.

Figure 4-18. Ramp/Scan scheme, interaction of ATP parameters

To program a Ramp/Scan scheme, both the Scan Decrement and Ramp Decrement are programmed to values greater than 0 ms.

ATP Pulse Width and ATP Amplitude

The ATP Pulse Width is the duration of a pacing pulse. The ATP Amplitude is the leading edge voltage of a pacing pulse.

The programmed ATP Pulse Width and ATP Amplitude are shared for all ATP schemes regardless of zone and position in a prescription. The ATP amplitude and pulse width share the same programmable value as the post-therapy pacing settings.

Ventricular ATP Time-out

The Ventricular ATP Time-out forces the pulse generator to skip over any remaining ATP therapy in a ventricular zone to begin delivering ventricular shock therapy programmed in the same zone. This parameter is effective only for ventricular therapy delivery.

The ATP Time-out may be used in the VT or VT-1 zone as long as ATP therapy is programmed to On. Timer values are independent, although VT-1 ATP Time-out must be equal to or greater than the VT ATP Time-out.

The timer starts when the first burst is delivered and continues until any of the following occur:

- The timer expires (Figure 4-19 on page 4-19)
- A ventricular shock is delivered
- The ventricular episode ends

The time-out is examined after each redetection sequence to determine if further ATP bursts can be delivered. If the time-out has been reached or exceeded, further ATP therapy will not be initiated during that ventricular episode. The time-out will not terminate a burst in process.

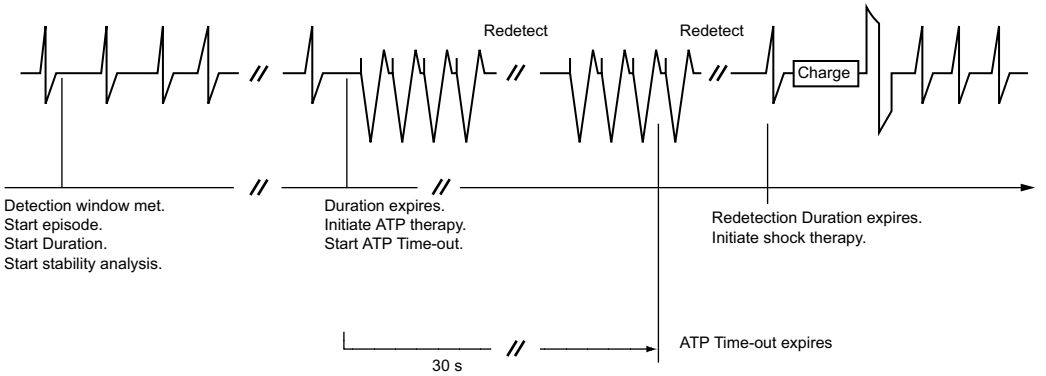


Figure 4-19. ATP Time-out expiration

NOTE: *Once a ventricular shock has been delivered during a ventricular episode, ATP will no longer be invoked, irrespective of the time remaining on the ATP Time-out timer.*

The timer alone does not invoke therapy; the rate and duration criteria and detection enhancements must still be satisfied in order for a shock therapy to be delivered.

If three zones are programmed, you may program ATP Time-out settings in each of the lower two ventricular zones (Figure 4-20 on page 4-20).

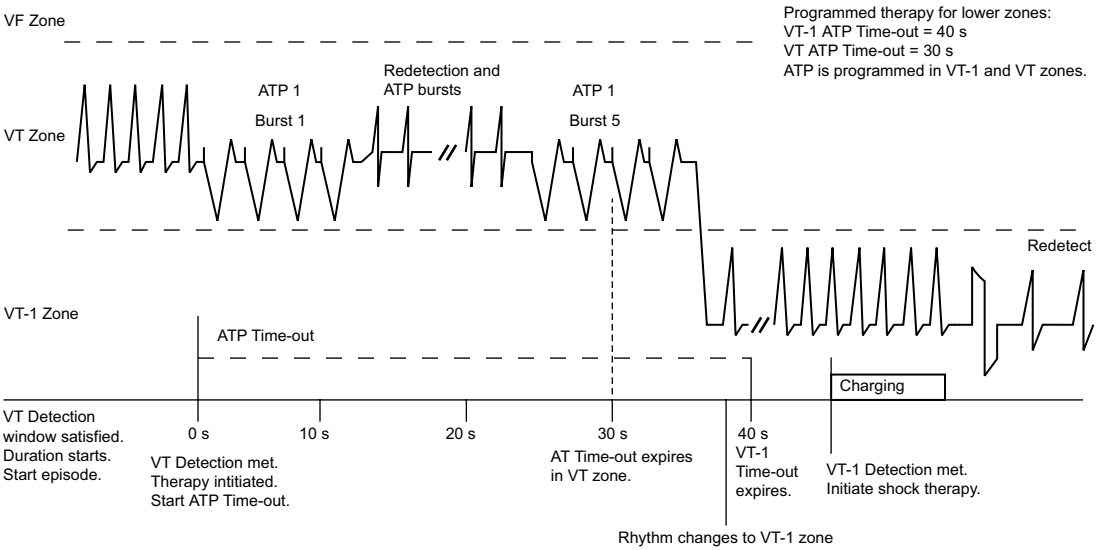


Figure 4-20. ATP Time-outs, 3-zone configuration

QUICK CONVERT ATP

QUICK CONVERT ATP provides you with an additional option to treat fast, monomorphic VT that is detected in the VF zone.

When QUICK CONVERT ATP is programmed to On, the pulse generator delivers one burst of ATP for an episode detected in the VF zone in an attempt to avoid an otherwise scheduled charge and painful shock for a pace-terminable fast VT.

When delivering QUICK CONVERT ATP therapy, the pulse generator delivers one burst of ATP for an episode detected in the VF zone. This therapy consists of 8 pacing pulses at 88% Coupling Interval and 88% BCL. It is delivered only as the first therapy attempted in an episode and is followed by reconfirmation (2 out of 3 intervals faster than the lowest rate threshold) prior to the shock sequence.

In the event that QUICK CONVERT ATP was unsuccessful in converting the rhythm and shock therapy is required, the feature's algorithm minimizes the delay to begin charging. QUICK CONVERT ATP is not applied to any rhythm above a maximum rate of 250 bpm.

VENTRICULAR SHOCK THERAPY AND PARAMETERS

The pulse generator delivers shocks synchronous to a sensed event. The shock vector, energy level, and polarity of the shocks are programmable.

Ventricular Shock Vector

The programmed Ventricular Shock Vector indicates the vector of energy delivery for ventricular shock therapy.

The following programmable configurations are available:

- RV Coil to RA Coil and Can—this vector is also known as the V-TRIAD vector. It uses the metallic housing of the pulse generator as an active electrode (“hot can”) combined with the ENDOTAK two-electrode defibrillation lead. Energy is sent via a dual-current pathway from the distal shocking electrode to the proximal electrode and to the pulse generator case.

- RV Coil to Can—this vector uses the metallic housing of the pulse generator as an active electrode (“hot can”). Energy is sent from the distal shocking electrode to the pulse generator case. This configuration should be selected when using a single-coil lead.

- RV Coil to RA Coil—this vector removes the pulse generator case as an active electrode and is also known as a “cold can” vector. Energy is sent from the distal shocking electrode to the proximal electrode. This vector should never be used with a single-coil lead, as a shock will not be delivered.

Ventricular Shock Energy

Ventricular shock energy determines the strength of shock therapy delivered by the pulse generator.

Shock output remains constant over the lifetime of the pulse generator, regardless of changes in lead impedance or battery voltage. The constant output is accomplished by varying pulse width to adjust to changes in lead impedance.

The first two shocks in each ventricular zone can be programmed to optimize charge time, longevity, and safety margins. The remaining shock energies in each zone are nonprogrammable at the maximum-energy value.

Charge Time

Charge time is the time the pulse generator requires to charge for delivery of the programmed shock energy.

Charge time is dependent on the following:

- Programmed output energy level
- Battery condition
- Condition of the energy storage capacitors

Charge times increase as the pulse generator is programmed to higher energy output levels and as the battery depletes (Table 4-1 on page 4-22).

Capacitor deformation can occur during inactive periods and may result in a slightly longer charge time. To reduce the impact of capacitor deformation on charge time, the capacitors are automatically reformed.

Table 4-1. Typical charge time required at 37 degrees C at BOL

Energy Stored (J)[a]	Energy Delivered (J)[b]	Charge Time (seconds)[c]
11.0	10.0	1.9
17.0	15.0	2.9
26.0	22.0	4.7
41.0[d]	35.0	8.4

a. Values indicate the energy level stored on the capacitors and correspond to the value programmed for shock energy parameters.
b. The energy delivered indicates the shock energy level delivered through the shocking electrodes.
c. Charge times shown are at BOL after capacitor re-formation.
d. HE.

Waveform Polarity

Waveform polarity reflects the relationship between the leading edge voltages on the defibrillating output electrodes. All shocks will be delivered using a biphasic waveform (Figure 4-21 on page 4-23).

The selection of the shock polarity applies to all shocks delivered by the device. If the preceding shocks in a zone are unsuccessful, the last shock of that zone will be automatically delivered at an inverted polarity to the previous shock (initial or reversed) (Figure 4-22 on page 4-23).

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.

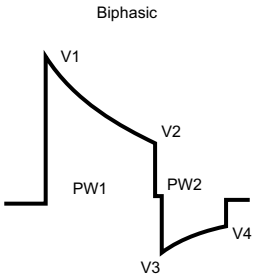


Figure 4-21. Biphasic waveform

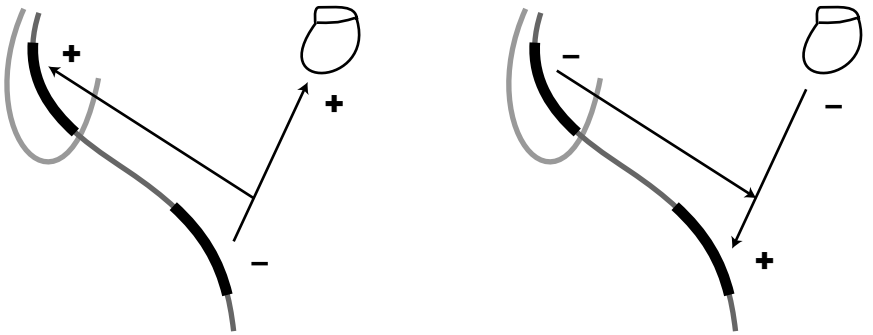


Figure 4-22. Polarity of shock delivery

Committed Shock/Reconfirmation of the Ventricular Arrhythmia

Committed Shock/Reconfirmation refers to the monitoring performed by the pulse generator before delivery of a ventricular shock.

If the patient is subject to non-sustained arrhythmias, reconfirmation may be desirable in order to prevent delivery of unnecessary shocks to the patient.

The device monitors tachyarrhythmias during and immediately following capacitor charging. During this time, it checks for the spontaneous conversion of the tachyarrhythmia and determines whether ventricular shock therapy should be delivered; it does not affect therapy selection.

Ventricular shock therapy can be programmed as committed or non-committed. If the Committed Shock feature is programmed to On, the shock is delivered synchronously with the first sensed R-wave following a 500-ms delay after the capacitors are charged, whether the arrhythmia is sustained or not (Figure 4-23 on page 4-24). The 500-ms delay allows a minimum time for a divert command to be issued from the PRM, if desired. If there is no sensed R-wave detected within 2 seconds following the end of charging, the ventricular shock is delivered asynchronously at the end of the 2-second interval.

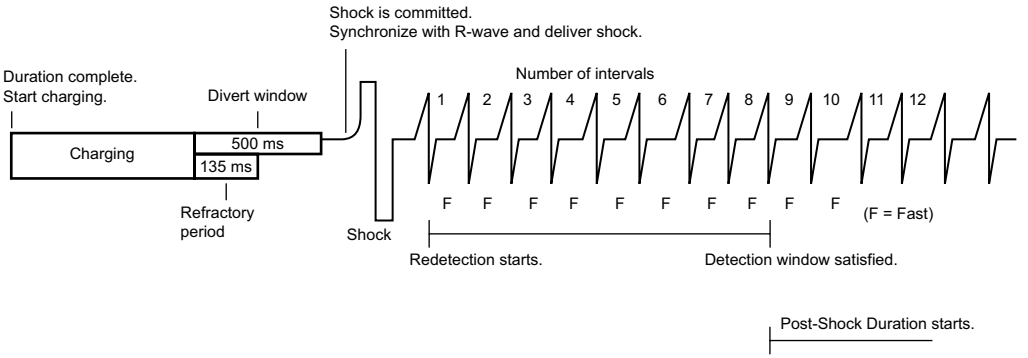


Figure 4-23. Committed Shock is programmed to On, Reconfirmation is Off

NOTE: *There is a forced 135-ms refractory period following the end of charging; events that occur during the first 135 ms of the 500-ms delay are ignored.*

If the Committed Shock feature is programmed to Off, Reconfirmation consists of the following steps:

1. During capacitor charging, the pulse generator continues to sense the arrhythmia. Sensed and paced beats are evaluated. If 5 slow beats (sensed or paced) are counted in a 10-beat detection window (or 4 consecutive slow beats after an unsuccessful QUICK CONVERT ATP attempt), the pulse generator stops charging and considers this a Diverted-Reconfirm.

2. If 5 of 10 beats are not detected as slow (or less than 4 consecutive slow beats after an unsuccessful QUICK CONVERT ATP attempt) and charging completes, post-charge reconfirmation is performed after charging ends.

After the post-charge refractory and the first sensed event, the pulse generator measures up to 3 intervals following charging and compares them to the lowest rate threshold.

- If 2 of the 3 intervals following charging are faster than the lowest rate threshold, the shock will be delivered synchronously with the second fast event.

- If 2 of the 3 intervals following charging are slower than the lowest rate threshold, the shock will not be delivered. If no beats are sensed, pacing will begin at the programmed LRL following the 2-second no-sense period. If a shock is not delivered, or if pacing pulses are delivered, this is also considered a Diverted-Reconfirm.

If a shock is required after redetection, the charge time for the shock may be short.

The reconfirmation algorithm will not allow two consecutive Diverted-Reconfirm cycles. If the arrhythmia is detected after a Diverted-Reconfirm, the next shock in the episode is delivered as if Committed Shock were programmed to On. Once a shock has been delivered, the reconfirmation algorithm can be applied again (Figure 4-24 on page 4-25).

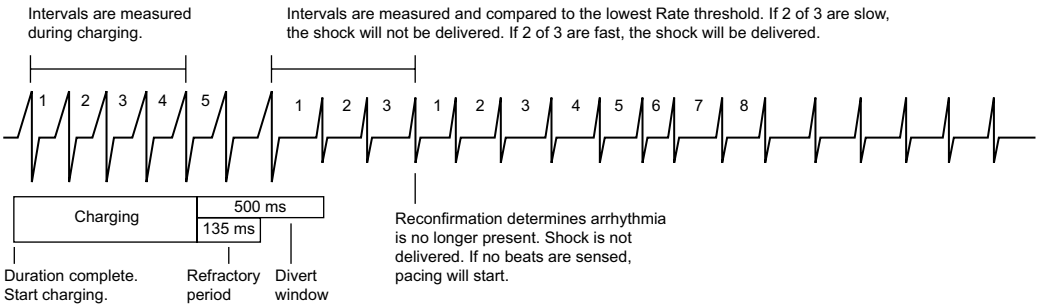


Figure 4-24. Committed Shock is programmed to Off, reconfirmation is On

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Part 1 of 2

- DRAFT -

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SYSTEM GUIDE

COGNIS™ 100-D

CARDIAC RESYNCHRONIZATION THERAPY HIGH ENERGY DEFIBRILLATOR

REF N118, N119

CAUTION: Federal law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

- DRAFT -

PACING THERAPIES

CHAPTER 5

This chapter contains the following topics:

DEVICE PROGRAMMING RECOMMENDATIONS

It is important to program device parameters to the appropriate settings to ensure optimal CRT delivery. Please consider the following guidelines in conjunction with the patient's specific condition and therapy needs.

CAUTION: This device is intended to provide biventricular pacing therapy. Programming the device to provide RV-only pacing, or programming the RV pace amplitude below the pacing threshold (resulting in LV-only pacing), is not intended for the treatment of heart failure. The clinical effects of LV-only or RV-only pacing for the treatment of heart failure have not been established.

Pacing mode—Program a dual-chamber tracking mode (VDD or DDD). Adaptive-rate pacing modes are intended for patients who exhibit chronotropic incompetence and who would benefit by increased pacing rates concurrent with physical activity ("Brady Mode" on page 5-7).

Pacing chamber—Program to BiV (nominal) unless medical discretion dictates the selection of a different pacing chamber ("Ventricular Pacing Chamber" on page 5-14).

BiV Trigger—Program to On unless there is a medical contraindication.

LRL—Program below a sinus rate normally reached while still providing an appropriate rate for bradycardia support ("Lower Rate Limit (LRL)" on page 5-10).

MTR—Program high enough to ensure 1:1 AV synchrony. A MTR at 130 ppm is recommended unless medical discretion dictates otherwise ("Maximum Tracking Rate (MTR)" on page 5-11).

Pacing output—Program for a minimum 2x voltage safety margin for each ventricular chamber based on the capture thresholds ("Pace Threshold Test" on page 6-8).

Paced AV Delay—The Paced AV Delay setting should be individualized for each patient to ensure consistent CRT delivery. Several methods are available to determine the Paced AV Delay setting, including:

- Intrinsic QRS duration assessment
- Echocardiogram
- Pulse pressure monitoring

Since optimizing the Paced AV Delay can significantly influence CRT effectiveness, consider using methods that demonstrate the hemodynamic impact of different Paced AV Delay settings, such as echocardiography or pulse pressure monitoring.

Atrial pacing may prolong the interatrial delay; therefore, it may be necessary to program different Paced AV Delay settings to optimize CRT during normal sinus rhythm and atrial pacing.

Sensed AV Delay—Sensed AV Delay is used to achieve a shorter AV Delay following sensed atrial events while the longer, programmed Paced AV Delay is used following paced atrial events. When programmed to the DDD(R) mode, it is recommended that the patient be tested to determine the optimal Sensed AV Delay during atrial sensing and pacing.

Dynamic AV Delay—Dynamic AV Delay is set automatically based on the following ("Paced AV Delay" on page 5-46):

- If the minimum and maximum Paced AV Delays are equal, then AV Delay is fixed.
- If the minimum Paced AV Delay is less than the maximum, then AV Delay is set to Dynamic.

PVARP—Program PVARP to 280 ms. For heart failure patients with intact AV conduction, a long intrinsic intracardiac AV interval and a long programmed PVARP can cause a loss of atrial tracking below the MTR, resulting in a loss of BiV stimulation (CRT). If you believe a loss of atrial tracking below the MTR is occurring, program Tracking Preference to On (nominal) ("A-Refractory (PVARP)" on page 5-52).

PVARP after PVC—Program PVARP after PVC to 400 ms (nominal) to potentially reduce the number of PMTs at high rates. The occurrence of PMTs may also be due to other factors ("PVARP after PVC" on page 5-54).

ATR—If ATR is used, Entry and Exit Counts should be programmed to ensure appropriate and timely mode switching ("Atrial Tachy Response" on page 5-27).

Note that VRR and BiV Trigger have the potential to increase CRT delivery during atrial tachyarrhythmias. BiV Trigger should be programmed to On, and VRR should be programmed to On at the maximum setting to increase the percent of ventricular pacing and maximize consistent CRT delivery during conducted atrial tachyarrhythmias.

PMT Termination—Program to On (nominal) to prevent PMTs at high rates ("PMT Termination" on page 5-35).

LVPP—Program to 400 ms (nominal) to prevent the device from pacing in the LV vulnerable period ("Left Ventricular Protection Period (LVPP)" on page 5-55).

Tracking Preference—Program to On (nominal) to support CRT delivery for atrial rates below, but near, the MTR. Use this feature when PVARP and the patient's intrinsic intracardiac AV interval are longer than the programmed MTR interval ("Tracking Preference" on page 5-36).

LV lead configuration—Program in accordance with the number of electrodes on the LV lead ("Left Ventricular Electrode Configuration" on page 5-42).

MAINTAINING CRT

Certain conditions may cause the temporary loss of CRT or AV synchrony due to Wenckebach-like behavior, and heart failure patients may become symptomatic if CRT is compromised. Please consider the following when you are programming the device.

MTR

Rapid atrial rates with a fast ventricular response above MTR can cause:

- Temporary inhibition of CRT if AV conduction is intact
- Wenckebach-like behavior if second- or third-degree AV block is present

CRT delivery and programmed AV synchrony return when normal sinus rates are restored.

MTR should be programmed sufficiently high to maintain CRT at fast atrial rates. In addition, please consider the following for maintaining CRT:

- Rate Smoothing may be used to prevent sudden drops in rate
- VRR may help promote CRT by increasing the percent of ventricular pacing during conducted atrial arrhythmias
- SVTs may require medical management to preserve CRT as well as protect the patient from the potential hemodynamic compromise associated with fast rates

- Medical management of fast atrial rates can maximize the amount of time that the patient remains below MTR and help ensure consistent CRT delivery

NOTE: *If a patient has slow VT, the ability to program higher MTR values is limited by the lower rate threshold of the lowest tachyarrhythmia zone.*

For CRT delivery at heart rates that correspond to the slow VT rate, consider managing the slow VT by alternate means such as antiarrhythmic drugs or catheter ablation to ensure consistent CRT.

AFR

AFR may delay or inhibit an atrial paced event and prevent pacing into the atrial vulnerable period and to provide immediate fallback for atrial rates higher than the AFR programmable rate. This changes the AV Delay and may impact CRT effectiveness if the AFR rate is programmed slower than the patient's sinus rate.

Rate Smoothing

When Rate Smoothing Up is programmed to On, CRT is compromised during episodes of atrial rate increases exceeding the programmed value. For patients with AV block, this occurs because Rate Smoothing Up prolongs AV Delay from the optimal setting (controls the biventricular pacing rate while the atrial rate increases).

Features that Switch to VVI or VVI-like Behavior

VTR/ATR may result in Wenckebach-like behavior or the temporary loss of CRT. CRT delivery with programmed AV synchrony will return when the SVT/VT/VF event is resolved and a normal sinus rhythm is restored.

For patients programmed to VDD with sinus rates below LRL, CRT will not be synchronized with atrial events and loss of AV synchrony will result. You can either program a lower LRL or enable a pacing mode that provides atrial pacing with synchronous ventricular pacing [e.g., DDD(R)], as medically appropriate.

STAT PACE delivers CRT in VVI mode with a loss of AV synchrony. The permanent, programmed settings resume when the pulse generator is programmed out of STAT PACE.

PACING THERAPIES

CRT-Ds provide both atrial and biventricular normal and post-therapy bradycardia pacing, including adaptive-rate modes.

The bradycardia pacing function is independent of the tachycardia detection and therapy functions of the device, with the exception of interval-to-interval sensing.

The pulse generator provides the following types of therapies:

CRT

- When the patient's intrinsic atrial rate is below the MTR and the programmed AV Delay is less than the intrinsic intracardiac AV interval, the device delivers pacing pulses to the ventricles at the programmed settings in order to synchronize ventricular contractions

- Independent programmability of the RV and LV leads allows therapeutic flexibility for restoring the mechanical coordination

CAUTION: To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.

Normal Bradycardia Pacing

- If the intrinsic heart rate falls below the programmed pacing rate (i.e., LRL), the device delivers pacing pulses at the programmed settings

- Sensor-based rate modulation allows the pulse generator to adapt the pacing rate to the patient's changing activity levels

Post-Therapy Pacing—alternative bradycardia pacing therapy may be delivered for a programmed period to ensure capture after delivery of a shock.

Additional Options

- **Temporary Bradycardia Pacing**—allows the clinician to examine alternate therapies while maintaining the previously programmed Normal pacing settings in the pulse generator memory.

- **STAT PACE**—initiates emergency ventricular pacing at high output settings when commanded via the PRM using telemetry communication.

BASIC PARAMETERS

By programming device parameters, the pulse generator provides CRT for the intent of providing mechanical synchronization. The programming options used for CRT include those used for bradycardia pacing therapy.

LV stimulation is delivered using a Guidant coronary venous lead. The device uses bipolar atrial pacing and sensing to coordinate AV contractions with CRT.

Normal Settings include the following:

- Pacing parameters, which are independently programmable from post-therapy and temporary pacing parameters

NOTE: *These parameters are also used for CRT.*

- Pacing and Sensing
- Leads
- Sensors and Trending

Post-Therapy Settings include the following:

- Pacing parameters, which are independently programmable from normal and temporary pacing parameters
- Post-ventricular shock

Brady Mode

Brady modes provide you with programmable options to help individualize patient therapy.

This pulse generator includes the pacing modes identified in the Programmable Options appendix.

CRT Modes

The objective of CRT is to deliver continuous pacing to the ventricles. CRT can only be delivered in modes that provide ventricular pacing.

The maximal CRT benefit can be achieved when biventricular stimulation is delivered. Atrial pacing and adaptive-rate modes may be appropriate for patients who also experience bradycardia.

WARNING: Do not use atrial-only modes in patients with heart failure because such modes do not provide CRT.

NOTE: *The safety and effectiveness of CRT was evaluated in clinical studies using the VDD mode. Use medical discretion when programming the pulse generator to pacing modes other than VDD.*

NOTE: *Atrial pacing may prolong interatrial conduction, desynchronizing right and left atrial contractions. The effect of atrial pacing on CRT has not been studied.*

DDD and DDDR

- Could be appropriate for heart failure patients with sinus bradycardia since DDD(R) can provide atrial-synchronous biventricular pacing at rates above the LRL and AV-sequential biventricular pacing at the LRL or sensor-indicated rate—DDDR
- DDD mode may be preferred over VDD mode for patients with sinus bradycardia or atrial rates below the LRL to preserve AV synchrony with CRT delivery

DDI and DDIR

- May not be appropriate for heart failure patients with normal sinus activity
- Could be appropriate for heart failure patients who have no underlying intrinsic sinus rhythm but might experience episodes of atrial tachyarrhythmias such as brady-tachy syndrome
- Provide AV-sequential biventricular pacing only at the LRL or sensor-indicated rate, DDIR, in the absence of sinus activity
- During periods of intrinsic atrial activity above the LRL, non-atrial-synchronous biventricular pacing is delivered at the LRL or sensor-indicated rate

VDD

- VDD is appropriate for heart failure patients with normal sinus activity, since VDD delivers atrial-synchronous biventricular pacing but no atrial pacing
- Consider programming a low LRL for bradycardia support since AV asynchrony is likely to occur during LRL ventricular pacing
- If frequent pacing at the LRL is anticipated or observed, consider programming a DDD(R) mode to maintain AV synchrony during LRL pacing

VDDR

- VDDR may not be appropriate for heart failure patients with normal sinus activity due to the increased potential for loss of AV synchrony
- While this mode can provide atrial-synchronous biventricular pacing during normal sinus activity, sensor-driven ventricular pacing will result in the loss of AV synchrony if the sensor-indicated rate exceeds the sinus rate

VVI and VVIR

- May be detrimental for heart failure patients with normal sinus activity
- Could be appropriate for heart failure patients with chronic atrial tachyarrhythmias or during episodes of atrial tachyarrhythmia since they provide biventricular pacing at the LRL or sensor-indicated rate—VVI(R)
- If patients have AV conduction during atrial tachyarrhythmias that results in inhibition of biventricular pacing (loss of CRT), consider programming an elevated LRL in an attempt to increase the delivery of biventricular pacing and/or to VVI(R), if not already programmed

Dual-Chamber Modes

Do not use DDD(R) and VDD(R) modes in the following situations:

- In patients with chronic refractory atrial tachyarrhythmias (atrial fibrillation or flutter), which may trigger ventricular pacing
- In the presence of slow retrograde conduction that induces PMT, which cannot be controlled by reprogramming selective parameter values

Atrial Pacing Modes

In DDD(R), DDI(R), and AAI(R) modes, atrial pacing may be ineffective in the presence of chronic atrial fibrillation or flutter or in an atrium that does not respond to electrical stimulation. In addition, the presence of clinically significant conduction disturbances may contraindicate the use of atrial pacing.

WARNING: Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF.

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.*

If you have any questions regarding the individualization of patient therapy, contact your sales representative or call Technical Services at the number shown on the back cover of this manual.

Lower Rate Limit (LRL)

LRL is the number of pulses per minute at which the pulse generator paces in the absence of sensed intrinsic activity.

The following interactive limits are effective when programming the LRL. Exercise caution when programming permanent pacing rates below 50 ppm or above 100 ppm.

- LRL must be less than:
  - MPR
  - MSR
  - MTR
- LRL must be at least 15 ppm less than the lowest tachy zone threshold
- The greater of the following values must be at least 10 ppm less than the lowest tachy zone threshold:
  - MPR
  - MSR
  - MTR

In VDD mode, biventricular pacing at the LRL may result in the loss of AV synchrony, which will diminish the benefit of CRT. To promote atrial-synchronous biventricular pacing and minimize the loss of AV synchrony, consider programming the LRL below a sinus rate normally reached while still providing an appropriate rate for bradycardia support.

In VVI mode, biventricular pacing only occurs when the intrinsic ventricular rate is below the LRL. To increase the likelihood of delivering biventricular pacing when the patient has intrinsic AV conduction, consider programming an elevated LRL and/or consider an adaptive-rate pacing mode (VVIR).

Runaway Protection

Runaway protection is designed to prevent pacing rate accelerations for most single-component failures. This feature is not programmable and operates independently from the pulse generator's main pacing circuitry.

The basic pulse period is equal to the pacing rate and the pulse interval (without hysteresis). Runaway protection prevents the pacing rate from increasing above 205 ppm.

NOTE: *Magnet application does not affect the pacing rate (pulse interval).*

NOTE: *Runaway protection is not an absolute assurance that runaways will not occur.*

During PES, Manual Burst pacing, and ATP, runaway protection is temporarily suspended to allow for high-rate pacing.

Maximum Tracking Rate (MTR)

The MTR is the maximum rate at which the paced ventricular rate tracks 1:1 with nonrefractory sensed atrial events. MTR applies to atrial synchronous pacing modes, namely DDD(R) and VDD(R).

The following are considerations for programming the MTR:

- Interactive limits ("Lower Rate Limit (LRL)" on page 5-10).

- For heart failure patients with normal AV conduction, biventricular stimulation (CRT) may not be delivered when the atrial rate exceeds the MTR. This can occur if the AV Delay lengthens beyond the patient's intrinsic intracardiac AV interval and AV conduction occurs, which inhibits ventricular pacing. In both situations (AV block and AV conduction) CRT is compromised when the atrial rate exceeds the MTR, either because of the suboptimal, prolonged AV Delay or a loss of biventricular pacing, or both.

- If the patient's normal atrial rate exceeds the MTR, consider programming a higher MTR to ensure 1:1 atrial synchronous, biventricular pacing at the programmed AV Delay. If reprogramming a higher MTR is limited by the current TARP (AV Delay + PVARP = TARP), attempt to shorten the PVARP before shortening the AV Delay in order to avoid a suboptimal AV Delay for CRT.

- When the sensed atrial rate is between the programmed LRL and MTR, 1:1 ventricular pacing will occur in the absence of a sensed ventricular event within the programmed AV Delay. If the sensed atrial rate exceeds the MTR, the pulse generator might begin a Wenckebach-like behavior to prevent the paced ventricular rate from exceeding the MTR. This Wenckebach-like behavior is characterized by a progressive lengthening of the AV delay until an occasional P-wave is not tracked because it falls into the PVARP. This results in an occasional loss of 1:1 tracking as the pulse generator synchronizes its paced ventricular rate to the next sensed P-wave. Should the sensed atrial rate continue to increase further above the MTR, the ratio of sensed atrial events to sequentially paced ventricular events becomes lower until, eventually, 2:1 block results (e.g., 5:4, 4:3, 3:2, and finally 2:1).

- The PRM will not allow you to program an MTR interval shorter than TARP (AV Delay + PVARP = TARP). If TARP is less than the interval of the programmed MTR, then the pulse generator's Wenckebach-like behavior limits the ventricular pacing rate to the MTR.

- Rapid changes in the paced ventricular rate (e.g., Wenckebach-like, 2:1 block) caused by sensed atrial rates above the MTR may be dampened or eliminated by the implementation of any of the following:

  – AFR
  – ATR
  – Rate Smoothing parameters and sensor input
  – VRR

Maximum Sensor Rate (MSR)

MSR is the maximum pacing rate allowed as a result of sensor control from accelerometer input.

The following considerations are important when programming MSR:

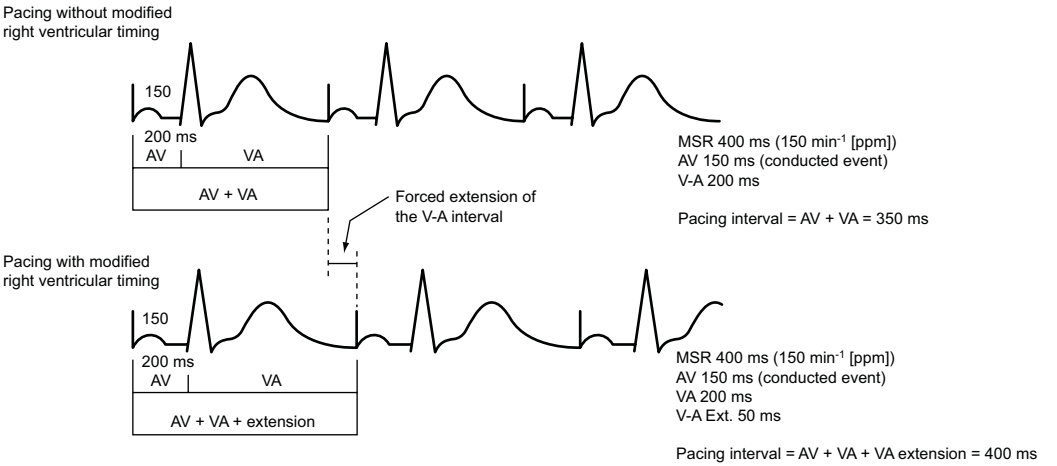
- Patient's condition, age, and general health:
  - Adaptive-rate pacing at higher rates may be inappropriate for patients who experience angina or other symptoms of myocardial ischemia at these higher rates
  - An appropriate MSR should be selected based on an assessment of the highest pacing rate that the patient can tolerate well
- Interactive limits ("Lower Rate Limit (LRL)" on page 5-10)

NOTE: *If the pulse generator is operating in DDD(R) or VDD(R) mode, the MSR and MTR may be programmed independently to different values.*

MSR is independently programmable at, above, or below the MTR. If the MSR setting is higher than the MTR, a pacing rate above the MTR may occur in the presence of high activity levels.

Pacing above the MSR can only occur in response to sensed intrinsic atrial activity.

With 1:1 conduction, the pulse generator maintains the A–A pacing rate by extending the V–V pacing rate. This extension is determined by the degree of difference between the AV Delay and the intrinsic ventricular conduction—often referred to as modified atrial-based timing (Figure 5-1 on page 5-14).



The pulse generator's timing algorithm provides effective pacing at the MSR with intrinsic ventricular conduction. Extending the VA interval prevents the A pace from exceeding the MSR at high rates.

Figure 5-1. VA interval extension and MSR

Ventricular Pacing Chamber

With the ventricular Pacing Chamber option, you can choose which chamber(s) will receive pacing pulses.

The following options are available:

- RV
- BiV (both RV and LV)—when selected, LV Offset becomes available

CAUTION: This device is intended to provide biventricular pacing therapy. Programming the device to provide RV-only pacing, or programming the RV pace amplitude below the pacing threshold (resulting in LV-only pacing), is not intended for the treatment of heart failure. The clinical effects of LV-only or RV-only pacing for the treatment of heart failure have not been established.

LV Offset

LV Offset provides programming flexibility by allowing you to adjust the delay between delivery of the LV and RV pacing pulses.

When the ventricular Pacing Chamber is set to BiV, the LV Offset feature is available to help coordinate the mechanical response of the ventricles (Figure 5-2 on page 5-15).

The device automatically accommodates the LV offset for the lowest programmed tachy rate threshold when biventricular pacing occurs near the upper rate limit.

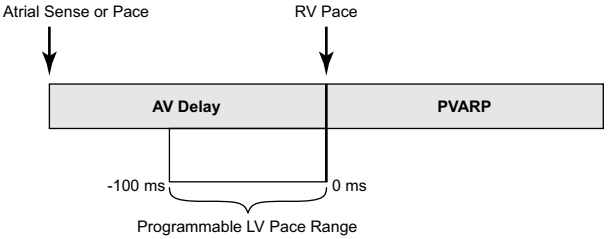


Figure 5-2. Programmable LV pace range

NOTE: *The programmed AV Delay is based on RV timing; therefore, it is not affected by LV Offset.*

Pulse Width

Pulse Width, also referred to as pulse duration, determines how long the output pulse will be applied between the pacing electrodes.

The following considerations are important when programming Pulse Width:

- Pulse widths are independently programmable.
- The energy delivered to the heart is directly proportional to the pulse width. Therefore, programming a shorter pulse width increases pulse generator longevity. To prevent loss of capture, exercise caution when you are programming permanent pulse width values of less than 0.3 ms (Figure 5-3 on page 5-16).

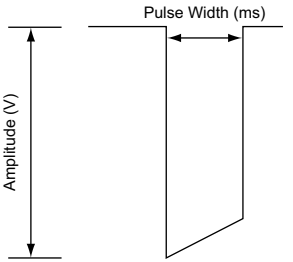


Figure 5-3. Pulse waveform

Amplitude

The pulse Amplitude, or voltage of the output pulse, is measured at the leading edge of the output pulse (Figure 5-3 on page 5-16).

Amplitudes are independently programmable. The following considerations are important:

- During temporary programming, the brady pacing mode may be programmed to Off. In effect, this turns Amplitude off to monitor the patient's underlying rhythm.
- A minimum 2x voltage safety margin is recommended for each chamber based on the capture thresholds, which should provide an adequate safety margin and help preserve battery longevity.
- The energy delivered to the heart is directly proportional to the square of the amplitude. In other words, doubling the amplitude quadruples the energy delivered, which will decrease pulse generator longevity. Programming to a lower Amplitude while maintaining an adequate safety margin may increase battery longevity.

Sensitivity

The Sensitivity parameter allows the pulse generator to detect intrinsic cardiac signals that exceed the programmed value.

All detection and timing decisions are based on the sensed cardiac cycle length. These pulse generators use an automatic gain control circuit to dynamically adjust the sensitivity.

- High Sensitivity (low value)—when Sensitivity is programmed to a very sensitive setting, the pulse generator may detect signals unrelated to cardiac depolarization (oversensing, such as sensing of myopotentials)

- Low Sensitivity (high value)—when Sensitivity is programmed to a less sensitive setting, the pulse generator may not detect the cardiac depolarization signal (undersensing)

POST-THERAPY PACING

Post-therapy pacing provides alternate pacing therapy following the delivery of any shock.

The pacing mode and pacing therapies used following a shock are the same as the programmed Normal pacing settings.

The following pacing parameters can be programmed independently from the Normal pacing settings:

- Pacing Parameters—LRL, Amplitude, and Pulse Width
- Post Therapy Period

Post-Shock Pacing Delay

The Post-Shock Pacing Delay determines the earliest possible start of post-shock pacing following the delivery of a ventricular shock and is fixed at 3 seconds.

The timing of the initial pacing pulse in the Post-Therapy Period depends on the cardiac activity during the Post-Shock Pacing Delay.

- If R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-Shock Pacing Delay, the device paces only when the sensed rate is slower than the post-therapy LRL.

- If no R-waves (and/or P-waves for dual-chamber pacing modes) are sensed during the Post-Shock Pacing Delay or if the interval since the preceding P- or R-wave was greater than the escape interval, a pacing pulse is delivered at the end of the Post-Shock Pacing Delay.

Subsequent pacing pulses are delivered as required, depending on the pacing prescription.

Post-Therapy Period

The Post-Therapy Period determines how long the pulse generator operates using the post-therapy parameter values.

The Post-Therapy Period functions as follows:

- The period starts when the Post-Shock Pacing Delay expires
- On completion of this pacing period, the pulse generator reverts to the programmed Normal pacing values
- While in process, the pacing period is not affected by the end of the current episode

TEMPORARY PACING

The pulse generator can be programmed with temporary pacing parameter values that differ from the programmed Normal Settings. This allows you to examine alternate pacing therapies while maintaining the previously programmed Normal Settings in the pulse generator memory. During the Temporary function, all other bradycardia features are disabled.

NOTE: *Post-therapy values are not affected.*

To use this function, follow these steps:

1. From the Tests tab, select the Temp Brady tab to display the temporary parameters. When the parameters are initially displayed, they are set to the Normal Settings values ("Programmable Options" on page A-1).

NOTE: *Post-therapy values are not shown even if post-therapy is presently in effect.*

2. Select the desired values; these values are independent from other pacing functions.

3. Establish telemetry communication, then select the Start button. Pacing begins at the temporary values. A dialog box indicates that temporary parameters are being used, and a Stop button is provided.

NOTE: *Temporary pacing cannot be started while a tachyarrhythmia episode is in progress.*

NOTE: *Emergency therapy is the only function that can be initiated until the Temporary function is stopped.*

4. To stop the Temporary pacing mode, select the Stop button. The Temporary pacing mode also stops when you command emergency therapy from the PRM or when you press the DIVERT THERAPY key. Once stopped, the pacing reverts to the previously programmed Normal/Post-Therapy settings.

SENSORS AND TRENDING

Sensor and trending therapies include the parameters as described.

Sensor Trending

Sensor Trending provides a graphical display of the sensor rate based on sensor data. This feature evaluates the pulse generator's rate response to the patient's detected activity level and provides useful information during exercise testing.

The pulse generator collects and stores rate and sensor data. The rate data represents the programmed parameters. The Sensor Replay option allows you to adjust the parameter values and view the result without having to repeat an exercise test. The pulse generator also collects and stores data in nonadaptive-rate modes; however, without the sensor data comparison, only rate data will be displayed.

The Sensor Trending screen is accessible from within Normal Settings (Figure 5-4 on page 5-19).

Figure 5-4. Sensor Trending screen

Setup includes the following options:

- Recording Method—programmable:
  - 30-Second Average
  - Beat to Beat
- Duration—programmable:
  - When Recording Method is set to Off or 30-Second Average—fixed, approximately 25 hours
  - When Recording Method is set to Beat to Beat—fixed, approximately 40 minutes at 75 bpm
- Data Storage—programmable:
  - Continuous—contains the most recent data available. Storage starts when setup is confirmed and continuously records the latest information, overwriting the oldest data until the information is retrieved. This option allows you to view data for the recording duration immediately prior to data retrieval.
  - Fixed—storage starts when setup is confirmed and continues until device memory storage is full. This allows you to view data from initial setup for a fixed amount of time.
  - Off—when Sensor Trending is programmed to Off, no trending data is gathered.

Select the View button to vary the time period for how much data is visible; options exist for 1–25 hours. To adjust the vertical axis, move the slider bar at the bottom of the display window.

Adaptive-rate Pacing

In adaptive-rate pacing modes, sensors are used to detect changes in the patient's metabolic demand and increase the pacing rate accordingly. Adaptive-rate pacing is intended for patients who exhibit chronotropic incompetence and who would benefit from increased pacing rates that are concurrent with physical activity.

CAUTION: Adaptive-rate pacing should be used with care in patients who are unable to tolerate increased pacing rates.

When adaptive-rate parameters are programmed, the pacing rate increases in response to increased activity, then decreases as the activity returns to a resting level.

NOTE: *Activity involving minimal upper body motion, such as bicycling, may result in only a moderate pacing response.*

NOTE: *Adaptive-rate pacing has been shown to be potentially proarrhythmic. Use caution when programming adaptive-rate features.*

Accelerometer

The accelerometer detects motion that is associated with a patient's physical activity and generates an electronic signal that is proportional to the amount of body motion. Based on accelerometer input, the pulse generator estimates the patient's energy expenditure as a result of exercise, then translates it into a rate increase.

The pulse generator senses body motion by means of an integrated circuit accelerometer located on the hybrid circuit. The accelerometer sensor responds to activity in the frequency range of typical physiologic activity (1–10 Hz). The accelerometer evaluates both the frequency and the amplitude of the sensor signal.

- Frequency reflects how often an activity occurs, such as the number of steps taken per minute during a brisk walk
- Amplitude reflects the force of motion (e.g., the more deliberate steps taken while walking)

Once detected, an algorithm translates the measured acceleration into a rate increase above the LRL.

Because the accelerometer is not in contact with the pulse generator case, it does not respond to simple static pressure on the device case.

There are three Accelerometer settings: Off, On, and ATR Only. When you program the respective rate-responsive modes for Normal Settings and ATR Fallback, that action automatically updates the Accelerometer setting. 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 mode using the accelerometer sensor. In this case, the Accelerometer field will display ATR Only.

The following programmable parameters control the pulse generator's response to the sensor values generated by the Accelerometer:

- Activity Threshold
- Reaction Time
- Response Factor
- Recovery Time

Activity Threshold

Activity Threshold prevents rate increases due to low-intensity, extraneous motion (e.g., motion caused by respiration, heart beat, or in some cases tremor associated with Parkinson's disease).

Activity Threshold represents the activity level that must be exceeded before the sensor-driven pacing rate will increase. The pulse generator will not increase the paced rate above the LRL until the activity signal increases above the Activity Threshold. An Activity Threshold setting should allow a rate increase with minor activity, such as walking, but be high enough so the pacing rate will not increase inappropriately when the patient is inactive (Figure 5-5 on page 5-23, Figure 5-6 on page 5-23).

- Lower setting—less motion is required to increase the pacing rate
- Higher setting—more motion is required to increase the pacing rate
- Nominal setting—shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

NOTE: *Programming the Activity Threshold for Normal Settings also changes the corresponding selection for Post-Therapy Settings.*

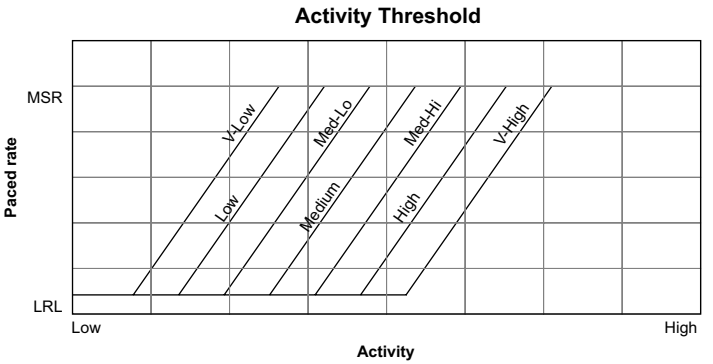
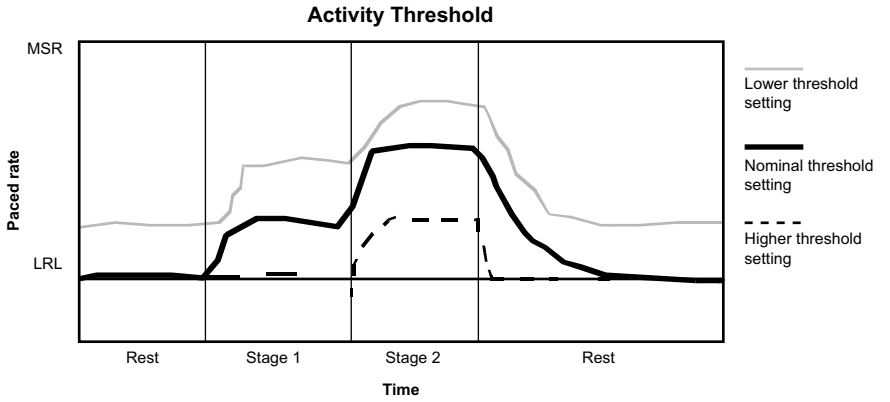


Figure 5-5. Activity Threshold and rate response



This figure demonstrates the effect of increased or decreased Activity Threshold settings in response to a theoretical two-stage exercise test.

Figure 5-6. Activity Threshold in exercise test

Reaction Time

Reaction Time determines how quickly the pacing rate will rise to a new level once an increase in activity level is detected.

Reaction Time affects only the time required for a rate increase to occur. The value selected determines the time required for the paced rate to move from the LRL to the MSR for a maximum level of activity (Figure 5-7 on page 5-24 and Figure 5-8 on page 5-24).

- Short Reaction Time: results in a rapid increase in the pacing rate

- Long Reaction Time: results in a slower increase in the pacing rate
- Nominal setting: shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

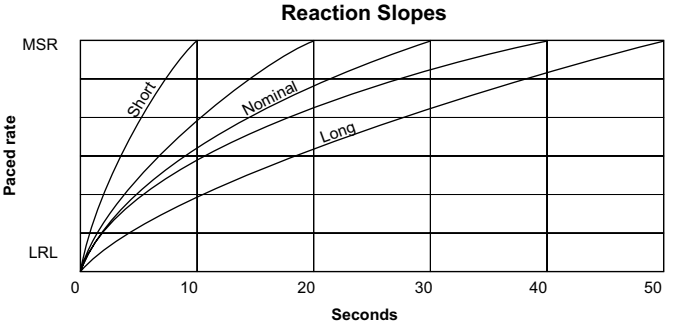


Figure 5-7. Reaction Time and paced rate

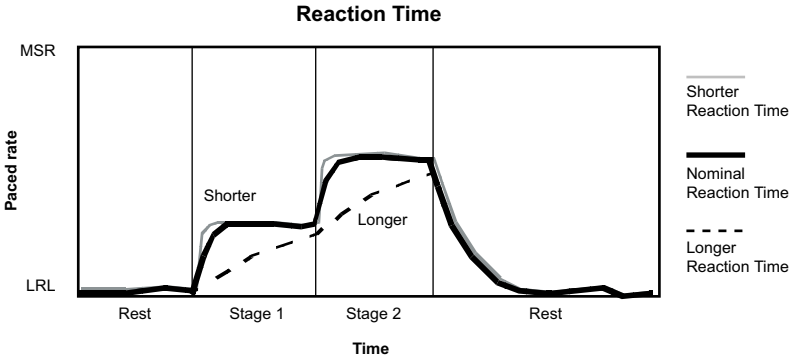


Figure 5-8. Reaction Time in exercise test

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

Response Factor (Accelerometer)

Response Factor (accelerometer) determines the pacing rate that will occur above the LRL at various levels of patient activity (Figure 5-9 on page 5-25).

- High Response Factor—results in less activity required for the pacing rate to reach the MSR

- Low Response Factor—results in more activity required for the pacing rate to reach the MSR

- Nominal setting—shown to be appropriate for the majority of patients in a previous Guidant study; therefore, it is recommended for use in monitoring the rate response prior to programming changes

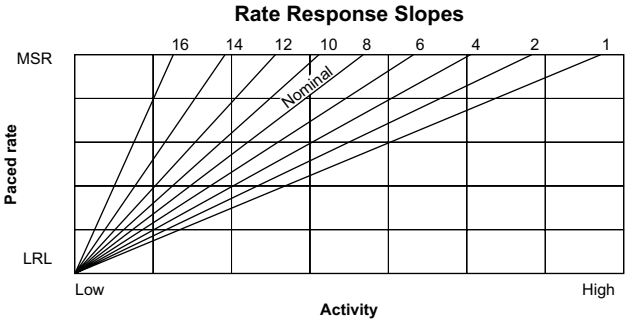
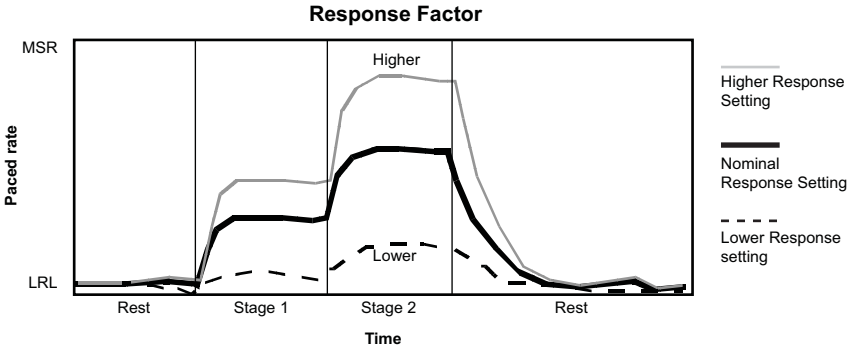


Figure 5-9. Response Factor and paced rate

The pacing rate achieved can be limited either by the detected activity level or the programmed MSR. If the detected activity level results in a steady-state rate below the MSR, the pacing rate can still increase when the detected activity levels increase (Figure 5-10 on page 5-25).



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

Figure 5-10. Response Factor in exercise test

Programming the LRL up or down moves the entire response up or down without changing its shape. The steady-state response is independent of the programmed reaction and recovery times.

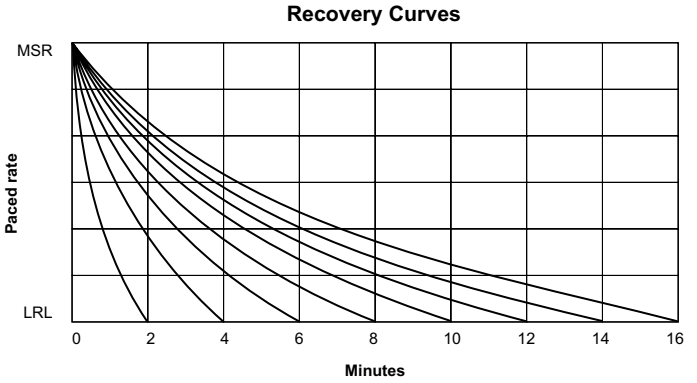
The Passive setting can be used to allow accelerometer trending without a rate response. In this setting, the Brady Mode is programmed to a non–rate-adaptive mode and the Recording Method for sensor trending is not programmed to Off.

Programming Response Factor for Normal Settings also changes the corresponding selection for Post-Therapy Settings.

Recovery Time

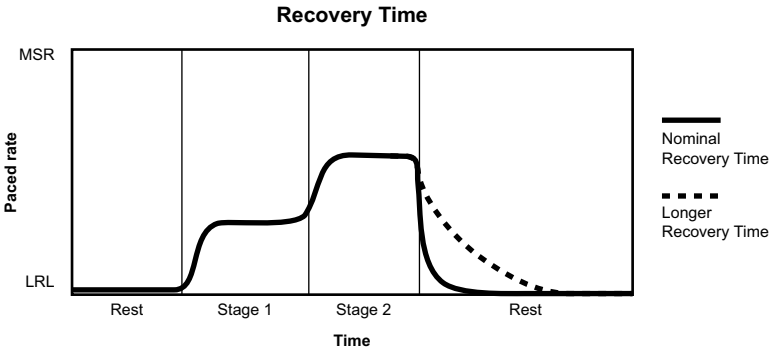
Recovery Time determines the time required for the paced rate to decrease from the MSR to the LRL in the absence of activity. When patient activity concludes, Recovery Time is used to prevent an abrupt decrease in pacing rate (Figure 5-11 on page 5-26 and Figure 5-12 on page 5-27).

- Short Recovery Time—results in a faster decrease in pacing rate after patient activity lowers or stops
- Long Recovery Time—results in a slower decrease in pacing rate after patient activity lowers or stops



There are 15 settings available; only the even-numbered settings are shown.

Figure 5-11. Recovery Time and paced rate



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

Figure 5-12. 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.

ATR also limits the amount of time that CRT is inhibited due to pathological atrial tachycardia.

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 5-13 on page 5-28).

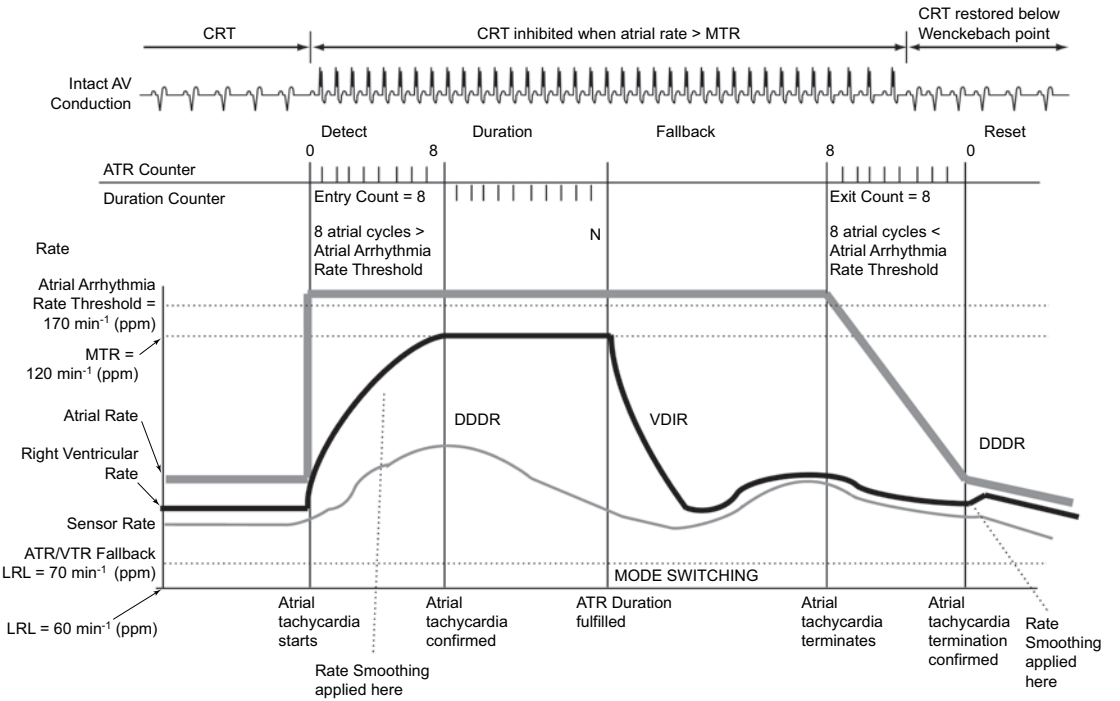


Figure 5-13. ATR behavior

CAUTION: ATR should be programmed to On if the patient has a history of atrial tachyarrhythmias. The delivery of CRT is compromised because AV synchrony is disrupted if the ATR mode switch occurs.

When a heart failure patient has an atrial tachyarrhythmia episode, the effectiveness of CRT is compromised because AV synchrony is disrupted. While ATR cannot resolve AV asynchrony, it can quickly bring the biventricular paced rate from the MTR to the ATR/VTR Fallback LRL, VRR rateor sensor-indicated rate (DDIR or VDIR). Programming a short ATR Duration and ATR Fallback Time allows a quicker mode switch and faster decrease in the biventricular pacing rate.

Patients with intact AV conduction may have conducted ventricular rates during ATR episodes. If the intrinsic ventricular rate exceeds the biventricular pacing rate during the ATR episode, biventricular pacing will be inhibited. For these patients, consider programming the VRR feature to On.

NOTE: *In ATR, the pacing chamber is always biventricular.*

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: *In Fallback Mode, the pacing chamber is biventricular.*

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
- 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 (BiV) 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.

The device automatically accommodates the AV delay for the lowest programmed tachy rate threshold when atrial pacing occurs near the upper rate limit.

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. In addition, VRR preserves CRT delivery during conducted atrial arrhythmias.

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.

- The degree of rate increase with sensed intervals is determined by the programmed setting (Min, Med, Max). The influence is tempered by the previous history because of the weighted-sum methodology stated above.

- The VRR-indicated rate is further bound by the LRL and the VRR MPR.

NOTE: *VRR has the potential to increase CRT delivery during atrial tachyarrhythmias and should be programmed on at the maximum setting to increase the ventricular pacing percent and maximize CRT delivery during conducted atrial tachyarrhythmias.*

The programmable values affect the degree of rate regulation.

- A higher setting will increase CRT pacing more than a lower setting (i.e., Max vs. Med)

- A higher setting will decrease V–V variability more than a lower setting

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 on in nontracking modes, VRR is continually active and updates the VRR-indicated pacing rate on each cardiac cycle.

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.

Biventricular Trigger

Biventricular Trigger is designed to promote synchronized RV and LV contractions in the presence of RV sensed events. It does this by pacing the left and right ventricles immediately after a sensed RV event. When used in conjunction with VRR, Biventricular Trigger is designed to provide additional CRT support during atrial tachycardias.

Biventricular Trigger may be applied during dual or single chamber ventricular pacing modes and also during ATR Fallback.

Biventricular Trigger operates between the LRL and the MPR.

Biventricular Trigger Maximum Pacing Rate (MPR)

The Biventricular Trigger MPR limits the maximum pacing rate that Biventricular Trigger can reach.

During VDD(R) or DDD(R) modes, MTR limits the Biventricular Trigger 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.

This changes the programmed AV Delay and may alter the effectiveness of CRT if the AFR rate is programmed slower than the patient's sinus rate.

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.

Tracking Preference

Tracking Preference is designed to maintain atrial-tracked ventricular pacing in DDD(R) and VDD(R) modes by identifying atrial events for tracking that are hidden in PVARP. This feature supports CRT delivery for atrial rates below but near the MTR; otherwise, therapy might be inhibited.

Hidden atrial events can occur when a patient has a combination of a long intrinsic intracardiac AV interval and a long PVARP. If two successive cycles occur in which a sensed RV event is preceded by an atrial sensed event in PVARP, the pulse generator shortens PVARP until normal atrial-tracked ventricular pacing is established. By programming Tracking Preference to On, continuous CRT is delivered at rates below MTR-rates which otherwise might be inhibited when the sum of PVARP and the intrinsic intracardiac AV interval is longer than the MTR interval.

As a result of Tracking Preference, the timing relationship between PVARP and the atrial event is changed such that the atrial events no longer fall within PVARP. Timing is changed by the pulse generator's use of the programmed AV Delay instead of the intracardiac AV interval. The effect of Tracking Preference on atrial rates is illustrated below (Figure 5-14 on page 5-36).

NOTE: *Tracking Preference is disabled if the atrial rate interval is greater than or equal to the MTR interval. This prevents the tracking of potentially pathological atrial rates and PMT.*

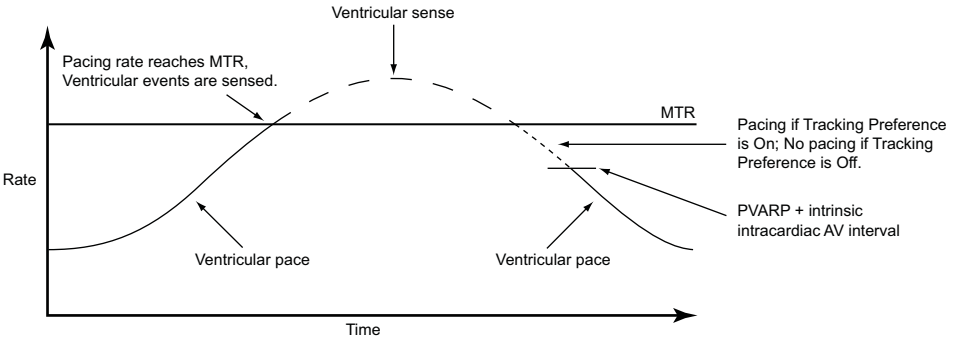


Figure 5-14. Tracking Preference on atrial events hidden in PVARP

Rate Hysteresis

Rate Hysteresis can improve device longevity by reducing the number of pacing stimuli. This feature is available in DDD and AAI modes and is activated by a single nonrefractory, sensed atrial 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

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.

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.

Rate Smoothing operates between the LRL and the MTR when programmed to DDD(R) or VDD(R), and it operates between the LRL and the MPR when programmed to DDI(R).

When the sensor is enabled and MSR is higher than MTR and MPR, 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.
- 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 5-15 on page 5-40):

- 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 R–R interval (RV event or LV paces when the Pacing Chamber is programmed to LV).

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

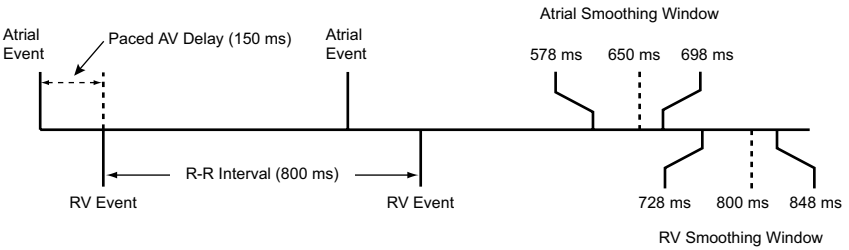


Figure 5-15. Rate smoothing synchronization window

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.

NOTE: *Rate Smoothing Up will transiently modify the programmed AV Delay. This could change the effectiveness of the AV Delay recommended with SmartDelay optimization.*

When Rate Smoothing Up is programmed on, CRT is compromised during episodes of atrial rate increases that exceed the programmed value.

- For patients with AV block, this occurs because Rate Smoothing prolongs the AV Delay from the optimal setting as it controls the biventricular pacing rate while the atrial rate increases.

- For patients with normal AV conduction, biventricular stimulation (CRT) may be inhibited in one or more cycles during the rate smoothing operation because intrinsic AV conduction may occur during the prolonged AV Delay and inhibit ventricular pacing.

While the effect of the Rate Smoothing Up operation may only be transient and its impact on CRT minimal, consider the following recommendations when programming this parameter on.

- Address only patient-specific, sudden atrial rate increases.

- Use the highest value that can achieve the desired control because the higher the value, the less the impact on the AV Delay extension.

Rate Smoothing Down

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

CRT delivery is not altered by programming Rate Smoothing Down on. However, it is important to consider that when Rate Smoothing Down is on in the DDD(R) mode, atrial pacing will occur during the downward rate smoothing operation. The AV Delay for optimal CRT may be different during atrial pacing than during intrinsic sinus rhythm.

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
- Right Ventricle
- Left Ventricle

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

The Lead Settings screen (accessible from Normal Settings) allows you to choose pacing and sensing configurations for the LV lead.

Left Ventricular Electrode Configuration

The LV electrode configuration provides programmable options for LV lead pacing and sensing.

CAUTION: Proper programming of the LV coronary venous lead configuration is essential for proper LV lead function. Program the lead configuration in accordance with the number of electrodes on the LV lead; otherwise, erratic LV sensing, loss of LV pacing, or ineffective LV pacing might occur.

The following programming options are available:

- **Dual**—used when an LV lead with two electrodes is implanted
- **Single**—used when an LV lead with only one electrode is implanted
- **None**—used when an LV lead is not implanted. These pulse generators are intended for use with an LV lead; however, there may be clinical situations such as those described below in which an LV lead is not used:
  - The LV lead cannot be positioned, and a decision is made to temporarily use the pulse generator without an LV lead (plug the unused LV port).
  - The LV lead dislodges to a suboptimal position, and a decision is made to leave the lead implanted and connected but not use it.

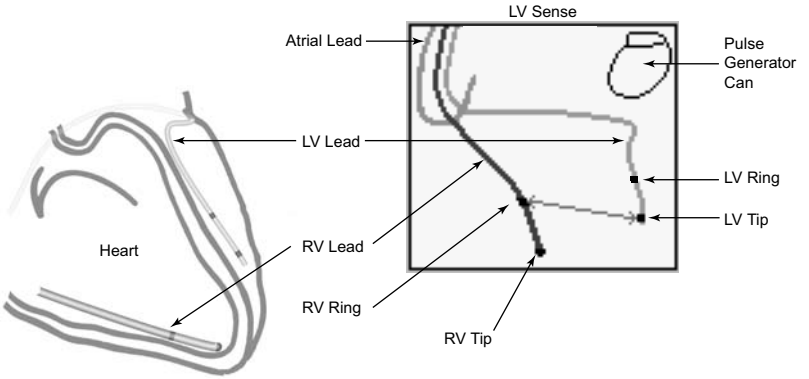
  The pulse generator cannot detect whether an LV lead is present or absent.

When None is selected, the Pacing Chamber must be RV only, which will result in no LV sensing or LV pacing. With this option, the following are unavailable:

- LV electrograms
- LV markers
- LV intervals
- SmartDelay optimization
- LV Daily measurements

Any time a change is made to the electrode configuration, it is important to verify lead system baseline measurements to ensure optimal functioning.

The programmed selections are reflected in the electrode configuration illustration on the programmer screen (Figure 5-16 on page 5-44).



Left illustration: heart with LV and RV leads. Right illustration: leads on the programmer screen.

Figure 5-16. Heart, LV, and RV lead in situ

LV Pace and Sense Configurations

Multiple LV pace and sense configurations are available for the lead, allowing you to change the pacing or sensing vectors for increased signal selection. Additional programming options are available when a dual-electrode LV lead is implanted and the corresponding electrode configuration is programmed to Dual.

Illustrations of pace and sense configurations are shown below (Table 5-1 on page 5-44).

Table 5-1. Programming options for the LV lead configuration

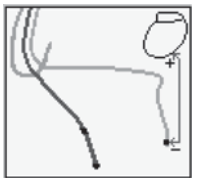
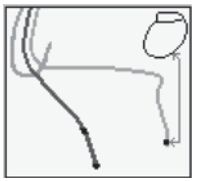
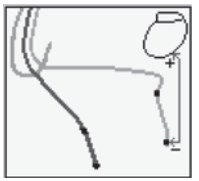
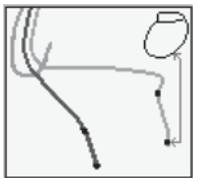
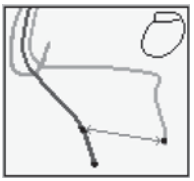
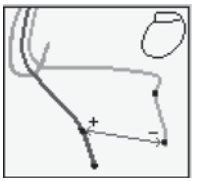
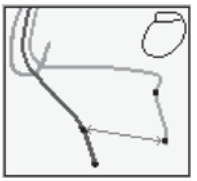
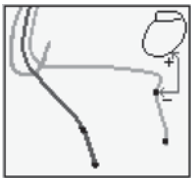
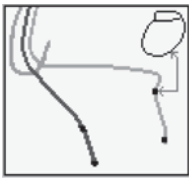
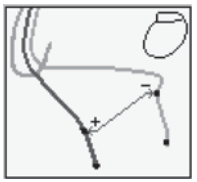
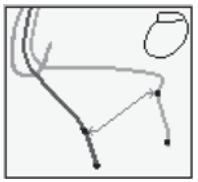
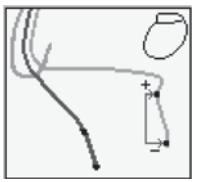
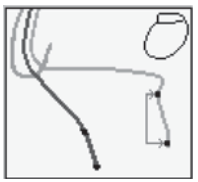
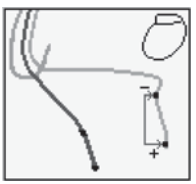
Programmable Value	Single Electrode		Dual Electrode	
	Pace	Sense	Pace	Sense
LVtip>>Can (Unipolar[a])				

Table 5-1. Programming options for the LV lead configuration (continued)

Programmable Value	Single Electrode		Dual Electrode	
	Pace	Sense	Pace	Sense
LVtip>>RV (Extended Bipolar[c])				
LVring>>Can (Unipolar[a])	N/A	LV Off[d]		
LVring>>RV (Extended Bipolar[c])	N/A	N/A		
LVtip>>LVring (Bipolar[b])	N/A	N/A		
LVring>>LVtip (Bipolar[b])	N/A	N/A		LV Off[d]

a. **Unipolar**: from one of the LV electrodes to the pulse generator can.
b. **Bipolar**: between the LV tip and the LV ring electrode; refers to a circuit where current travels between 2 electrodes located on the same lead—in this case, the LV lead.
c. **Extended Bipolar**: from one of the LV electrodes to the RV electrode; refers to a circuit where current travels between the cathode (negative [–] electrode) on the LV lead and the anode (positive [+] electrode) on the bipolar RV lead.
d. This configuration can be programmed to Off, which may be useful in instances such as lead fracture.

NOTE: *If LV electrograms were available at the start of temporary Brady/CRT pacing, then they will continue to be available. However, if LV electrograms were unavailable at the start of temporary Brady/CRT pacing, then they will continue to be unavailable.*

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 when the Ventricular Pacing Chamber is programmed to BiV or RV only.

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

CAUTION: To ensure a high percentage of biventricular pacing, the programmed AV Delay setting must be less than the patient's intrinsic PR interval.

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.

The Paced AV Delay setting should be individualized for each patient to ensure consistent CRT delivery. Several methods are available to determine the Paced AV Delay setting, including:

- Intrinsic QRS duration assessment
- Echocardiogram evaluation
- Pulse pressure monitoring

The following technique was a suggested protocol during the CONTAK CD Study:

1. Program progressively shorter Paced AV Delay settings until the maximum pre-excitation is observed.

2. Shorten the Paced AV Delay by an additional 50 ms but no lower than 70 ms.

3. If the Paced AV Delay is still greater than 200 ms, program the Paced AV Delay to 200 ms.

4. Evaluate the ventricular pacing function with a Holter recording, if possible, to ensure pacing without significant fusion or pseudofusion.

5. Evaluate the patient's intrinsic PR interval (intrinsic intracardiac AV interval) during exercise. Dynamic AV Delay is permitted for patients who demonstrate significant shortening of the PR interval during exercise.

Since optimization of the Paced AV Delay can significantly influence CRT effectiveness, consider using methods that demonstrate the hemodynamic impact of different Paced AV Delay settings, such as echocardiography or pulse pressure monitoring.

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.

Dynamic AV Delay was not evaluated in the CONTAK CD study.

When using Dynamic AV Delay, consider evaluating the Paced AV Delay in effect when the patient has an elevated heart rate to ensure that CRT is still effective.

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 5-17 on page 5-48).

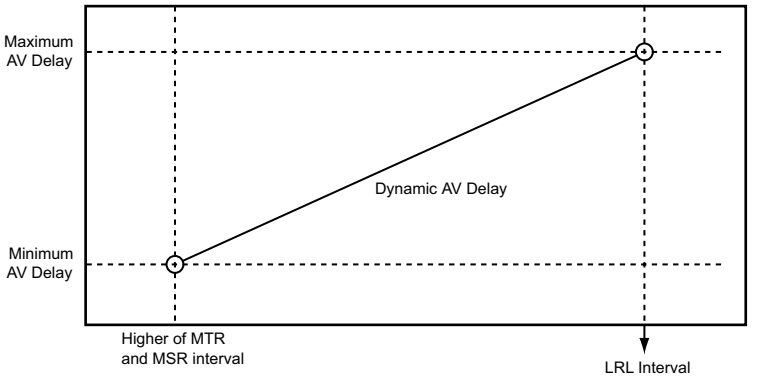


Figure 5-17. Dynamic AV Delay linear relationship

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 5-18 on page 5-49).

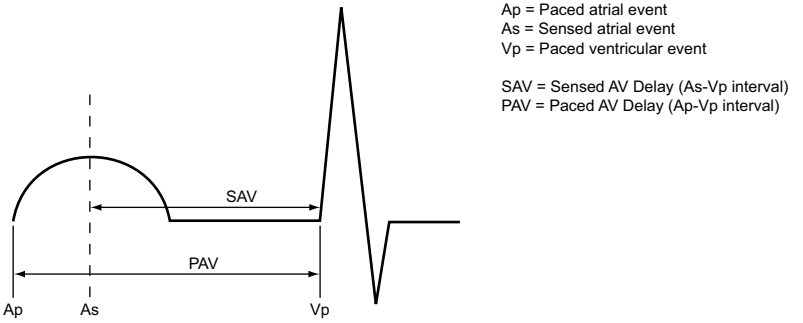


Figure 5-18. Sensed AV Delay

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.

When the DDD(R) mode is used to deliver biventricular stimulation (CRT), it may be necessary to program different Paced and Sensed AV Delay settings to optimize CRT during normal sinus rhythm and during atrial pacing because atrial pacing may prolong the interatrial delay. The prolonged interatrial delay may require a longer Paced AV Delay to achieve an optimal timing relationship between left atrial activation and biventricular pacing.

When programmed to DDD(R), it is recommended that the patient be tested to determine the optimal AV Delay during atrial sensing and atrial pacing. If the optimal AV Delays are different, this can be reflected by programming different Paced AV Delay and Sensed AV Delay parameter settings.

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 5-19 on page 5-50). 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.

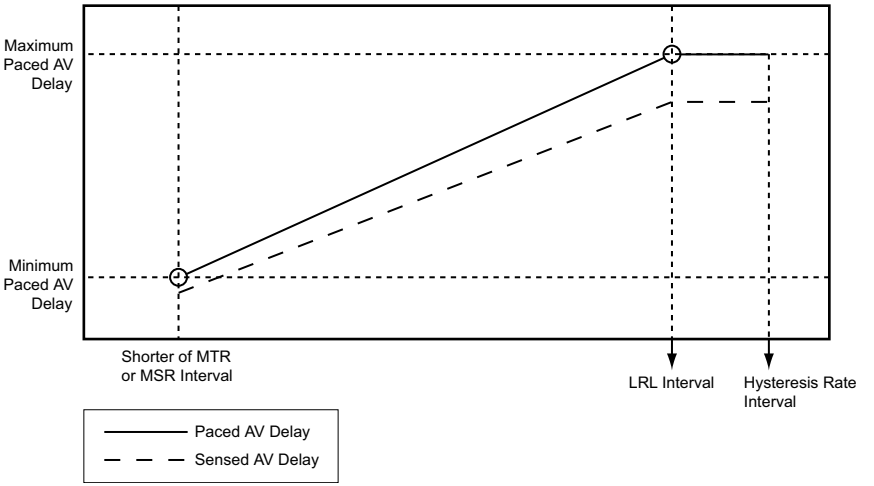


Figure 5-19. Dynamic and Sensed AV Delay as a function of the escape interval

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

SmartDelay Optimization

The SmartDelay optimization test uses atrial sensed and paced events to determine suggested settings for the following:

- Paced AV Delay
- Sensed AV Delay
- Ventricular Pacing Chamber
- LV Offset

These suggested settings can be used when programming the pulse generator for CRT.

NOTE: *Before making a programming change, it is important to assess whether the suggested settings are appropriate for the patient.*

The SmartDelay optimization screen is shown below (Figure 5-20 on page 5-51).

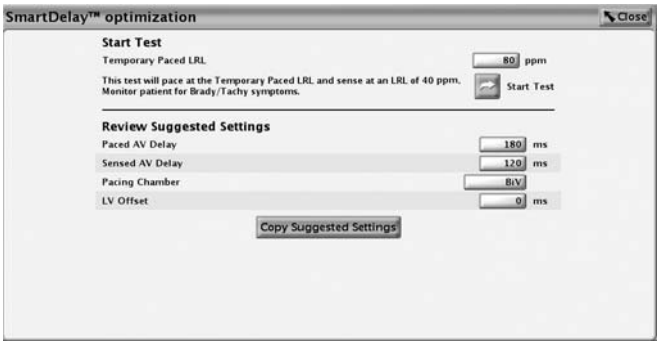


Figure 5-20. SmartDelay optimization screen

SmartDelay optimization automatically switches to a unipolar sensing configuration (LVtip>>Can) for the duration of the test. The test runs automatically when Start Test is pressed. The SmartDelay optimization test will not run under the following conditions:

NOTE: *Tachy therapy is disabled while the test is in progress.*

- During the post-therapy period
- When the LV Electrode Configuration is programmed to None
- During an ATR mode switch
- During a tachycardia episode as determined by the pulse generator detection criteria

NOTE: *When collecting atrial sensed events during the test, backup DDD pacing is provided at 40 ppm.*

NOTE: *When collecting atrial paced and sensed events, backup DDD pacing is provided at the temporary LRL, which can be selected from the SmartDelay optimization screen. This temporary LRL is nominally set to 80 ppm.*

Follow these steps to run the SmartDelay optimization test.

1. From the Normal Settings screen, select the mode.

- In DDD(R) mode, the recommendation is for both Paced AV Delay and Sensed AV Delay.
- In VDD(R) mode, the recommended AV Delay is the Sensed AV Delay; the Paced AV Delay does not apply.

When changing modes from DDD(R) to VDD(R) or vice versa, it is important to rerun the SmartDelay optimization test.

2. Select the SmartDelay optimization button.
3. Maintain telemetry throughout the test.
4. Before beginning the test, advise the patient to remain still and to avoid talking during the test.
5. Press the Start Test button. A notification window indicates that the test is in progress. If it is necessary to cancel the test, select the Cancel Test button.

NOTE: *The test is automatically cancelled if a STAT PACE, STAT SHOCK, or DIVERT THERAPY command is selected.*

6. When the test is complete, the test date is displayed and saved, and the suggested settings appear. For ease in programming, select the Copy Suggested Settings button to transfer the suggested settings to the Normal Brady and CRT Settings screen.

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 the tracking of retrograde atrial activity initiated in the ventricle.

For heart failure patients with intact AV conduction, a long intrinsic intracardiac AV interval and a long programmed PVARP can cause the loss of atrial tracking below the MTR, resulting in the loss of biventricular stimulation (CRT). If an atrial event, such as a PAC or a P-wave that immediately follows a PVC, falls into PVARP, it will not be tracked. This allows for AV conduction of an intrinsic ventricular event, which restarts PVARP. Unless the next atrial event occurs outside of PVARP, it too will not be tracked, and another intrinsic AV-conducted ventricular event will occur, again restarting PVARP. This pattern can continue until an atrial event is finally sensed outside of PVARP (Figure 5-21 on page 5-53).

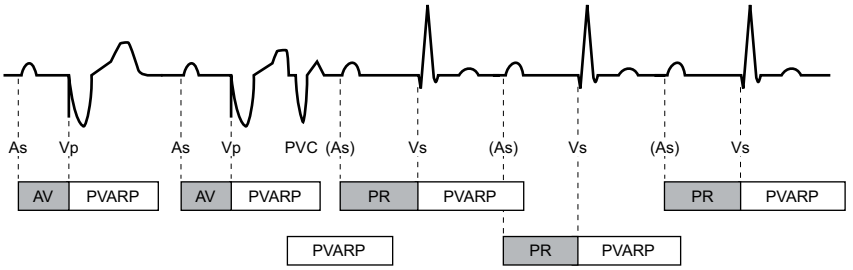


Figure 5-21. Atrial sensed event in PVARP

If you believe a loss of atrial tracking below the MTR is occurring, program Tracking Preference to On. If the loss of CRT below MTR continues to be a problem or if Tracking Preference is not used, consider reprogramming a shorter PVARP.

For heart failure patients with second- and third-degree AV block, 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.

For heart failure patients with intact AV conduction, PVARP after PVC has the potential to cause inhibition of CRT if the atrial cycle length is shorter than the intrinsic intracardiac AV interval (PR interval) + PVARP. If this occurs, program Tracking Preference to On in conjunction with the PVARP after PVC feature.

RV-Refractory (RVRP)

The RVRP provides an interval following an RV pace event, or leading ventricular pace event when LV Offset is not programmed to zero, 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 5-22 on page 5-55):

- 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.

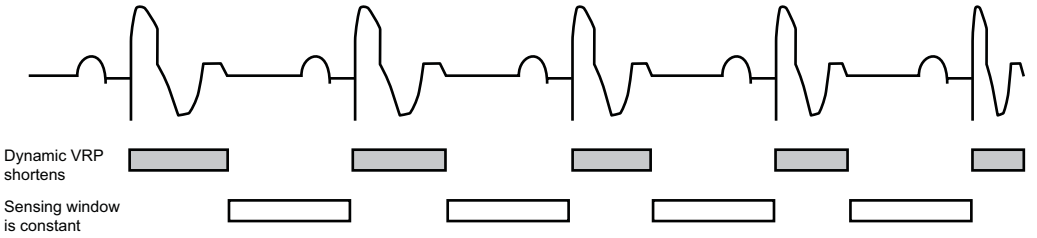


Figure 5-22. Relationship between ventricular rate and refractory interval

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

LV-Refractory (LVRP)

The LVRP prevents sensed electrical events from causing an inappropriate loss of CRT following a sensed or paced event, such as a left-sided T-wave. Proper programming of this feature will help maximize CRT delivery while reducing the risk of accelerating the patient's rhythm to a ventricular tachyarrhythmia.

CRT should be delivered continuously to maximize the patient benefit; however, there are circumstances when it may be appropriate to inhibit therapy delivery. LVRP provides an interval following an LV sense or pace event, or leading ventricular pace event when LV Offset is not programmed to zero, during which LV sensed events do not impact the timing of therapy delivery. Use of a long LVRP shortens the LV sensing window.

LVRP is available in any mode where LV sensing is enabled. The LV interval remains at the programmed fixed value between the LRL and the applicable upper rate limit.

LV oversensing of a T-wave may inhibit LV pacing. To prevent inappropriate inhibition of LV pacing, program LVRP to a duration sufficiently long to include the T-wave.

Left Ventricular Protection Period (LVPP)

The LVPP prevents the pulse generator from inadvertently delivering a pacing stimulus during the LV vulnerable period if, for example, a left-sided PVC

occurs. Proper programming of this feature will help maximize CRT delivery while reducing the risk of accelerating the patient's rhythm to a ventricular tachyarrhythmia.

CRT should be delivered continuously to maximize the patient benefit; however, there are circumstances when it may be appropriate to inhibit therapy delivery. LVPP is the period after a paced or sensed LV event when the pulse generator will not pace the left ventricle. LVPP prevents the pulse generator from pacing into the LV vulnerable period.

CAUTION: Use of a long LVPP reduces the maximum LV pacing rate and may inhibit CRT at higher pacing rates.

NOTE: *If LVPP inhibits in LV-only, the pulse generator will issue an RV pace for bradycardia support.*

LVPP is available in any mode where ventricular sensing and LV pacing are enabled.

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.

LV-Blank after A-Pace

LV-Blank after A-Pace, a cross chamber blanking period, inhibits LV 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 an RV or LV 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:

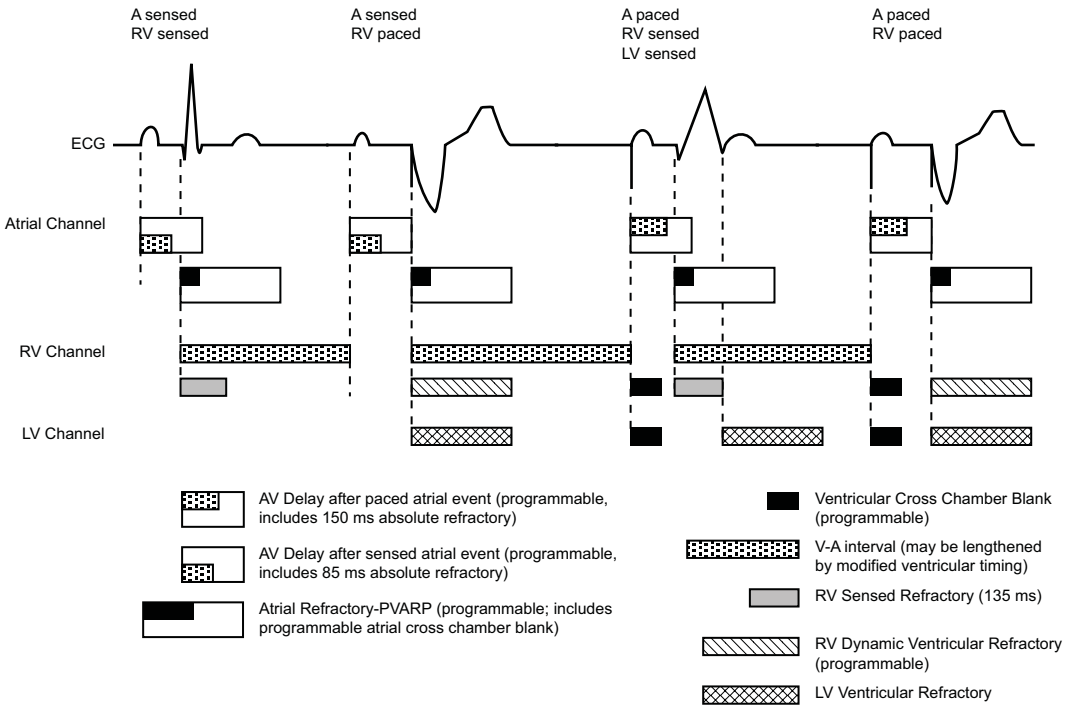


Figure 5-23. Refractory periods, dual-chamber pacing modes; RV only

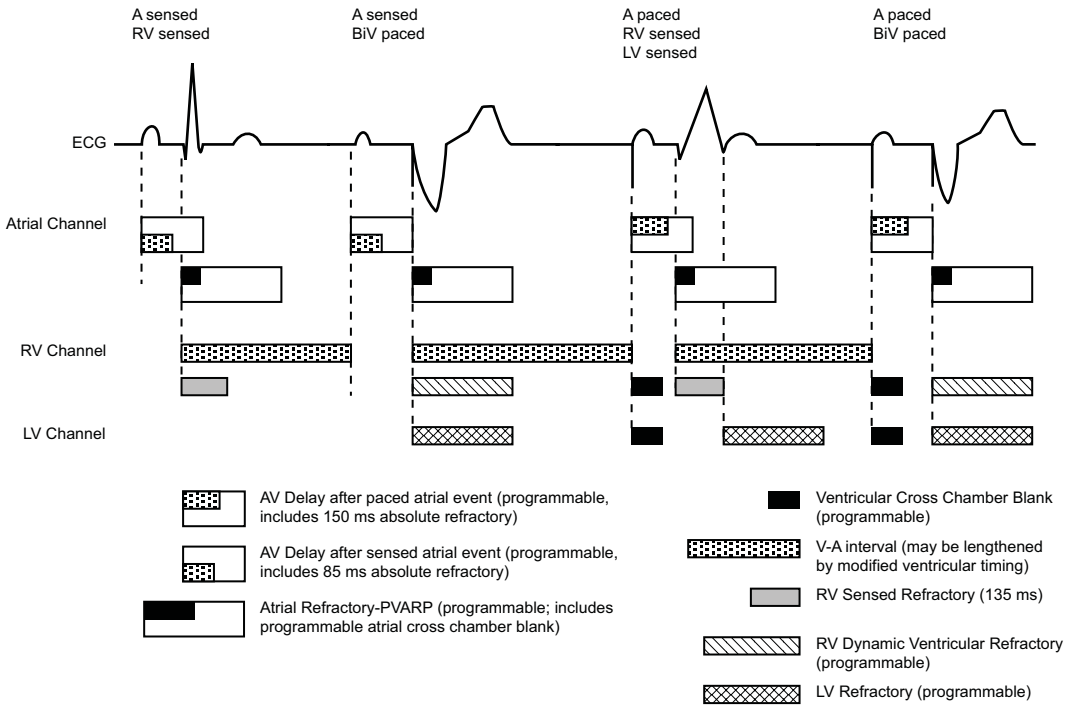


Figure 5-24. Refractory periods, dual-chamber pacing modes; BiV

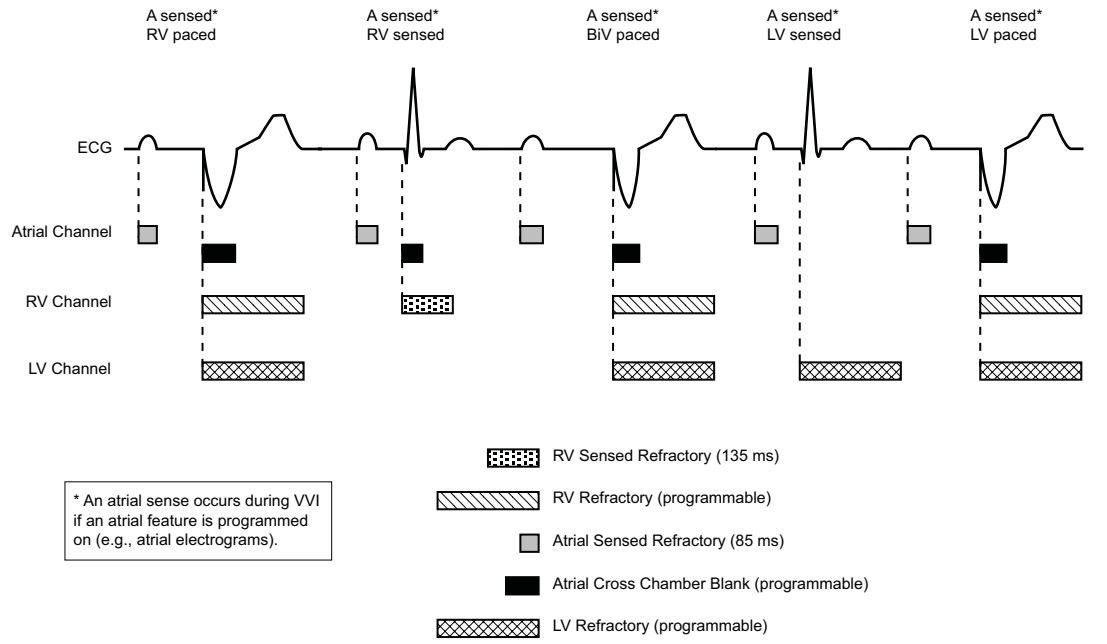


Figure 5-25. Refractory periods, VVI pacing modes; LV only

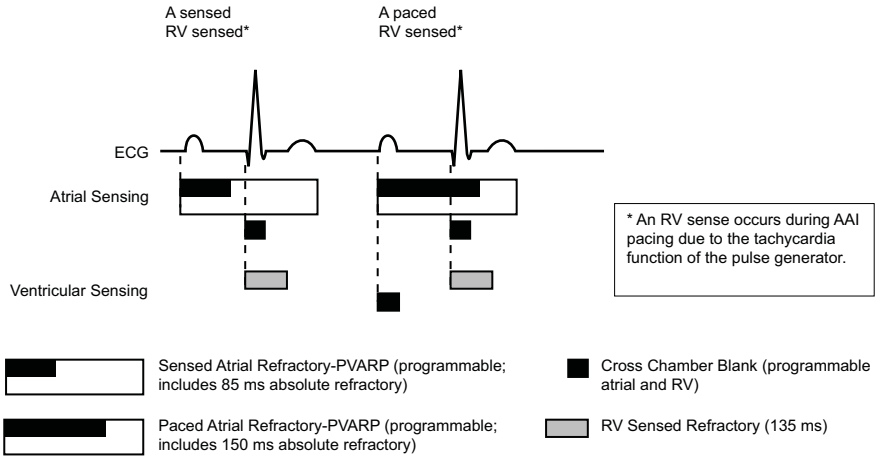


Figure 5-26. Refractory periods, AAI pacing mode

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 5-27 on page 5-61 and Figure 5-28 on page 5-61.

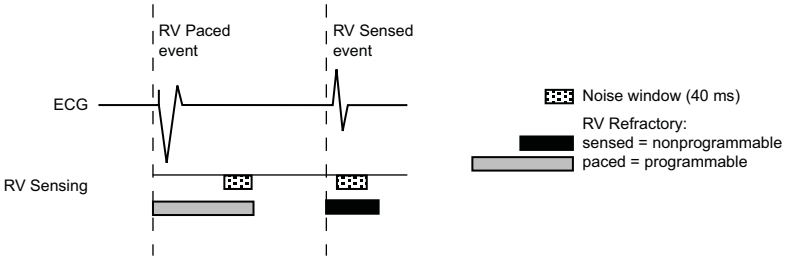


Figure 5-27. Refractory periods and noise windows, RV

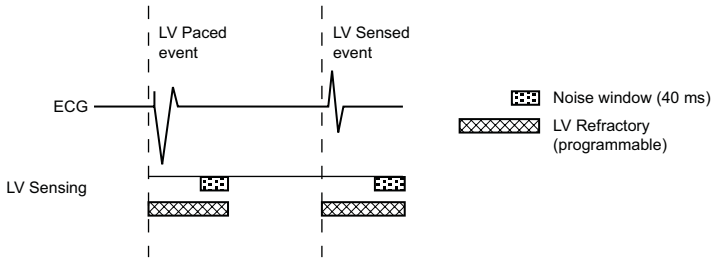


Figure 5-28. Refractory periods and noise windows, LV

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, depending on the chamber where noise is occurring, the marker [AS], [RVS], or [LVS] will occur when the noise window is triggered, followed by the marker AN, RVN, or LVN if the noise window is retriggered for 340 ms. The AN, RVN, or LVN marker will occur frequently if the noise window continuously retriggers for 340 ms.

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 5-29 on page 5-63).

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.*

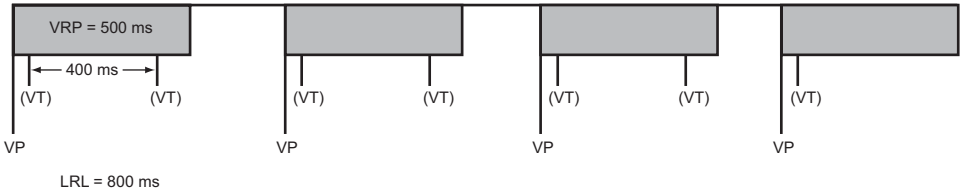


Figure 5-29. Ventricular undersensing due to VRP

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.*

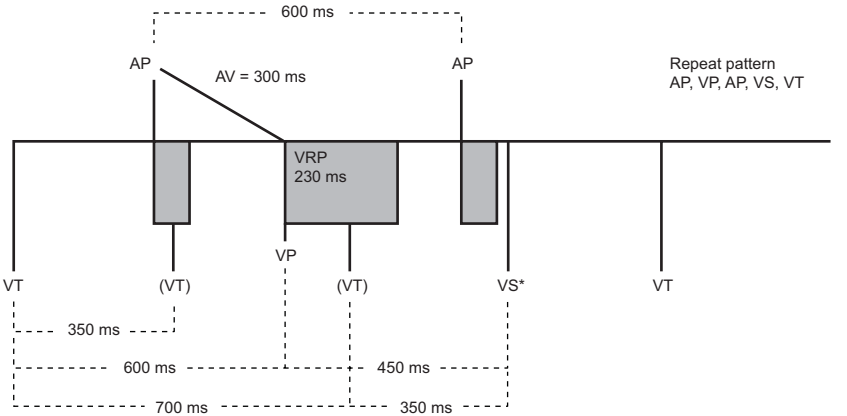


Figure 5-30. Ventricular undersensing due to V-Blank after A-Pace