Tech Corner

SafeR Pacing Mode

NOTE: PLEASE NOTE THAT THE FOLLOWING INFORMATION IS A GENERAL DESCRIPTION OF THE FUNCTION. DETAILS AND PARTICULAR CASES ARE NOT DESCRIBED IN THE ARTICLE. FOR ADDITIONAL EXPLANATION PLEASE CONTACT YOUR SALES REPRESENTATIVE.

MicroPort™ CRM

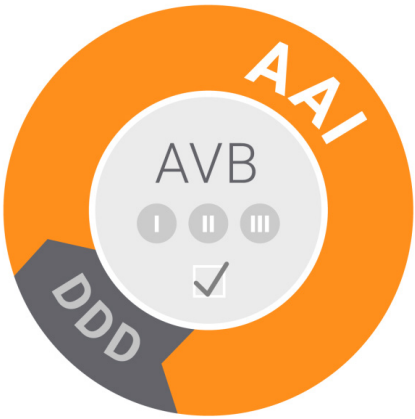
Table of Contents

SafeR Pacing Mode

SafeR is the only AV management algorithm which has been proven to strongly reduce ventricular pacing for AV block patients as well as for SND patients.[2,4] SafeR reduces the risk of HF hospitalization or cardiac death by 51%.[2]

The SafeR algorithm provides AAI pacing while continuously monitoring AV conduction (ADI mode). The device temporarily switches to DDD mode upon the occurrence of AV Block III, AV Block II, AV Block I and Pause. Once in DDD mode, the device will apply the programmed AV delay and will function in a normal DDD mode. While in DDD mode, SafeR will continuously monitor the AV conduction and periodically switch into AAI mode to check if AV conduction has resumed.

SafeR is designed to intelligently manage AV conduction, diagnosing all types of AV block[2,9] and has been proven to be safe and effective for all brady patients.[2,6,7,9]



AVAILABILITY

This algorithm is available in following models:

Pacemakers

- REPLY™ CRT-P*
- KORA™ 250 DR*
- KORA 100 DR*
- REPLY 200 DR*
- REPLY DR, REPLY D*
- SYMPHONY® DR 2550, SYMPHONY D 2450

Defibrillators and CRT-D

- PLATINIUM™ DR 1510 – 1540, PLATINIUM CRT-D 1711, PLATINIUM SonR CRT-D 1811* – 1841*, PLATINIUM 4LV SonR CRT-D 1844*
- INTENSIA™ DR 154, INTENSIA SonR CRT-D 184*
- PARADYM™ RF DR 9550, PARADYM RF CRT-D 9750, PARADYM RF SonR CRT-D 9770*
- PARADYM 2 DR 8552*, PARADYM 2 CRT-D 8752*, PARADYM 2 SonR CRT-D 8772*
- PARADYM DR 8550, PARADYM CRT-D 8750, PARADYM SonR CRT-D 8750*
- OVATIO™ DR 6550, OVATIO CRT-D 6750

SYNONYMS

AAIsafeR, AAIsafeR 2.

Both names may be found in former literature. AAIsafeR and AAIsafeR 2 are the previous names used for SafeR.

INDICATION

The SafeR AV management algorithm is designed for patients requiring AAI pacing (sinus node dysfunction) and/or who are at risk of AV conduction disorders (paroxysmal AV block, permanent first degree AV block, or exercise-induced AV block).

* *Not available for distribution or sale in the USA*

DESCRIPTION OF OPERATION

When operating in AAI mode, the device will continuously monitor the AV conduction activity (ADI mode) and will switch to DDD mode following one of four criteria in the event of AV conduction failure (see section “Temporary switches from AAI into DDD mode”, page 6). When operating in DDD mode, the device will either switch back to AAI in the event of physiological AV conduction or will periodically try to promote intrinsic conduction.

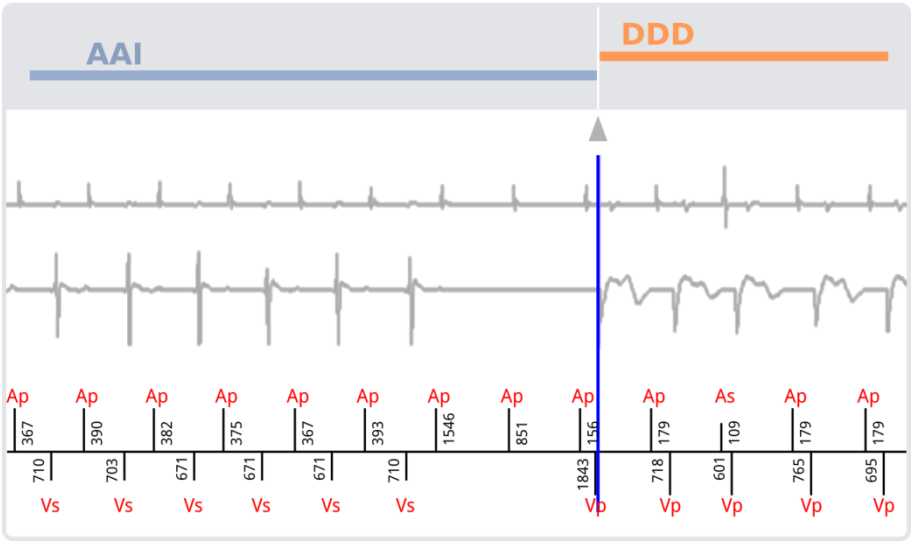
SafeR can be programmed with or without Rate Response. In the remainder of this document, when SafeR is programmed with Rate Response (SafeR-R), AAI refers to AAIR and DDD to DDDR.

Temporary switches from AAI into DDD mode

The device operates in AAI mode and switches temporarily to DDD mode in the following cases:

Third degree AV block

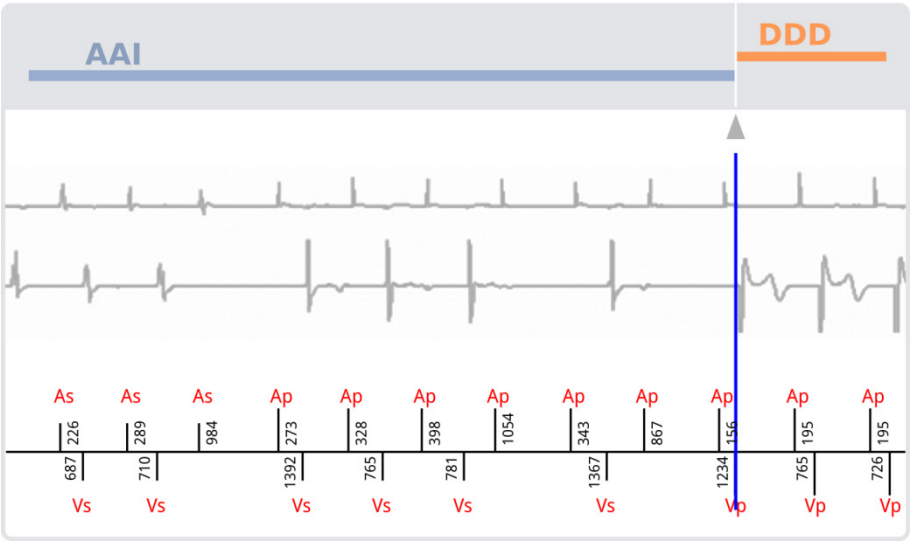
The device detects two consecutive blocked atrial events (paced or sensed).



Definition: An atrial event is considered as “blocked” when there is no ventricular detection during the atrial cycle.

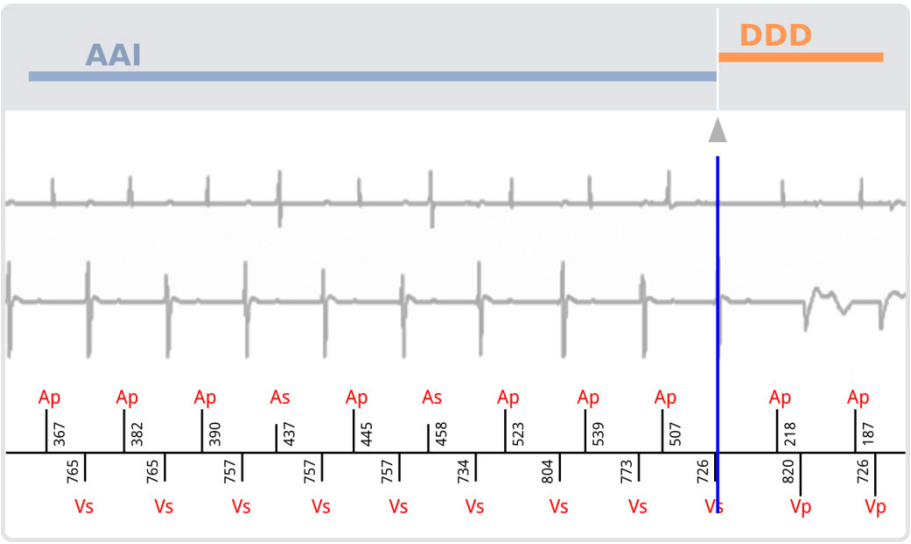
Second degree AV block

The device detects 3 blocked atrial events in the last 12 ventricular cycles.



First degree AV block

The device detects 6 consecutive PR or AR intervals longer than the programmed maximum value.



Programmable parameters

Depending on the device model, one or two parameters are programmable:

	Programmable PR interval	Corresponding AR interval
SYMPHONY	Max PR	Max PR + 100 ms
Other devices	Long PR max (at rest)	Long PR max + 100 ms
	Long PR min (at Max rate)	Long PR min + 100 ms

Automatic long PR interval interpolation

The Long PR intervals are automatically adapted by the device (except in SYMPHONY) to mimic the physiologic PR interval.

Long PR interpolation according to actual rate

The AVB I criterion can be programmed to:

- Rest + Exercise: the device will switch to DDD mode during rest and exercise phases. It is intended for patients who suffer from first degree AV block whatever the cardiac rate.
- Exercise only: the device will switch to DDD mode during exercise only. It is intended for patients who do not suffer from first degree AV block at rest but who would benefit from ventricular pacing during exercise.

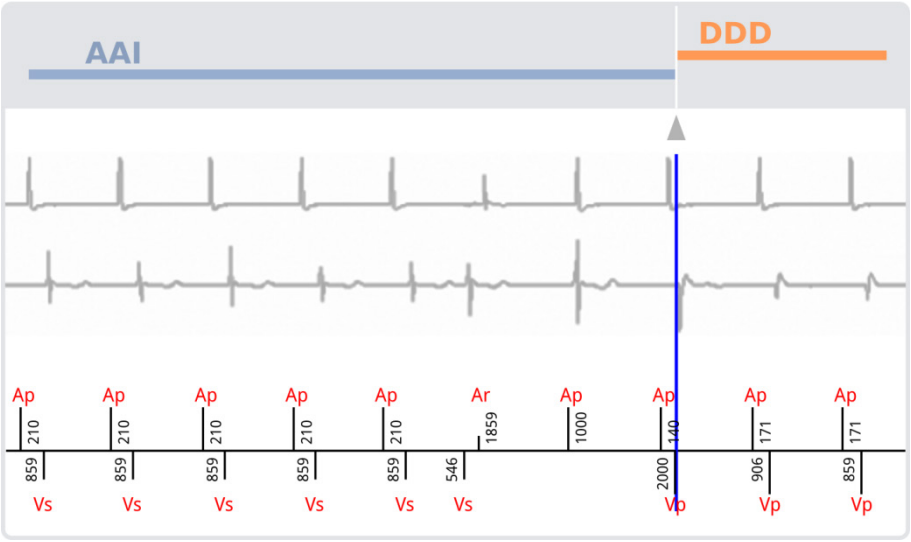
Definition of exercise

The values of rates at the onset and at the end of exercise depend on the programmed basic rate:

- When the programmed basic rate (BR) is 70 bpm or less, the exercise rate will be 100 bpm and the end of exercise rate will be 90 bpm.
- When the programmed basic rate (BR) is 75 bpm or more, the exercise rate will be the basic rate + 30 bpm and the end of exercise rate will be the basic rate + 20 bpm.

Pause

A ventricular pauses longer than the programmed value (parameter: Max Pause).



Temporary switch to DDD mode at the end of a 2-second pause (programmed value in the example)

Note: The Pause is automatically set to 2 seconds in the event of atrial arrhythmias (except on SYMPHONY, REPLY, OVATIO and PARADYM). The as-shipped value is 3 seconds.

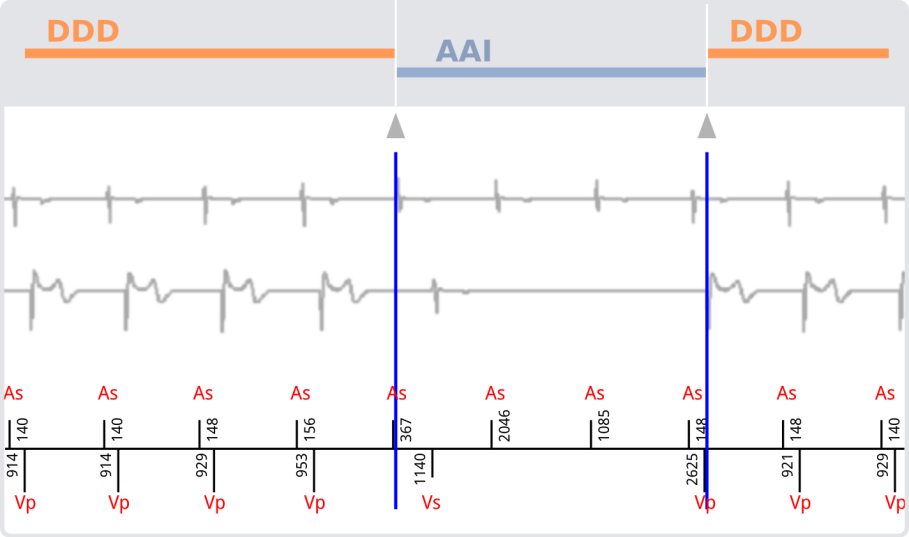
The ventricular pause may be slightly longer or shorter than the programmed value, depending on the AV delay.

Back to AAI mode after a temporary switch

The device switches back to AAI mode:

- after sensing 12 consecutive spontaneous ventricular events
- automatically every 100 paced ventricular cycles.

After an automatic switch to AAI mode, if the intrinsic AV conduction has not resumed, the device switches back to DDD mode according to the criteria listed above (third degree AVB, second degree AVB, first degree AVB or the ventricular pause).



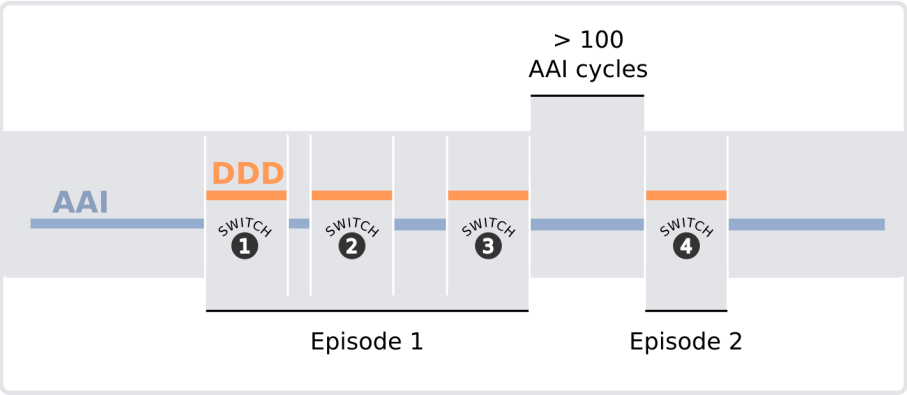
Automatic switch to AAI mode after 100 paced ventricular cycles. As the AV block is still present there is a new switch to DDD mode using the third degree AVB criterion.

Many switches from AAI to DDD: what happens?

In the event of sustained AV blocks, the device will switch to DDD mode for a longer duration.

Definitions

- AAI/DDD switch: any switch from AAI to DDD.
- AV block episode: several switches which are separated by less than 100 AAI cycles. This definition corresponds to the physiological definition of an AV block.



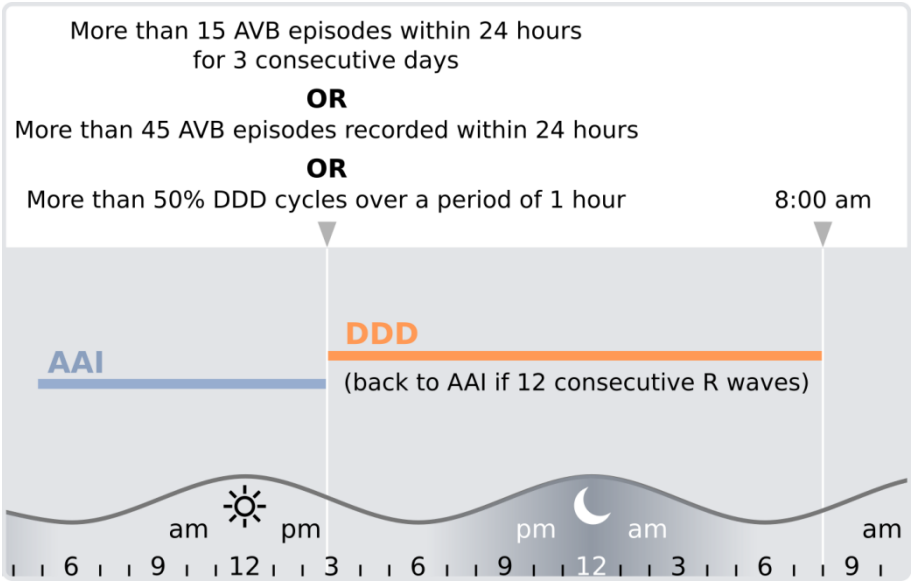
Several switches (3) in the AV block episode 1

The device switches to DDD mode and remains in DDD mode when it has:

- 45 episodes of AV block or more within the last 24 hours
- 15 episodes of AV block or more per 24-hour period for 3 consecutive days
- 50% DDD pacing or more within a one-hour period

In these cases, the automatic switch to AAI following every 100 ventricular paced cycles is suspended. It remains in DDD mode until 8:00 am the next morning.

The only way the device can switch back to AAI mode function before 8:00 am the next morning is if it detects12 consecutive spontaneous R waves.

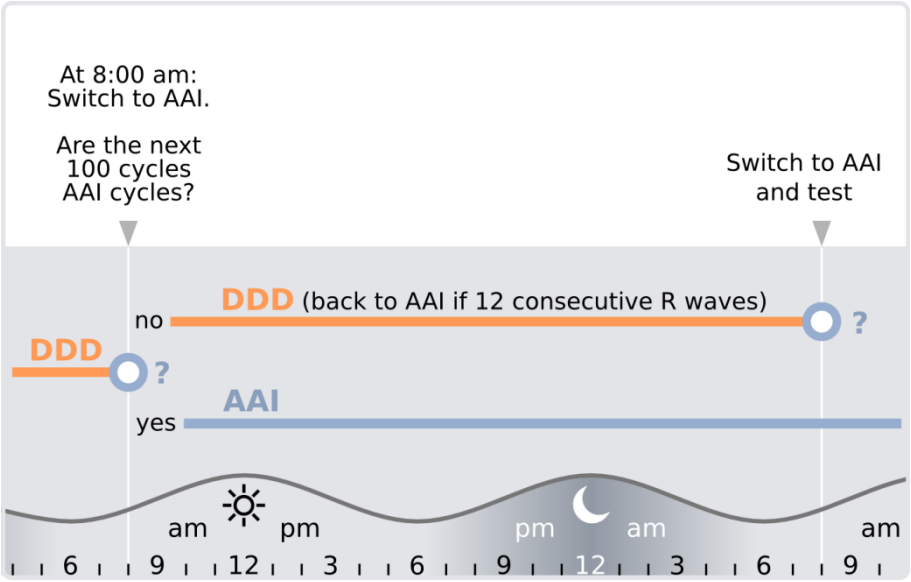


In the event of sustained AV blocks, the device will switch to DDD mode for a longer duration.

Back to AAI function following a switch to DDD until 8:00 am next morning

If the device does not sense 12 consecutive R waves in DDD mode functioning before 8:00 am it switches to AAI mode at 8:00 am in order to promote intrinsic AV conduction.

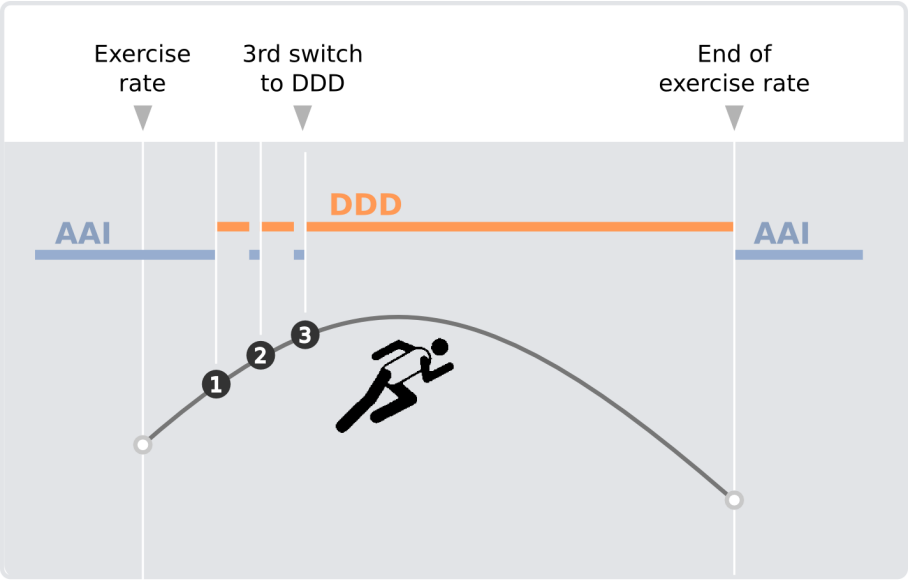
In the event of AV conduction failure the device switches back to DDD mode using one of the criteria listed above (third degree AVB, second degree AVB, first degree AVB or the ventricular pause) and it will remain in DDD mode until the next switch to AAI mode at 8:00 am next morning unless it detects 12 consecutive R waves: in this case it switches back to AAI mode before 8 am.



Test at 8:00 am when the device has switched to DDD until 8:00 am

Switch to DDD during exercise

When an AV block occurs during exercise, after 3 switches the device remains in DDD mode until the end of the exercise period in order to avoid patient symptoms during exercise (see the "definition of exercise", page 9).



Switch to DDD until the end of exercise after three switches to DDD during exercise

MORE DETAILS ON SAFER

AAI functioning

In AAI mode, the device starts an escape interval on:

- each sensed atrial event: P waves and premature atrial contraction (PAC),
- each atrial paced event,
- each premature ventricular contraction (PVC).

Definition: A premature ventricular contraction (PVC) is a sensed ventricle without any previous atrial event in the ventricular cycle.

Atrial events (P waves, PAC and atrial paced event) do not start any AV delay.

When the device switches to DDD mode, it applies the programmed AV delay values.

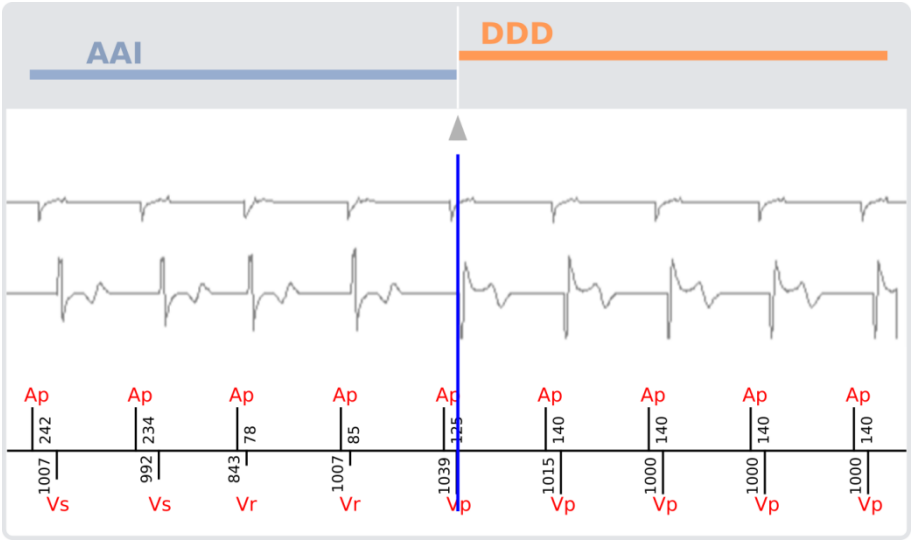
Detection in the committed window

The committed window starts after each paced atrial event and lasts 95 ms.

When the device operates in AAI mode and a ventricular event is sensed in the committed window:

- the device does not pace the ventricle at the end of the committed window.
- the spontaneous ventricular event sensed in the committed window is not “valid”; thus the paced atrial event which comes before the ventricular detection in the committed window is counted as a blocked atrial event
- the second degree AV block criteria is suspended for 12 cycles.

In case of an AAI/DDD switch because of ventricular sensing in the committed window (3rd degree AV block or Ventricular pause criteria is reached), the switch will be labeled as a “Safety switch” and a message will be displayed in AIDA†.

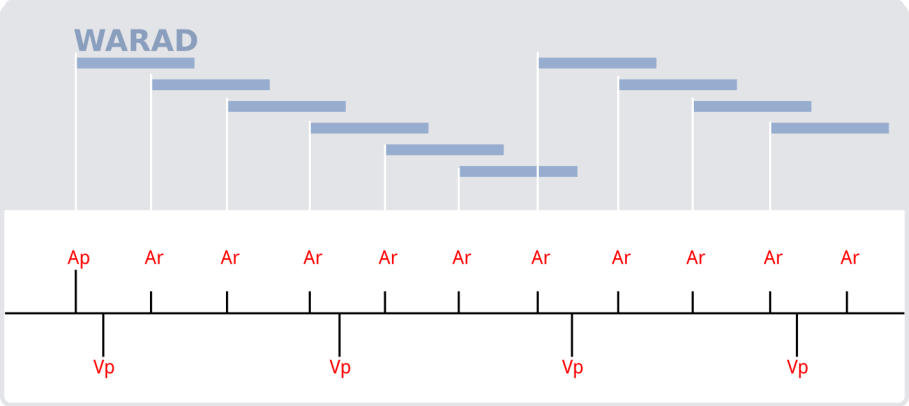


The two ventricular detections in the committed window (Vr) are not counted: the paced atria are considered as blocked (example: REPLY model)

† *Automatic Interpretation for Diagnosis Assistance*

Atrial arrhythmia

The device enters into suspicion of atrial arrhythmia when it detects one or several atrial event(s) in the WARAD (Window of Atrial Rate Acceleration Detection).



Conducted atrial arrhythmia

When the atrial arrhythmia is conducted to the ventricles the device switches directly from AAI to DDI mode following a Fallback Mode Switch criterion. Thus, in the event that an atrial arrhythmia fails to conduct to the ventricles, the device will operate safely in DDI mode.

Non-conducted atrial arrhythmia

When the atrial arrhythmia is not conducted to the ventricles the device switches first from AAI to DDD mode on the Pause criterion, applying the programmed AV delay (the three AV block criteria are suspended in case of atrial detection in the WARAD). Then it switches to DDI mode following a Fallback Mode Switch criterion.

Note: The Pause is automatically set to 2 seconds in the event of atrial arrhythmias (except on SYMPHONY, REPLY, OVATIO and PARADYM). The as-shipped value is 3 seconds.

Atrial noise marker in SafeR mode: An

The marker “An” means “atrial noise”: pacing in the atrium in the event of noise detection in the atrial channel.

It is also the labelling used when the device paces inside an atrial refractory period.

“An” markers can be seen during AAI functioning of SafeR because A and V are independent and the device has to pace the atrium at the end of the atrial escape interval whatever the occurrence of ventricular events.

SAFER AND CARDIAC RESYNCHRONISATION THERAPY (CRT)

OVATIO CRT-D 6750

SafeR is programmable when the pacing site is RV only.

This programming can be useful when the left ventricular pacing lead is ineffective (failed to implant, or dislodged), and the Physician prefers to preserve spontaneous ventricular rhythm rather than right ventricular pacing only which may increase the ventricular dyssynchrony.

PARADYM, PARADYM 2, PARADYM RF, INTENSIA, PLATINIUM CRT-D and REPLY CRT-P models

SafeR is programmable in RV only and in biV pacing.

SafeR-CRT may be an appropriate option for some patients who suffer from first degree AV block and who do not need resynchronisation at rest, but would benefit from CRT during exercise (first degree AV block criterion programmed to exercise only).

At rest, these devices will operate in AAI mode and the patient will have his/her spontaneous ventricular rhythm. During exercise, the device will synchronize both ventricles in DDD mode if there is a switch on AVB 1.

INTERACTION BETWEEN SAFER AND OTHER FUNCTIONS

Fallback Mode Switch: As soon the device enters into suspicion of atrial arrhythmia, it will suspend the three AV block criteria. The only way to switch is the Pause criteria.

Magnet mode: The pacing mode applied during the magnet mode is DOO for the pacemakers and DDD for the ICDs. When removing the magnet, the pacing mode is the one used by SafeR (AAI or DDD) before applying the magnet.

SUMMARY

SafeR evaluates AV conduction, identifying all different types of AV block and as a result only pacing the ventricle when necessary. SafeR reduces unnecessary ventricular pacing to almost 0%.

Temporary switches

The device will switch temporarily from AAI to DDD:

- after 2 consecutive blocked atrial events: third degree AV block criterion
- after 3 blocked atrial events out of the 12 last atrial cycles: second degree AV block criterion
- after 6 long PR/AR intervals: first degree AV block criterion
- after a ventricular pause longer than the programmed duration of the pause (2, 3 or 4 seconds): safety criterion

The device will switch from DDD to AAI:

- every 100 ventricular paced or sensed cycles
- after 12 consecutive detected R waves

During exercise:

- the device remains in DDD until the end of exercise if the patient had more than 3 AAI to DDD switches.

Long duration switches

The device will switch from AAI to DDD until 8:00 am next morning:

- after 50% of DDD pacing within a one-hour period
- after 45 AV block episodes over 24 hours
- after 15 AV block episodes over 24 hours for three consecutive days

After a long duration switch to DDD the device will switch back from DDD to AAI:

- after 12 consecutive detected R waves
- every morning at 8:00 am

Programmable parameters

SafeR is programmable from the list of pacing modes. It can be programmed with or without Rate Response. SafeR is compatible with AF Prevention Algorithms.

When SafeR is programmed, 4 additional parameters are available (3 parameters in Symphony):

- First degree AV block criterion: at rest and during exercise or during exercise only
- Long PR max
- Long PR min
- Pause duration

Note: The “Long PR max” and “Long PR min” parameters are not available in SYMPHONY, instead there is a “Max PR” parameter.

Please refer to the implant manual to obtain the list of all programmable parameters.

Programming constraints

When SafeR pacing mode is programmed:

- Fallback Mode Switch is automatically programmed to ON. SafeR pacing mode is indicated for Sinus Node Disease Patients.
- Ventricular Autothreshold is automatically programmed to OFF. The percentage of ventricular pacing is low so it is unnecessary to perform a ventricular pacing threshold test every 6 hours. Moreover the V Autothreshold algorithm can only perform the test in the event that the ventricle is being paced.

STUDIES AND RESULTS

1. Ricci, Botto, Bénéze et al. Association between ventricular pacing and persistent atrial Fibrillation in patients indicated to elective pacemaker replacement: Results of the Prefer for Elective Replacement MVP (PreFER MVP) randomized study. Heart Rhythm 2015.
2. Stockburger.M, Boveda.S, Defaye.P et al.. Long-term clinical effects of ventricular pacing reduction with a changeover mode to minimize ventricular pacing in general population (ANSWER study). European Heart Journal. 2015; 36 (3):151-157
3. Fauchier L, Boveda S, Moreno J, Defaye P, Stockburger M. SafeR is associated with a risk reduction of first-onset AF in patients with atrio-ventricular blocks: results from the ANSWER study. Abstract. EHRA EUROPACE, Volume 17, Issue suppl 3, 1 June 2015
4. Stockburger M; Defaye P, Boveda S et al. Safety and efficiency of ventricular pacing prevention with an AAI-DDD changeover mode in patients with sinus node disease or atrioventricular block: impact on battery longevity—a sub-study of the ANSWER trial. Europace Nov. 2015
5. Boriani G, Tukkie R, Manolis A et al. Atrial antitachycardia pacing and managed ventricular pacing in bradycardia patients with paroxysmal or persistent atrial tachyarrhythmias: the MINERVA randomized multicentre international trial. European Heart Journal (2014) 35, 2352–2362
6. Davy JM, Hoffmann E, Frey A et al. Near elimination of ventricular pacing in SafeR mode compared to DDD modes: a randomized study of 422 patients. Pacing Clin Electrophysiol. 2012; 35(4): 392–402.
7. Benkemoun H, Sacrez J, Lagrange P et al. Optimizing pacemaker longevity with pacing mode and settings programming: results from a pacemaker multicenter registry. Pacing Clin Electrophysiol. 2012; 35(4): 403–8..
8. Wiegand U et al. Combined effect of atrial arrhythmia preventive algorithm and SafeR pacing mode on atrial arrhythmias burden in dual-chamber paced patients. Europace 2010 Vol. 12, (Sup. 1) 56P/42 (abs).
9. Stockburger M, Trautmann F, Nitardy A et al. Pacemaker-Based Analysis of AV Conduction and Atrial Tachyarrhythmias in Patients with Primary Sinus Node Dysfunction. Pacing Clin Electrophysiol2009; 32: 604-13.
10. Thibault B et al. Impact of Atrioventricular Conduction Disorders on SafeR Mode Performance. PACE 2009; 32:S231–S235.

12. Pioger G. et al., AAIsafeR Limits Ventricular Pacing in Unselected Patients, PACE, Vol 30, Supplement 1, January 2007 pp S66-S69.

13. Defaye P. et al., Impact of Pacing indications on AAIsafeR2 performances, Europace 2006, Vol 8, Suppl 1, June 2006: 223/4.

14. Davy JM et al., Determining the optimal pacing mode to prevent ventricular pacing: SAVE R study results, Heart Rhythm 2006, Vol.3, Issue 1S, May 2006 P2/94.

15. Fröhlig G, Ducloux P, Victor J, Mabo P, Galley D, Savouré A, et al. Use of a new cardiac pacing mode designed to eliminate unnecessary ventricular pacing. *Europace* 2006; 8:96-101.

16. F. Anselme et al., First clinical results of AAIsafeR 2, a new mode to prevent ventricular pacing, Heart Rhythm 2005, Vol. 2, Issue 1S, 2005 May; P4-99.

17. Savouré A, Fröhlig G, Galley D, Defaye P, Reuter S, Mabo P, et al. A new dual-chamber pacing mode to minimize ventricular pacing. *Pacing Clin Electrophysiol* 2005; 28 (Suppl 1):S43-S46.

Refer to user's manual furnished with the device for complete instructions for use (www.microportmanuals.com).