Tech Corner

Fallback Mode Switch (FMS)

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

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Fallback Mode Switch (FMS)

The FMS function is designed to diagnose atrial arrhythmias and manage their occurrence using the WARAD (Window of Atrial Rate Acceleration Detection)[1]: in the event of atrial arrhythmia, FMS switches from DDD(R), SafeR(R) or Dplus(R) pacing mode to an inhibited dual- chamber pacing mode DDI(R) to avoid prolonged ventricular pacing at a high rate for the entire duration of the sustained atrial arrhythmia.

The detection criteria are designed to mode switch even in the presence of intermittent atrial undersensing.[1]

Operation is independent of the programmed Max rate: an atrial arrhythmia slower than the Max rate setting will be recognized, and appropriate mode switching will occur.[1]

As soon as atrial arrhythmia ceases, the device switches back to the previous programmed pacing mode.

1 Refer to the article on the « Window of Atrial Rate Acceleration Detection (WARAD) » for more information.

AVAILABILITY

The Mode Switch function is available in all dual chamber MicroPort pacemakers, ICDs, CRT-D and CRT-P models.

SYNONYM

- Mode Switch
- Fallback

CLINICAL NEED

Prevention of inappropriate tracking of atrial tachycardias resulting in accelerated or irregular ventricular pacing rates and patient symptoms including lightheadedness and syncope.[2]

INDICATION

Fallback Mode Switch is indicated for ALL adult patients:

- Patients at risk of atrial arrhythmias
- Patients who are not diagnosed with atrial arrhythmias yet must be also protected in the event that they develop atrial arrhythmias. It avoids rapid ventricular response to atrial arrhythmia leading to adverse hemodynamics and symptoms.[3]

DESCRIPTION OF OPERATION

The Fallback function comprises 3 separate phases:

1. Suspicion phase/Confirmation
2. Dissociation phase
3. Reassociation phase.

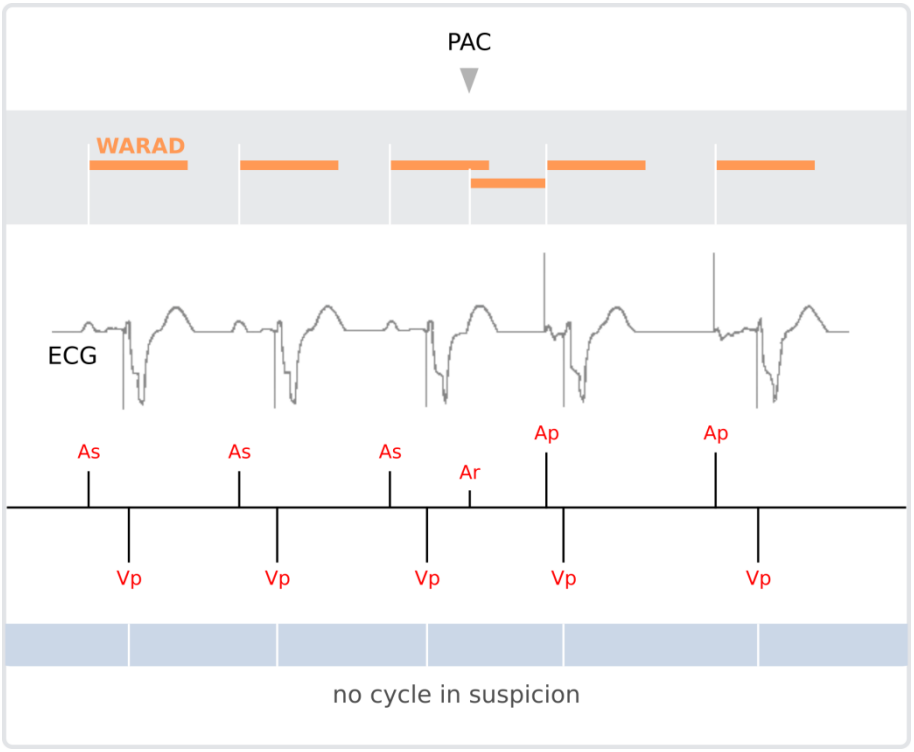
Suspicion phase/Confirmation

Suspicion: Atrial event falling in the WARAD

If a PAC (atrial event in the WARAD) is sensed and if the ventricular cycle ends without atrial pacing, the device enters in suspicion phase of atrial arrhythmia.

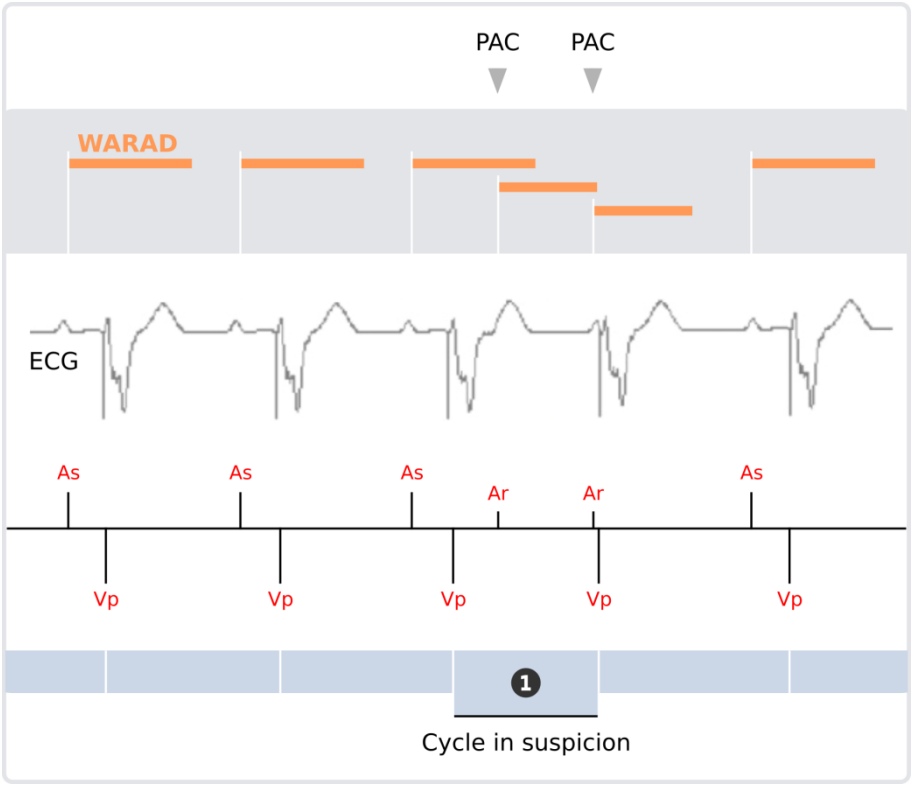
Once the device has entered in suspicion phase, each following ventricular cycle containing a PAC (or PACs) is identified as a cycle in suspicion. The cycles in suspicion are logged and statistically analyzed (see the section "*Confirmation*" on page 10 in this article).

Example: Isolated PAC (Sinus rhythm: 60 bpm, REPLY DR, DDD mode)



After sensing the PAC, the ventricular cycle ends with an atrial pacing so it is not considered as a cycle in suspicion of atrial arrhythmia.

Example: Two consecutive non-conducted PACs (Sinus rhythm: 60 bpm, REPLY DR, DDD mode)



In this example we can see one ventricular cycle in suspicion of atrial arrhythmia (contains two PACs). All other cycles are not in suspicion (they do not contain any PAC). Refer to the WARAD Tech Corner for more details on the WARAD duration and the ventricular rate management.

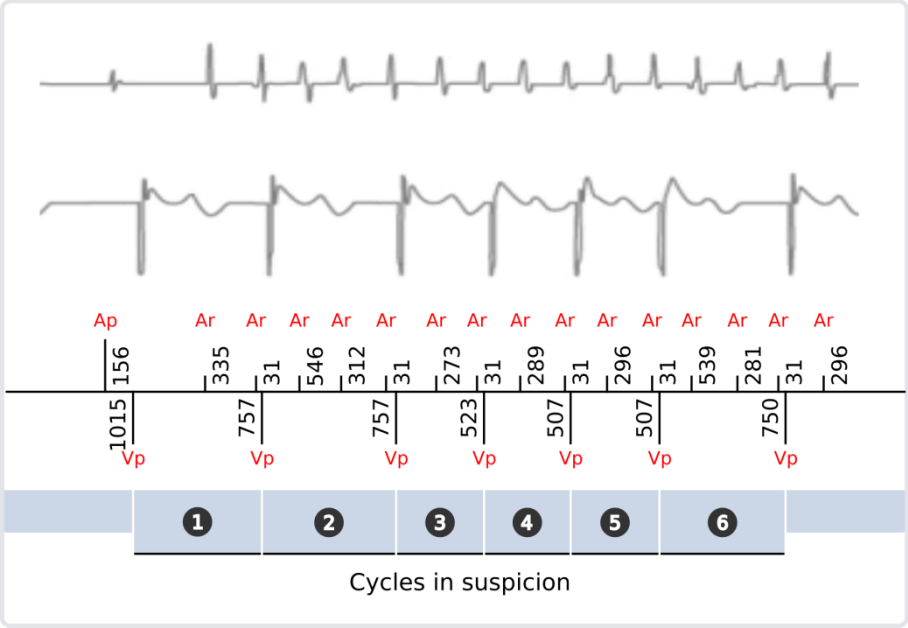
In the event the atrial arrhythmia is not conducted to the ventricle (DDD functioning)

During the suspicion phase, the ventricular pacing tracks atrial events with an N:1 AV association.

The ventricular pacing rate is limited to 120 bpm (the minimum ventricular pacing interval is 500 ms). For more details, see the Tech Corner article on the WARAD, section "*Ventricular rate management during the suspicion phase*".

Note: If the programmed maximum rate is lower than 120 bpm, the device will apply the programmed maximum rate during suspicion of atrial arrhythmia:

Example: Atrial arrhythmia onset (REPLY DR, DDD mode)



In this example we can see the onset of an atrial arrhythmia: ventricular cycles containing two or three PACs are considered as cycles in suspicion. Note that during the suspicion phase, the ventricular cycles are at least 500 ms (max ventricular rate: 120 bpm). Refer to the WARAD Tech Corner for more details on the ventricular rate management

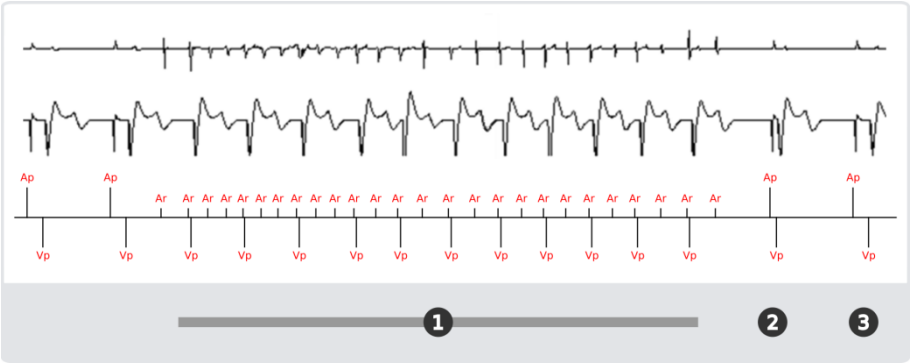
AV Delays

When the device is in the suspicion phase, the AV delay is automatically reduced to optimize the atrial sensing. It is reduced to:

- 31 ms after a sensed atrial event (Ar) when the 469 ms interval has been reached
- 110 ms (or the exercise AV delay, if programmed shorter) after the paced atrial event (Ap).

If no PAC is present in the previous ventricular cycle, the AV delay returns to its programmed value (+ paced/sensed offset if atrial pacing).

Example: Short atrial run (REPLY DR, DDD mode)



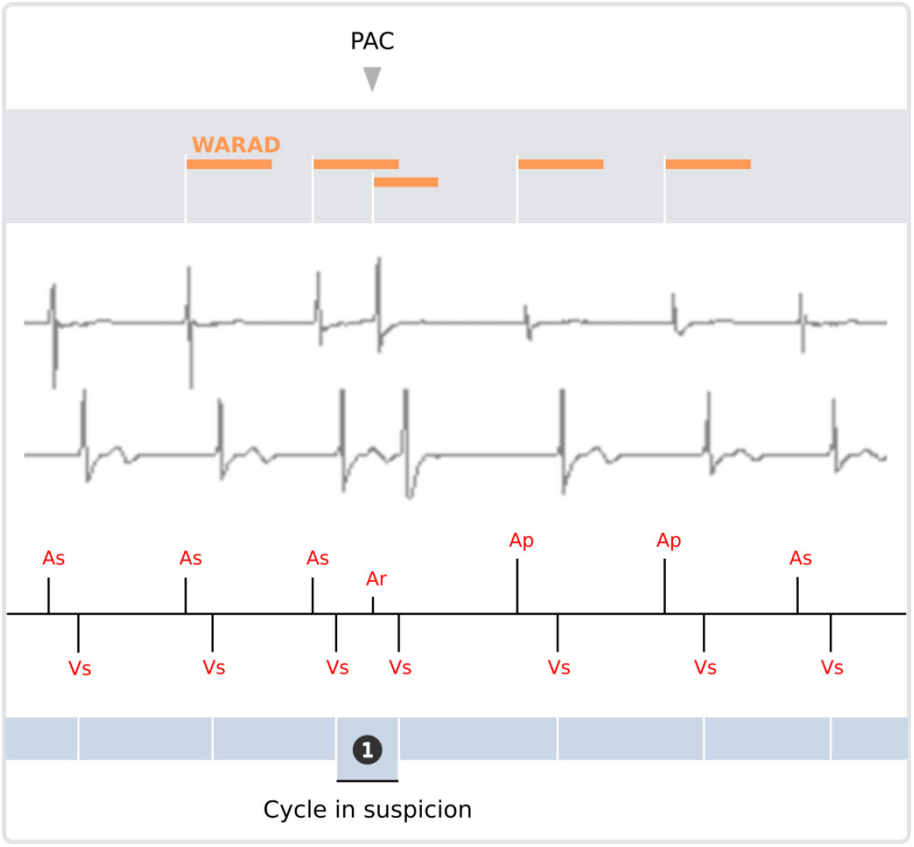
Event	Description
1	Atrial run with very short AV delay (31 ms). The V pacing rate is limited to 120 bpm
2	Atrial pacing with a short AV delay = min [110 ms ; exercise AV delay]
3	Atrial pacing with programmed AV delay + paced/sensed offset (exit of the suspicion phase)

Note: Refer to the WARAD Tech Corner for more details on the ventricular rate management

In the event a PAC is conducted to the ventricle

The device enters a suspicion phase, since the ventricular cycle ends without atrial pacing.

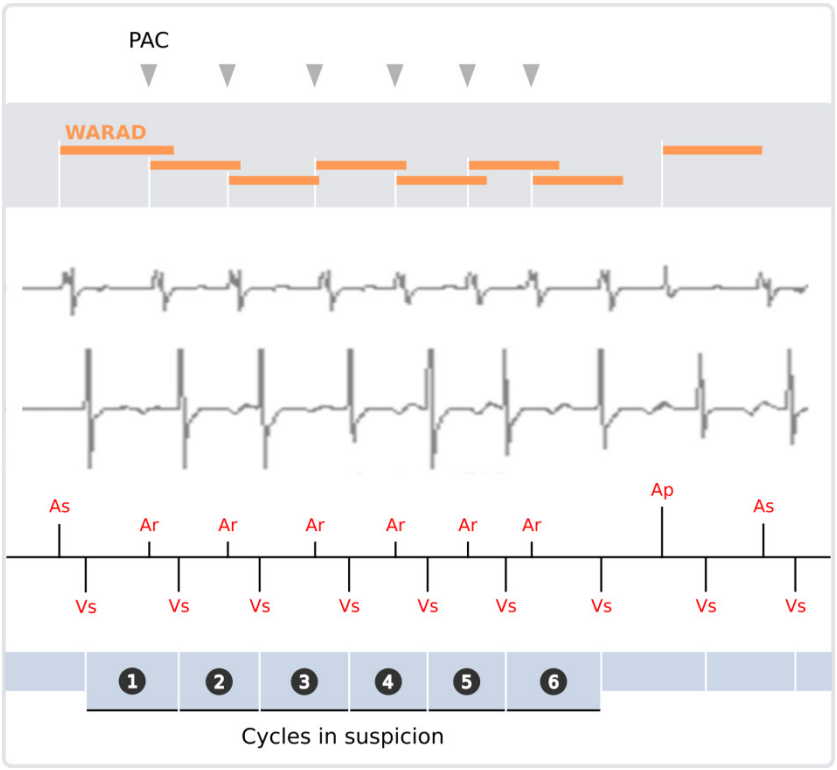
Example: Isolated PAC (Sinus rhythm: 60 bpm, REPLY DR, SafeR mode)



After sensing the PAC, the ventricular cycle does not end with atrial pacing so it is considered as a cycle in suspicion of atrial arrhythmia. All other cycles are not in suspicion since they do not contain any PAC.

In the event the atrial arrhythmia is conducted to the ventricle

Example: Short atrial run (REPLY DR, SafeR mode)



All ventricular cycles containing a PAC are considered as cycles in suspicion of atrial arrhythmia.

The cycles in suspicion phase are logged and statistically analyzed (see the section "*Confirmation*" on page 10).

Confirmation

The atrial arrhythmia is confirmed if one of the 2 following criteria is met:

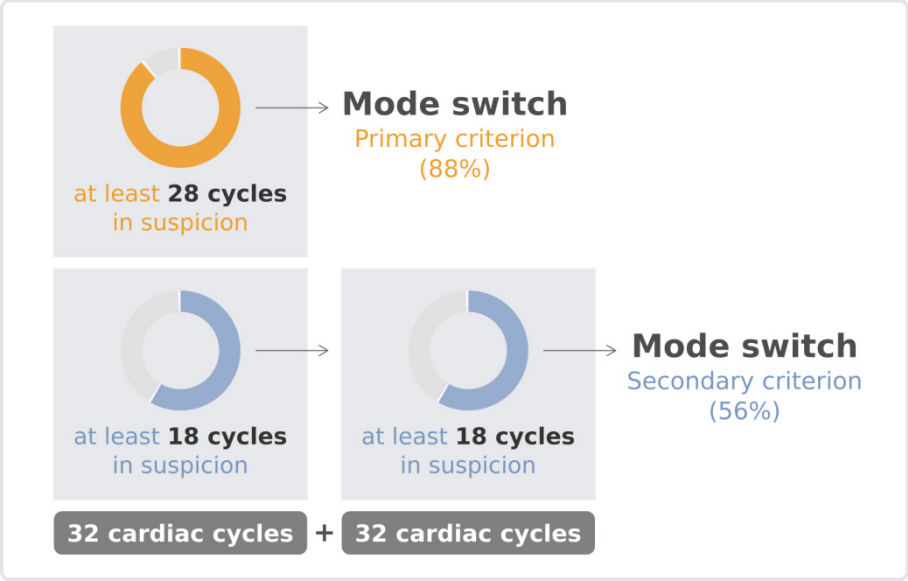
Primary criterion: for atrial arrhythmia with good atrial sensing

The presence of atrial arrhythmia is confirmed when the device records 28 cycles or more in suspicion over the last 32 ventricular cycles (88%). As soon as the primary criterion is met, the device switches to DDI(R) mode, which corresponds to about 15 seconds.

This criterion allows atrial undersensing during 4 cycles or less.

Secondary criterion: Automatic management of atrial undersensing during AF

The device examines a second criterion: If the device records at least 18 suspicion cycles over a period of 32 ventricular cycles (56%), it starts a second observation phase of 32 ventricular cycles. If it records at least 18 more suspicion cycles during that second phase, atrial arrhythmia is confirmed.



Suspicion of sustained atrial arrhythmia: mode switch, with automatic management of atrial loss of atrial sensing during atrial arrhythmia

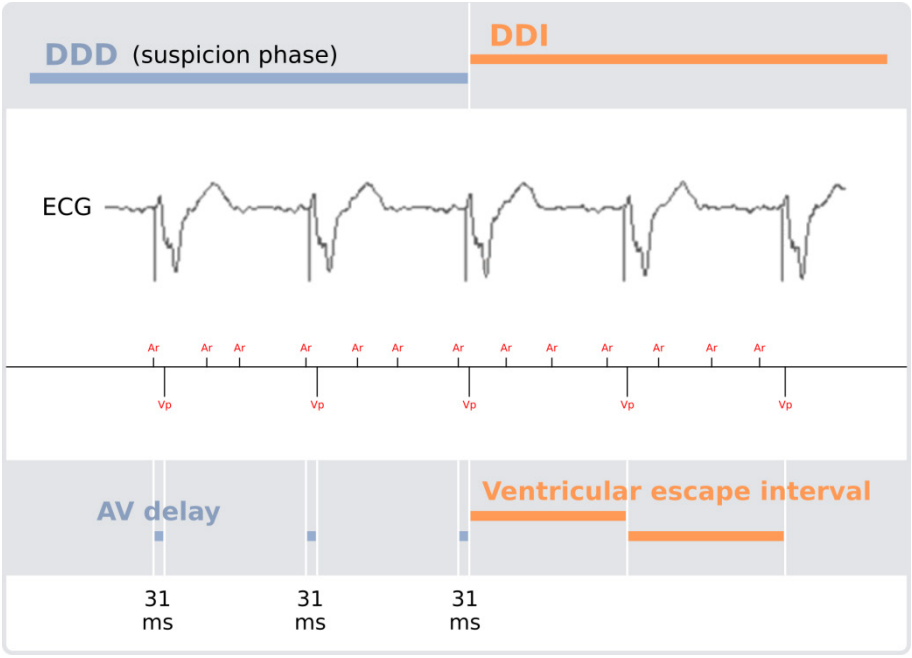
Thanks to this criterion the device will desynchronize the atria and the ventricles and will provide a physiological ventricular pacing rate to the patient even if the atrial sensing is poor during atrial arrhythmias.

Dissociation phase

Once the primary criterion or the secondary criterion has been met, the atrial arrhythmia is confirmed which results in immediate Fallback Mode Switch: DDI(R). The atria and ventricles are dissociated.

To prevent rate oscillations which may be uncomfortable for the patient, the device gradually increases or decreases the ventricular pacing rate to reach the basic rate, or sensor rate, or Fallback Mode Switch rate[2], using an internal rate smoothing algorithm (works even if rate smoothing is programmed OFF).

Example: Fallback Mode Switch on REPLY DR (programmed in DDD mode)



As long as the device is in the suspicion phase, it applies the 31 ms AV delay and limits the ventricular pacing rate at 120 bpm. Once it switches into DDI mode, it progressively paces the ventricles at the basic rate (or sensor rate).

Reassociation phase

End of atrial arrhythmia: AV reassociation

The device considers that the rhythm disturbance has ceased when the atrial rate and the ventricular rate both fall below 107 bpm.

[2] on ICDs, CRT-Ds and CRT-Ps only. This parameter is not available in the US.

If sinus rhythm resumes:

The ventricular pacing rate is gradually adapted to reach the sinus rhythm. As soon as the ventricular rate reaches the atrial rhythm, the device exits the Fallback Mode Switch and switches back to the programmed mode (DDD, SafeR, Dplus or VDD mode).

To prevent rate oscillations (uncomfortable for the patient), the reassociation occurs progressively.

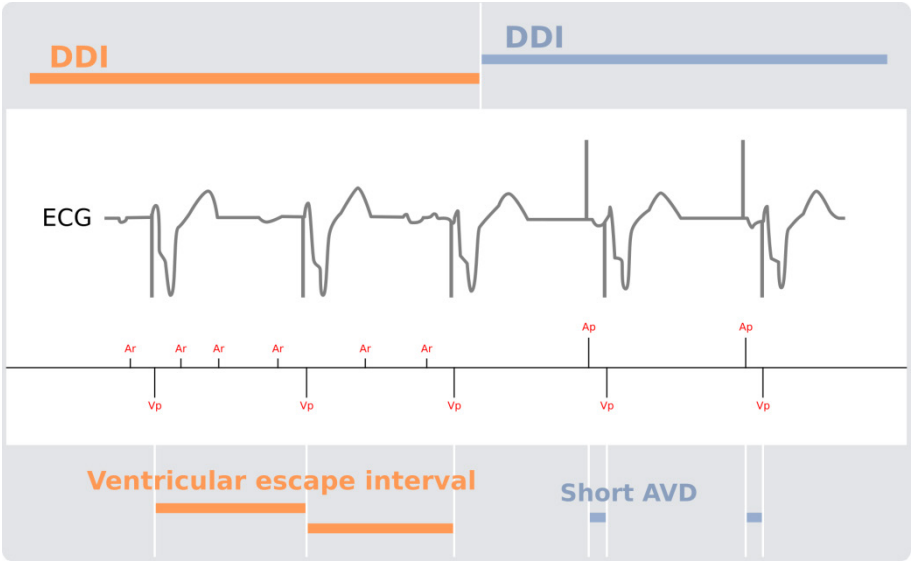
If sinus rhythm does not resume:

At the end of the atrial arrhythmia, if sinus node does not resume, the device immediately paces the atrium at the same rate as the ventricle, applying a short AV Delay (110 ms or exercise AV Delay if programmed shorter).

It will pace the ventricle during 24 cardiac cycles with the same ventricular rate as before (basic rate or sensor rate) and:

- If no PAC is sensed during the last 12 cycles, the device exits the Fallback Mode Switch and switches back to DDD mode (or SafeR, Dplus or VDD).
- If a PAC is sensed within the last 12 cycles, the device reset the counter until having 12 consecutive cardiac cycles without PACs

Example: End of atrial arrhythmia, when the sinus rhythm does not resume (REPLY DR)



At the end of atrial arrhythmia, the device immediately paces the atrium applying a short AV delay for 24 cardiac cycles.

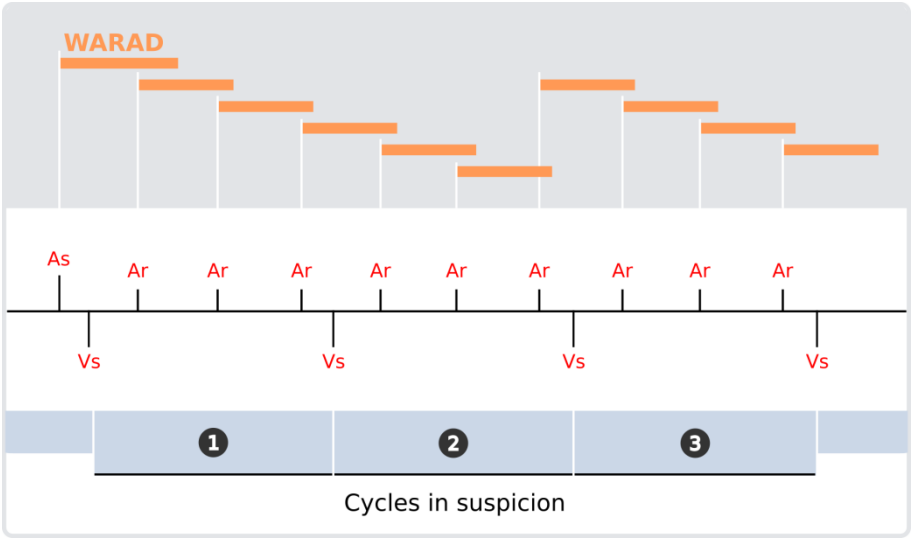
Fallback Mode Switch and SafeR pacing mode

In SafeR mode, the non conducted PACs are not considered as blocked P waves. Refer to the Tech Corner on SafeR Pacing Mode for more details on SafeR.

Conducted atrial arrhythmia

When the atrial arrhythmia is conducted to the ventricles, the device switches directly from AAI to DDI mode following one of the Fallback Mode Switch criteria (see the section "*Confirmation*" on page 10 in this article). Thus in the event that an atrial arrhythmia fails to conduct to the ventricles, the device will operate safely in DDI mode.

Example: Onset of a conducted atrial arrhythmia (REPLY DR, SafeR mode)



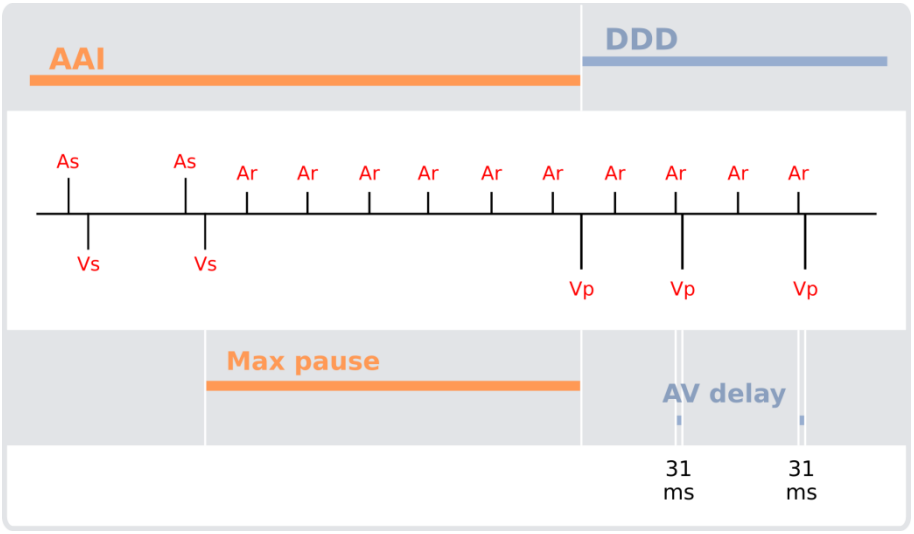
Ar events are not considered as blocked atrial events. In the event of a conducted atrial arrhythmia, the device will switch directly from AAI to DDI mode following one of the Fallback Mode Switch criteria.

Non-conducted atrial arrhythmia

In the event of a non-conducted atrial arrhythmia, the only criterion to switch to DDD mode is the ventricular pause because the three AV block criteria (1st degree, 2nd degree and 3rd degree) are suspended in the event of an atrial detection in the WARAD. At the end of the Max ventricular pause, the device triggers ventricular pacing (AAI/DDD switch) and then starts counting the cycles in suspicion. It switches to DDI at the end of the suspicion phase.

Note: The Max ventricular pause is automatically set to 2 seconds in the event of atrial arrhythmias on all MicroPort devices, except on SYMPHONY, REPLY, OVATIO and PARADYM. The as-shipped value is 3 seconds.

Example: Onset of a non-conducted atrial arrhythmia (REPLY DR, SafeR mode)



When the atrial arrhythmia is not conducted to the ventricles the device switches first from AAI to DDD mode on the Pause criterion. Then it will switch to DDI mode following one of the Fallback Mode Switch criteria.

PROGRAMMING

Fallback Mode Switch is programmable with DDD, SafeR, Dplus and VDD pacing modes.

When programming DDD/DDIR, SafeR/DDIR, Dplus/DDIR, VDD/VDIR the sensor will be active only during the DDI phase. These modes are recommended for chronotropic competent patients, who only need the sensors during atrial fibrillation to adapt the ventricular pacing rate to the exercise.

Programming constraint: It is forced to ON when SafeR or Dplus pacing mode is programmed: both modes are indicated for patients with sinus node disease.

Programmable parameters: The programming of Fallback Mode Switch is: ON – OFF (as shipped value: ON).

SUMMARY

The Fallback function comprises 3 separate phases:

Suspicion/Confirmation phase: As soon as one or several PACs are detected in the ventricular cycle and the cycle does not end with an atrial pacing, the device considers this cycle as a cycle in suspicion and enters in suspicion phase of atrial arrhythmia. The atrial arrhythmia is confirmed if one of the 2 following criteria is met:

- 28 or more ventricular cycles are in suspicion over the last 32 cycles (primary criterion)
- 18 or more ventricular cycles are in suspicion for each of the last 2 groups of 32 cycles (secondary criterion)

Dissociation phase: Switch to DDI pacing to dissociate atria from ventricles. The ventricular pacing rate is gradually decreased to the basic rate, or sensor rate or Fallback Mode Switch rate[3].

Reassociation phase: As soon as the atrial arrhythmia ceased:

- if the sinus rhythm resumes, the ventricular pacing rate is gradually adapted to reach the sinus rhythm and the device will switch back to DDD mode (or SafeR, Dplus, VDD) as soon as the sinus rhythm has been reached,
- if the sinus rhythm does not resume, the device paces the atria at the same rate as the ventricle. After 24 cycles, if no PAC occurs, the device will switch back to DDD mode (or SafeR, Dplus, VDD).

Both atrial and ventricular rates have to be slower than 107 bpm to have AV reassociation.

STUDIES AND RESULTS

1. Geroux L, Limousin M, Cazeau S. Clinical performances of a new mode switch function based on a statistical analysis of the atrial rhythm. Herzschr Electrophys. 1999; 10 (suppl 1):15-21.
2. Marshall HJ, Kay N, Hess M, et al. Mode switching in dual chamber pacemakers: effect of onset criteria on arrhythmia-related symptoms. Europace. 1999;1:49-54.
3. Stabile G, De Simone A, Romano E. Automatic mode switching in atrial fibrillation. Indian J Pacing Electrophysiol. 2005;5(3):186-96.
4. Maillard L, Razani M, for the Chorus II Multicenter Study. Prevention of ELTS with an innovative fallback algorithm. PACE. 1995;18 (pt 2) Abstract 437:1213.
5. Bonnet JL, Brusseau E, Limousin M, Cazeau S. Mode switch despite undersensing of atrial fibrillation in DDD pacing. PACE. 1996;19 (pt 2):1724-1728.

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

[3] *on ICDs, CRT-Ds and CRT-Ps only. This parameter is not available in the US.*