

Tech Corner

PARAD/PARAD+ : P and R Based Arrhythmia Detection

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.

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PARAD/PARAD+: P And R Based Arrhythmia Detection

The challenge for any ICD is to determine whether an elevated ventricular rate corresponds to a true ventricular tachyarrhythmia requiring device therapy, or not in the event that the elevated rate is not of ventricular origin.

Detecting VF is basically a matter of sensing a sustained ventricular rate higher than the (programmable) VF cut-off rate (usually set to 200 bpm or higher).

However, the proper detection of VT requires a specific algorithm (arrhythmia discrimination) to discriminate ventricular tachycardia from Supraventricular tachycardia (SVT) or sinus tachycardia (ST). The MicroPort core algorithms used for rhythms within the VT zone are called PARAD and PARAD+.

PARAD stands for “**P And R** based **Arrhythmia Detection**”. PARAD+ is an enhancement over PARAD providing an additional criterion to further reduce the incidence of inappropriate therapy in patients presenting with episodes of atrial fibrillation: the “AF detect” criterion.

Throughout this article we will learn how PARAD and PARAD+ operate in the VT/Slow VT zones to discriminate VTs from other rhythms. Please refer to the Tachyarrhythmia Suspicion and Detection Tech Corner to explore how MicroPort detects arrhythmias in dual and triple chamber ICDs.



AVAILABILITY

This function is available on any MicroPort dual chamber ICDs and CRT-Ds.

OVERVIEW

The PARAD/PARAD+ decision tree has been designed with the typical ECG characteristics of the different tachycardia rhythms.

PARAD is the basic algorithm used to discriminate ventricular tachycardias (VT) from sinus tachycardias (ST) and supraventricular tachycardias (SVT). PARAD uses the following assumptions:

Combination of criteria	Hypothesis	Result
Unstable RR	Atrial fibrillation	No treatment
Stable RR, no PR association	Ventricular tachycardia	Treatment
Stable RR, N:1 PR association	Atrial flutter	No treatment
Stable RR, 1:1 PR association, no acceleration	Sinus tachycardia	No treatment
Stable RR, 1:1 PR association, atrial acceleration	Supraventricular tachycardia	No treatment
Stable RR, 1:1 PR association, ventr. acceleration	Ventricular tachycardia	Treatment

The PARAD template has been worked out as follows:

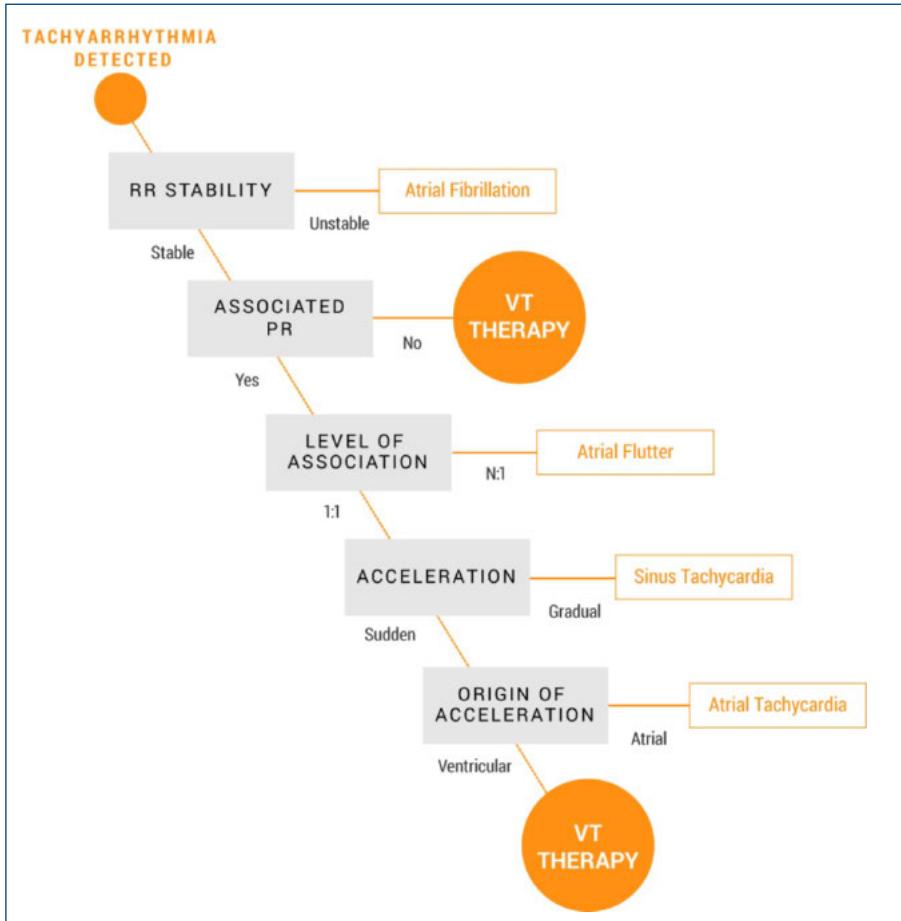


Figure 1 - PARAD

The PARAD+ template is an enhancement over the PARAD template to improve the arrhythmia discrimination in patients with a rather stable ventricular rate during episodes of paroxysmal atrial fibrillation. PARAD+ is based on the PARAD algorithm but additionally takes into account the occurrence of a 'long ventricular cycle' characteristic for AF patients. PARAD+ uses the following assumptions:

Combination of criteria	Hypothesis	Result
Unstable RR	Atrial fibrillation	No treatment
Stable RR, no PR association, no long cycle	Ventricular tachycardia	Treatment
Stable RR, no PR association, long cycle	Atrial fibrillation	Suspended treatment
Stable RR, N:1 PR association	Atrial flutter	No treatment
Stable RR, 1:1 PR association, no acceleration	Sinus tachycardia	No treatment
Stable RR, 1:1 PR association, atrial acceleration	Supraventricular tachycardia	No treatment
Stable RR, 1:1 PR association, ventr. acceleration	Ventricular tachycardia	Treatment

The PARAD+ template has been worked out as follows:

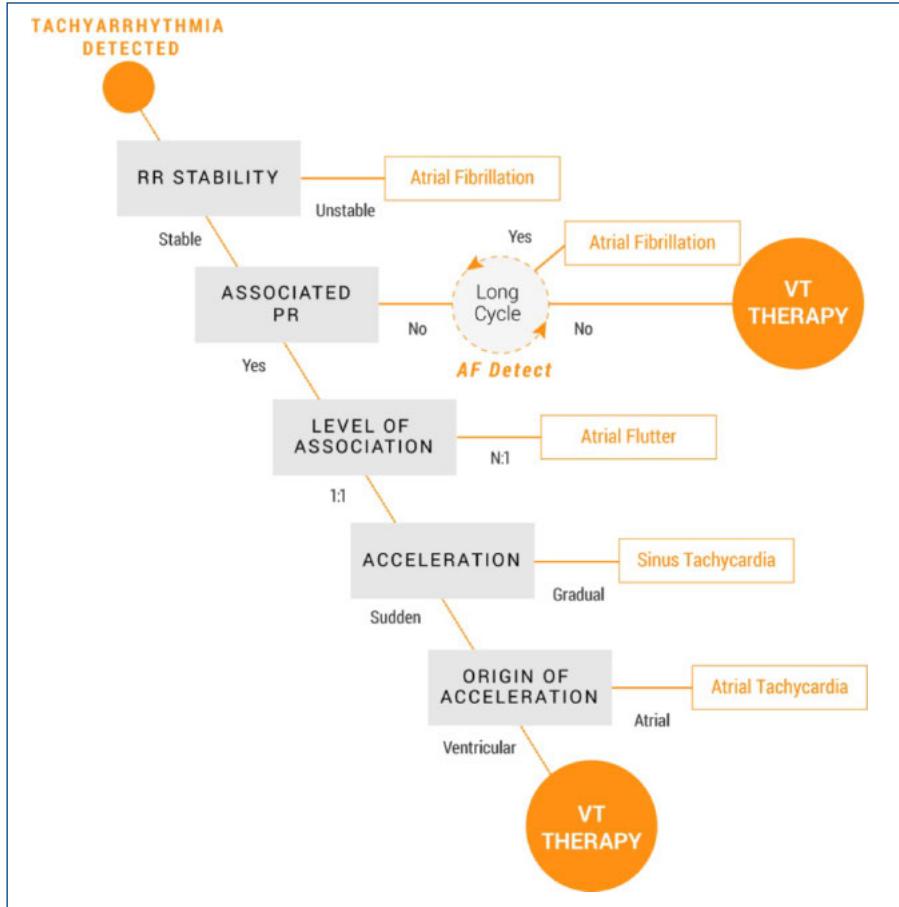


Figure 2 – PARAD+

Once and for as long as a TACHYCARDIA majority is reached, PARAD (or PARAD+) will - upon every ventricular cycle - analyze the last 8 cycles and apply one or more criteria to differentiate VT from ST or from any form of SVT.

STABILITY EVALUATION

The first criterion being evaluated by PARAD (or PARAD+) upon reaching a TACHYCARDIA majority is the “R-R stability”.

Figure 3 – Stability evaluation

A rhythm presenting with a TACHYCARDIA majority is considered as “unstable” if, among the cycles within the Tachycardia zone, less than 75%* have a coupling interval fitting within the “stability window” of 65 ms*. For as long as this is the case, the TACHYCARDIA will be declared to have “SVT majority” (and labeled as such).

* As-shipped values

An illustration of a rhythm labeled as having “SVT majority” (upon cycle 8) is given below:

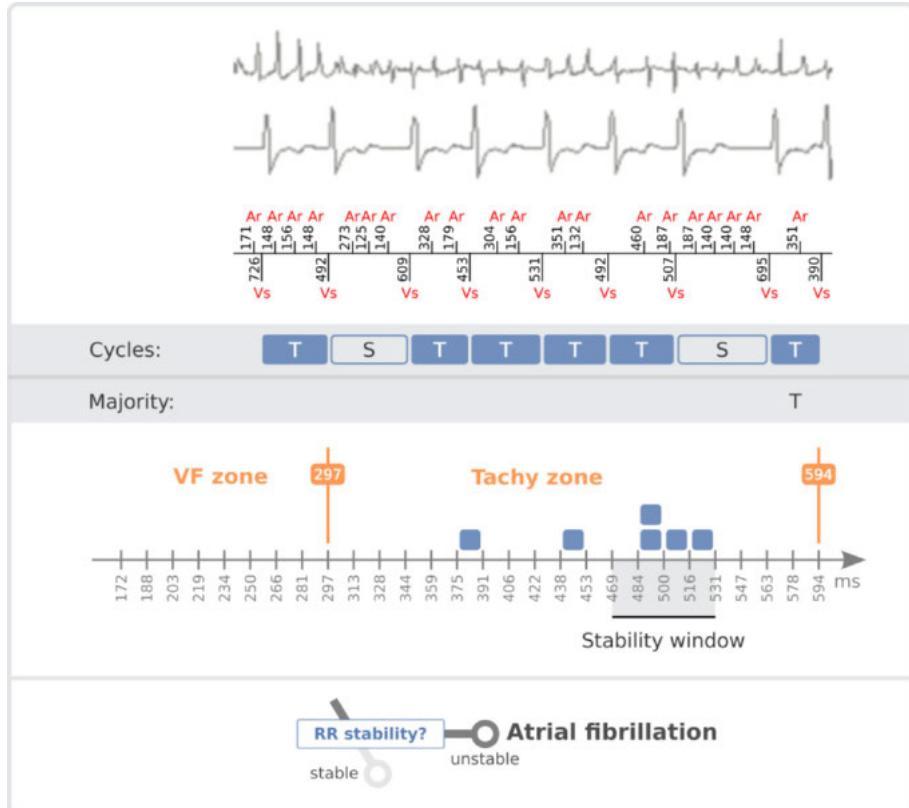


Figure 4 – Here the programmed zones are: VF zone = 200 bpm, VT zone = 100 bpm. In this example, 6 out of the last 8 cycles are in the Tachycardia zone (T) and 2 cycles are in the Slow rhythm zone (S): the Tachy majority is reached ($6/8 \geq 75\%$). Among the 6 cycles in the Tachycardia zone, a maximum of 4 cycles fits within the stability window: the stability criterion is not reached ($4/6 < 75\%$), the rhythm is unstable and PARAD/PARAD+ analysis is “Atrial fibrillation”.

Whenever the rhythm is found to be unstable, PARAD (or PARAD+) does not need to perform additional analysis because the rhythm is classified as “SVT/ST majority”.

A rhythm presenting with a TACHYCARDIA majority is considered “stable” if (and for as long as) at least 75%* of the cycles among the last 8 have a coupling interval fitting within a stability window of 65 ms (programmable value) and are in the Slow VT or VT zone.

* As-shipped value

An illustration of a rhythm reaching TACHYCARDIA majority (upon cycle 8) is given below:

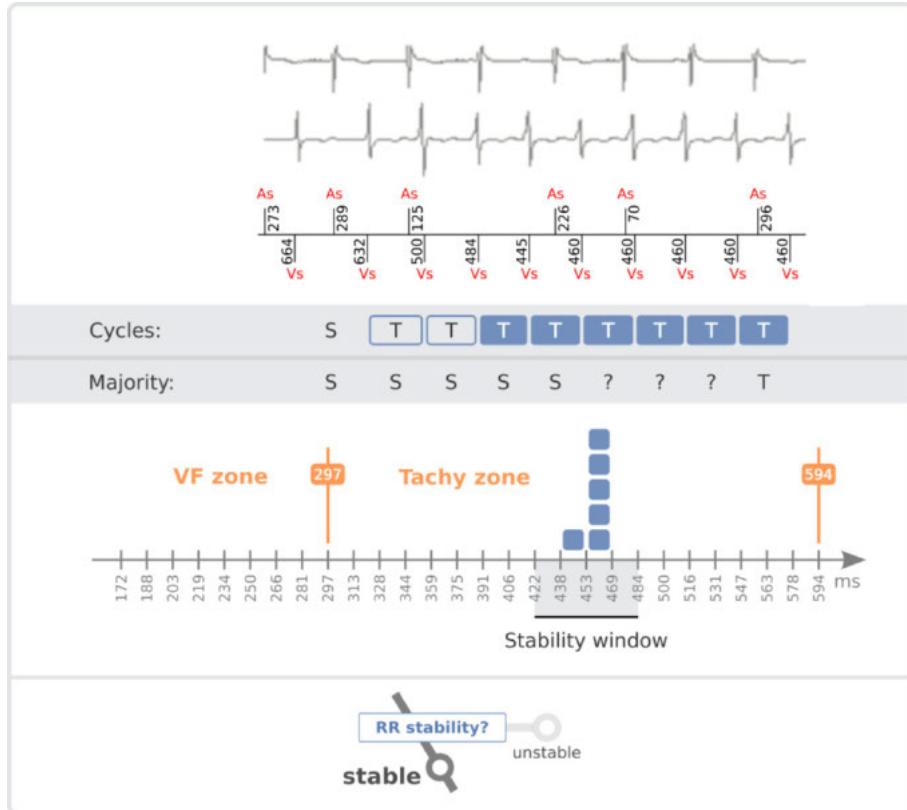


Figure 5 - In this example, among the last 8 cycles, the first 2 cycles are excluded from the analysis (onset of the tachycardia). The 6 next cycles are in the Tachycardia zone (T) (Tachy majority) and they all fit within the stability window: the majority of 75% is reached, the rhythm is stable and PARAD/PARAD+ analysis will continue to identify the ongoing rhythm.

However, a stable rhythm is not conclusive and more analysis is needed to determine the ongoing rhythm.

Please note that a given majority label can change from beat to beat (as the “R-R” stability is being evaluated upon every ventricular event). For instance, a SVT/ST majority can be updated into a VT majority if ongoing rhythm becomes stable.

Note: The first 2 cycles at the onset of a tachycardia are ignored as they may be unstable.

PR ASSOCIATION

In the event that the ventricular rhythm is found to be stable, PARAD (or PARAD+) performs deeper analysis. The next (processed in parallel) “test” will therefore be the evaluation of the presence (or absence) of “PR association”.



Figure 6 - PARAD

The idea behind this term is to evaluate the association between the occurrence of atrial events and ventricular events. This evaluation is performed on the same 8 ventricular cycles as the ones used for the evaluation of R-R stability.

The algorithm evaluates if a stable AV conduction is associated to the stable rhythm in the ventricles. It measures the PR intervals of the stable R-R intervals and checks if they are stable.

A PR association is reached if and as long as 75% of the stable cycles out of the last 8 cycles have a P-R interval fitting within a stability window of 65 ms.

For example, if the last 8 cycles were defined as stable, the evaluation of P-R association will be performed on these 8 cycles. But if only 7 cycles out of the last 8 cycles were defined as stable, the calculation of 75% of the stable cycles will be performed on these 7 cycles only, meaning $75\% \times 7 = 5.25$ cycles (rounded to 5 cycles) with PR intervals fitting within a stability window of 65 ms are necessary to define the PR association.

An illustration of a PR association confirmed is given below:

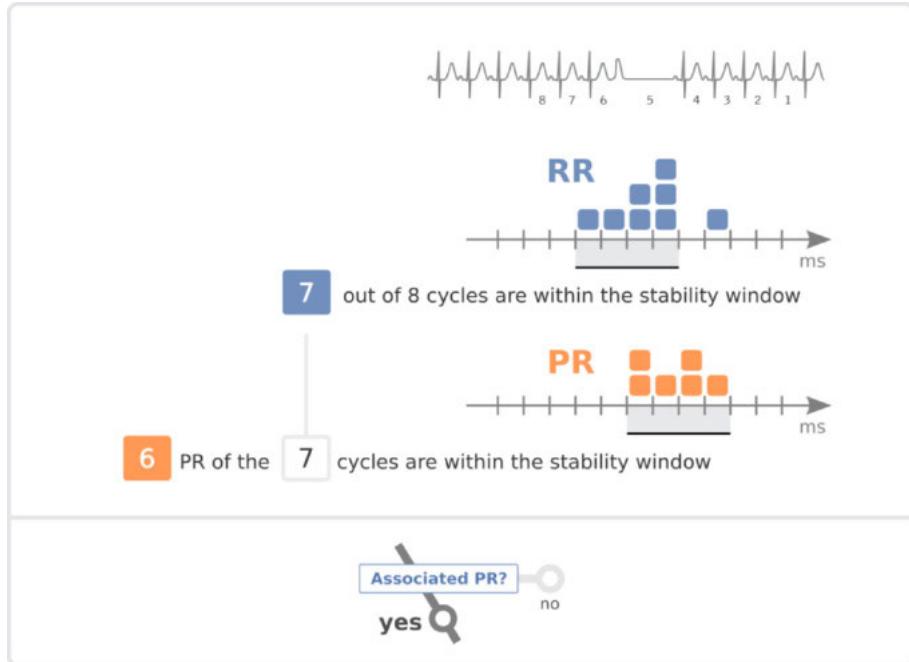


Figure 7

If no PR association is detected, PARAD will classify the rhythm as a VT and the programmed therapy will be applied.

With PARAD+, an additional step, the long cycles search, will be applied in order to better discriminate atrial fibrillation from ventricular tachycardias (see the section "[Long Cycle Search](#)", also called AF detect).

When a PR association is detected, PARAD (or PARAD+) is looking for the level of association (see the section "[Level of association](#)").

LONG CYCLE SEARCH (AF DETECT)

The long cycle search is specific to PARAD+. It is the only difference between PARAD and PARAD+. This step was added to increase the specificity of classification of arrhythmias in the event of atrial fibrillation.

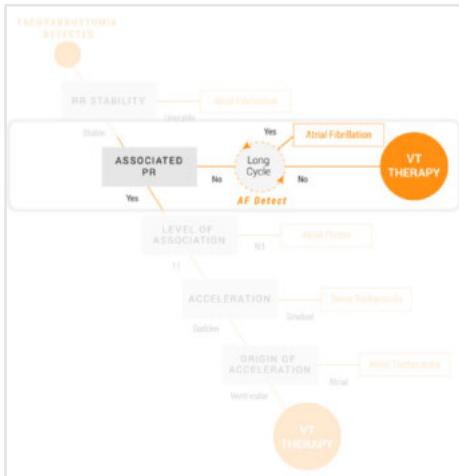


Figure 8 – PARAD+

After some years of experience with PARAD discrimination algorithm in Defender I and Defender II, some patients presented inappropriate therapies (ATP only or ATP + shock(s)) during Atrial Fibrillation. PARAD was detecting a stable ventricular rhythm dissociated from the atrial rhythm: the AV conduction could be chaotic during atrial fibrillation and the algorithm doesn't detect stable PR intervals. This occurred in 50% of the patients presenting atrial fibrillation with PARAD and all these patients had occasional longer ventricular cycles during atrial fibrillation episodes, seen at least every 20 ventricular cycles. These long cycles correspond to a longer diastole and are detected with PARAD+ discrimination algorithm.

The long cycle search will be applied when:

- The ventricular rhythm is stable
- But not associated with the atrial rhythm
- AND the fallback mode switch algorithm is in suspicion phase, already in DDI mode, in resynchronization phase or programmed OFF

A long cycle is defined as a cycle longer than the average of the last 4 cycles plus a programmable gap (*Long Cycle Gap*). The average of the last 4 cycles includes only cycles faster than the Slow VT/VT cut off rate.

If a long cycle is detected, an atrial fibrillation is suspected, and therapies to treat arrhythmias are delayed for 24 cycles. This means that as long as a long cycle is detected in the 24 cycles following a previous long cycle, no therapy will be delivered.

An illustration of this situation is given below:

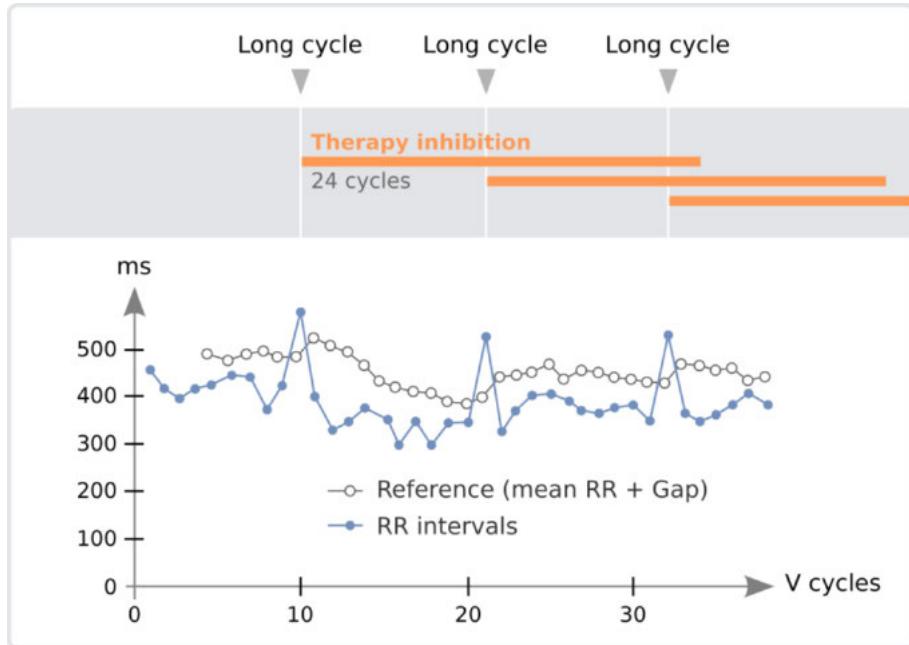


Figure 9

The average calculated of the last 4 cycles is re-initialized if the slow rhythm majority is reached, or after a therapy (ATP or shock).

When no long cycle is found for 24 cycles, a VT is confirmed and a therapy will be delivered.

LEVEL OF ASSOCIATION

If a PR association is established, the next step for PARAD (or PARAD+) is to define what is called “the level of the association”. This term means that the algorithm will check how many stable PR intervals occur between 2 consecutive ventricular cycles.



Figure 10

There are 2 possible levels of association:

- **1:1**, meaning the ratio is one atrial event for one ventricular event, with stable AV conduction,
- **N:1**, meaning the ratio is several atrial events for one ventricular event (with $N > 1$).

This classification is made in parallel to the stability and PR association analysis: it is made on the same 8 ventricular cycles as stability and PR association analysis.

Association Level N:1

The association level N:1 is defined if, for the ventricular cycles in TACHY zone (out of the last 8 cycles) less than 75% of all PR intervals fit within a stability window of 65 ms.

Note: The association level is evaluated only if the previous steps of the PARAD/PARAD+ analysis have been “validated”: (see [Annex 1](#) for details)

- 75% or more of the last 8 ventricular cycles are in TACHY zone,
- and 75% or more of the cycles in TACHY zone are stable,
- and PR association has been found for the stable ventricular cycles

The algorithm can analyze up to 5 PR intervals per ventricular cycle.

The PR association is analyzed for $50 \leq PR \leq 500$ ms.

PR shorter than 50 ms are considered as AV farfield sensing.

Then in the event of an association, it is possible to have several atrial events occurring between 2 consecutive R wave detections. This is the case in the figure presented below (see Annex 1 for details on the previous PARAD/PARAD+ step analysis).

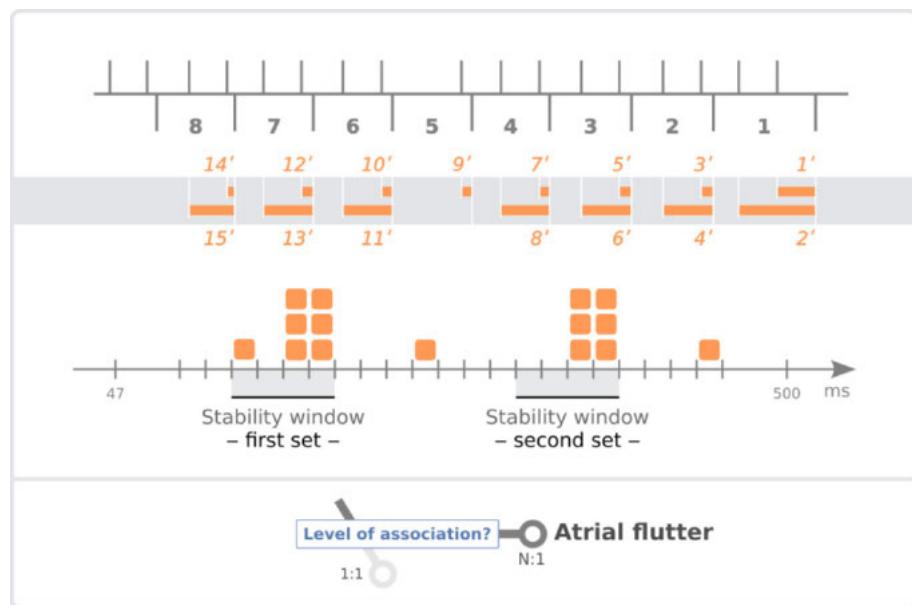


Figure 11 - The max number of PR intervals within a stability window is 7 (first set), which represents less than 75% of the total PR intervals (15): the association level is N:1.

In this example, each primed number represents the PR interval between the P wave detection and the following R wave detection. We can see 8 RR intervals (from 1 to 8) and 15 PR intervals (from 1' to 15').

Out of the 8 ventricular cycles (in TACHY zone), there are 15 PR intervals and two sets of stable PR intervals (see figure 11 above):

- 3',5',7,9',10',12' and 14' in the first set (7 stable PR intervals),
- and 4',6',8',11',13' and 15' in the second set (6 stable PR intervals).
- 1' and 2' are not stable

The majority for the level of association is not reached: out of the 15 PR intervals, a maximum of 7 PR intervals (first set) fits in the stability window (7/15 = 46.7%). The association level is therefore N:1.

If PARAD (or PARAD+) detects this type of association, the arrhythmia is classified as atrial flutter and no therapy is delivered.

Association Level 1:1

The association level 1:1 is defined if, out of the last 8 cycles, at least 75% of all PR intervals are stable.

In the example below (see [Annex 2](#) for details on the previous PARAD/PARAD+ step analysis):

Out of the 8 ventricular cycles (in TACHY zone), there are 7 PR intervals and 5 stable PR intervals: the majority for the level of association is reached (5/7 considered as > 75%): the association level is 1:1.

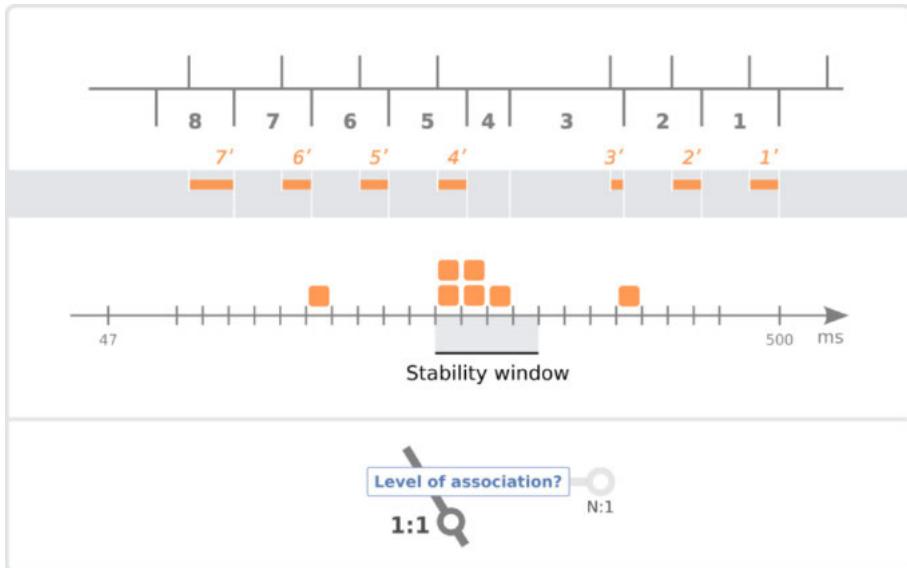


Figure 12: The max number of PR intervals within a stability window is 5, which represents at least 75% of the total PR intervals (7): the association level is 1:1.

If PARAD (or PARAD+) detects this type of association, it goes further in the analysis and determines if the ventricular acceleration leading to the actual rhythm was gradual or sudden.

VENTRICULAR ACCELERATION

To reach the TACHYCARDIA zone, the rhythm has to accelerate. A sudden ventricular acceleration can result from the onset of a ventricular or atrial arrhythmia. However, a constant and gradual increase of the cardiac rhythm is a sign of supraventricular origin. Because the cardiac rhythm detected by the device is based on RR intervals, PARAD (or PARAD+) characterizes the ventricular acceleration.



Figure 13

There are two types of possible accelerations in the ventricle:

- Sudden acceleration in the ventricle: the last ventricular event is detected in a window of prematurity detection
- Gradual acceleration in the ventricle: the last ventricular event is detected outside the window of prematurity detection.

On each ventricular cycle, a window of prematurity detection is triggered. The length of this window is equal to 75% (the acceleration prematurity is programmable) of the last RR interval, unless the ventricular event is asynchronous, or the ventricular interval is a pause, or the last ventricular event already occurred in a window of prematurity detection.

In these cases, the length of the window of prematurity detection is calculated as 75% (programmable value) of the average of the last 4 cycles which were not accelerated.

If the next ventricular event is outside the window of prematurity detection, the ventricular acceleration is characterized as gradual, a sinus tachycardia is detected and no therapy is applied.

If the next ventricular event is in the window of prematurity detection, the ventricular acceleration is considered as sudden, and PARAD (or PARAD+) goes to the next step and look for the origin of the ventricular acceleration.

ORIGIN OF ACCELERATION

A sudden ventricular acceleration can result from the onset of a ventricular tachycardia with retrograde conduction to the atria or from the onset of a conducted atrial tachycardia.



Figure 14

To determine the origin of a tachyarrhythmia suddenly accelerated, PARAD (or PARAD+) analyses the origin of acceleration.

Atrial origin

A tachyarrhythmia is detected as having an atrial origin if both ventricular events which define the first accelerated interval (i.e. the first interval shorter than the window of prematurity detection) are classified as conducted ventricular beats.

A conducted ventricular beat is a ventricular event preceded by an atrial event occurring in a time range of [31 ms ; 313 ms], as presented on the figure below.

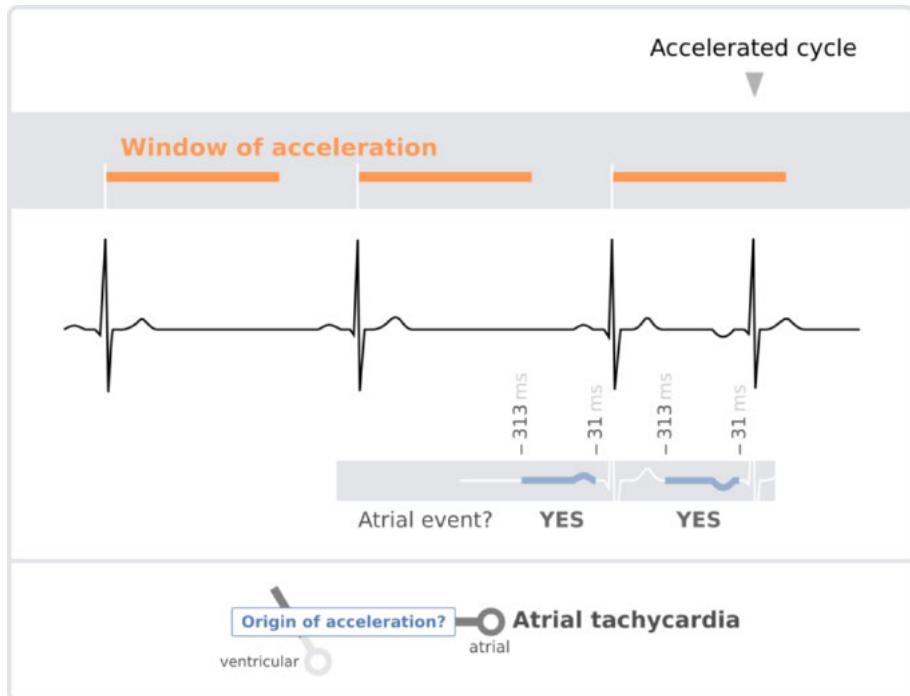


Figure 15

Ventricular origin

A tachyarrhythmia is detected as having a ventricular origin if at least one of the 2 ventricular events which define the first accelerated interval is not classified as conducted ventricular beat. An example of non conducted beat is presented below:

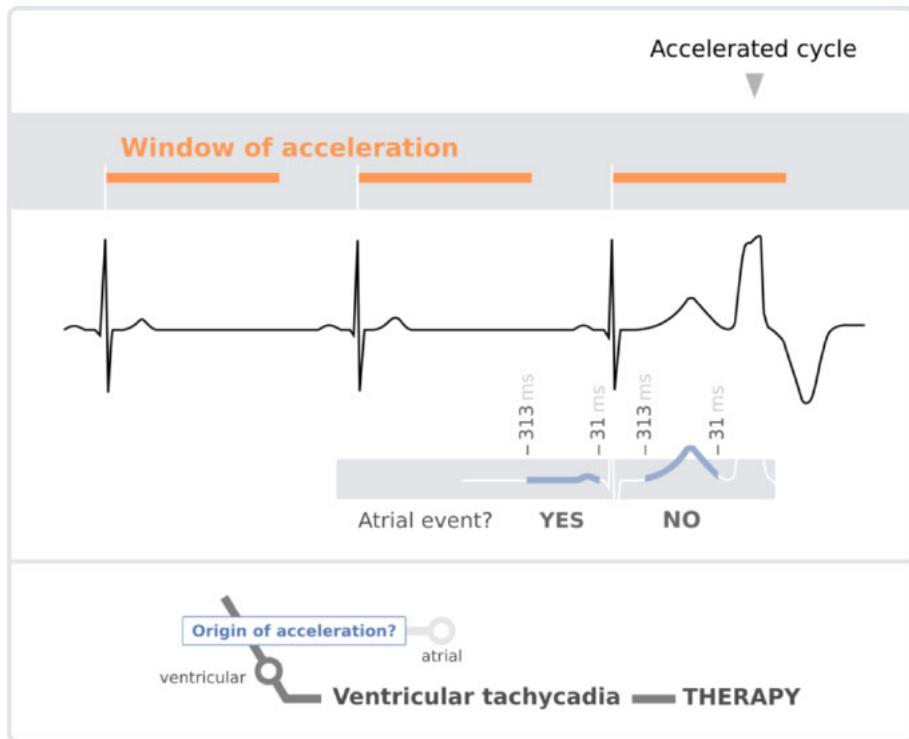


Figure 16

Classification of the rhythm

In the event of an arrhythmia with atrial origin, the rhythm is classified as atrial tachycardia, and no therapy is delivered.

In the event of an arrhythmia with ventricular origin, the rhythm is classified as ventricular tachycardia, and the algorithm then look for ventricular tachycardia persistence before delivering the programmed therapy.

PERSISTENCE

As presented previously, PARAD and PARAD+ are algorithms which can adapt their diagnosis on each cycle. To avoid launching a therapy on one misclassified cycle, the majority detected by the algorithm must be maintained for a programmable number of cycles (= persistence).

The persistence is programmable and is a number of cycles.

When the VT persistence is reached, the programmed therapy starts after the last cycle of the persistence phase (in the event of a shock, the charge of the capacitors starts at the end of the persistence phase).

The VT persistence and Slow VT persistence will be extended by the Long Cycle persistence (programmable) when the ventricular rhythm is stable and dissociated from the atria and the Fallback Mode Switch is detecting atrial arrhythmia or is programmed OFF.

The VT persistence and the Slow VT persistence can be programmed to different values (cf. "Tachyarrhythmia suspicion and detection" article)

On SVT/ST majority the VT persistence is applied to confirm the SVT/ST rhythm and to record it in AIDA. Note: Atrial fibrillation, atrial flutter, sinus tachycardia and atrial tachycardia are labeled SVT/ ST in the diagnostics).

The VT persistence is lost if a SVT/ST majority or a Slow Rhythm majority is reached before the end of the VT persistence, or if the detection of tachyarrhythmia resets because of programming modifications. It is not reset after a therapy to allow the second therapy to be delivered quicker in the event that the first one was not effective.

For more details, please read the Tech Corner article on Tachyarrhythmia suspicion and detection.

DUAL CHAMBER POST-DETECTION

After a therapy, some rules are applied in order to:

1. Ensure therapy delivery on sustained ventricular arrhythmias
2. Avoid a too long delay before the second therapy if the first therapy was not efficient.
3. Avoid inappropriate therapies.

After a therapy:

1. The acceleration is set to VENTRICULAR to ensure therapy delivery on sustained ventricular arrhythmias,
2. The persistence is not reset to avoid a too long delay before the second therapy. A new VT majority is needed to deliver the next therapy,
3. Therapies will be inhibited to avoid inappropriate therapy during sinus tachycardia if:
 - The rhythm was dissociated before the therapy
 - The rhythm is 1:1 associated after the therapy
 - The ventricular rate is less than or equal to 137 bpm

For more details, please read the Tech Corner article on Tachyarrhythmia suspicion and detection.

SUMMARY

Here are the few points of PARAD/PARAD+ to keep in mind:

- PARAD+ is an improvement of PARAD to improve the specificity of the algorithm for atrial fibrillation (the difference is the search for long cycles in the event of stable ventricular rhythm without PR association).
- PARAD (and PARAD+) is an algorithm using both atrial and ventricular channels. It is mandatory to have good functioning RA and RV leads to use this algorithm (PARAD is the algorithm used for the as-shipped configuration in DR ICDs and CRT-D devices. Always modify it when no atrial lead is implanted).
- PARAD and PARAD+ are based on a flowchart using multiple criteria to determine if the rhythm is from atrial or ventricular origin. These criteria are: RR stability, PR association (and level of association), long cycles, type of ventricular acceleration and origin of the acceleration.
- PARAD and PARAD+ adapt their diagnosis on each cardiac cycle to prevent inappropriate therapies.
- After a therapy, the majority count is reset but not the persistence count, and therapies are inhibited on non ventricular origin rhythm.

RESULTS OF THE OPTION[†] STUDY

Objective

The Option Study was designed to assess the benefit of MicroPort ICD dual chamber therapy by reducing inappropriate shocks and avoiding the deleterious effects of right ventricular overpacing.

Study Design

- 462 patients enrolled and followed for 2 years
- Randomized: either standard single chamber ICD therapy or optimized dual chamber therapy by programming PARAD+ and SafeR^{*}

Study Results

MicroPort dual chamber ICDs were associated with a lower occurrence of inappropriate shocks.

- At 2 years, 58% reduction of inappropriate shocks compared to single chamber
- At 1 year, 66% reduction of inappropriate shocks compared to single chamber

OPTION Study conclusion

Dual chamber discrimination algorithm (PARAD+) combined with minimized Vp (SafeR) results in:

- Low inappropriate shock rate at only 2.6% at one year with conventional settings
- Without deleterious effects associated with dual chamber pacing

^{*} Refer to the SafeR Tech Corner article for more information

A REVIEW OF PREVENTION OF INAPPROPRIATE SHOCKS IN ICD RECIPIENTS¹⁰

Objective

- Inappropriate shocks are strongly linked with poor mental health, reduced QOL and activity as well as increased anxiety and Depression^{11,12,13}
- Reports showed inappropriate shocks from dual chamber ICDs at 15-30%^{14,15}

Study Design

- Retrospective analysis of 5 clinical studies (1998 to 2003)
- 802 patients enrolled and followed for 10 months, all implanted with dual chamber MicroPort defibrillator.
- 9,690 episodes recorded in the diagnostics and analyzed by a board of Physicians

Study Results

Sensitivity for ventricular fibrillations	100%	34 episodes
Sensitivity for ventricular tachycardias \geq 150bpm	99.3%	955 episodes
Sensitivity for ventricular tachycardias < 150bpm:	94%	784 episodes
Specificity for sinus tachycardias	96%	6060 episodes
Specificity for atrial fibrillation with PARAD	82%	638 episodes
Specificity for atrial fibrillation with PARAD+	90%	

Overall specificity: 94%

Inappropriate shocks were documented in 5% of patients:

- 53% of these shocks were due to oversensing, which is not related to PARAD+ functioning. These shocks can be reduced with programming or system revision

Study conclusion

Dual chamber discrimination algorithm PARAD+ results in:

- Inappropriate shocks documented in 5% of patients.
- Overall specificity: 94%.

OTHER STUDIES AND RESULTS

1. Kolb C, Sturmer M, Sick P et al. Reduced Risk for Inappropriate Implantable Cardioverter-Defibrillator Shocks With Dual-Chamber Therapy Compared With Single-Chamber Therapy. Results of the randomized Option study. *JACC Heart Failure* 2014 Dec;2(6):611-9.
2. Ruwald AC, Sood N, Ruwald MH, et al. Frequency of Inappropriate Therapy in Patients Implanted with Dual- versus Single-Chamber ICD Devices in the ICD Arm of MADIT-CRT. *J Cardiovasc Electrophysiol*. 2013; 24(6):672-79.
3. Moss AJ, Schuger C, Beck CA, et al. for the MADIT-RIT Trial Investigators. Reduction in Inappropriate Therapy and Mortality Through ICD Programming. *N Engl J Med*. 2012; 367:2275-83.
4. Bänsch D, Castrucci M, Bocker D, et al. Ventricular tachycardias above the initially programmed tachycardia detection interval in patients with implantable cardioverter-defibrillators: incidence, prediction and significance. *J Am Coll Cardiol*. 2000 Aug;36(2):557-65.
5. Sadoul N, Mletzko R, Anselme F, et al. Incidence and Clinical Relevance of Slow Ventricular Tachycardia in Implantable Cardioverter-Defibrillator Recipients: An International Multicenter Prospective Study. *Circulation*. 2005; 112:946-53.
6. Hintringer F, Deibl M, Berger T, et al. Comparison of the Specificity of Implantable Dual Chamber Defibrillator Detection Algorithms. *Pacing Clin Electrophysiol*. 2004; 27:976-82.
7. Wilkoff BL, Cook JR, Epstein AE, et al. Dual Chamber and VVI Implantable Defibrillator Trial Investigators. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: the Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. *JAMA*. 2002 Dec 25;288(24):3115-23.
8. Garidiwal A, Yu H, Oswald H, et al. Right Ventricular Pacing Is an Independent Predictor for Ventricular Tachycardia/Ventricular Fibrillation Occurrence and Heart Failure Events in Patients with an Implantable Cardioverter-Defibrillator. *Europace*. 2008; 10(3):358-63.
9. Melzer C, Bohm M, Bondke HJ, et al . Chronotropic Incompetence in Patients with an Implantable Cardioverter Defibrillator: Prevalence and Predicting Factors. *Pacing Clin Electrophysiol*. 2005; 28(10):1025-31.
10. Anselme F, Mletzko R, Bowes R, et al. Prevention of inappropriate shocks in ICD recipients: a review of 10,000 tachycardia episodes. *PACE* 2007;30:S128-S133. Study made using dual-chamber ICDs with standard dual-chamber arrhythmia classification algorithms.
11. Carroll DL, Hamilton GA Quality of life in implanted cardioverter defibrillator recipients: the impact of a device shock. *Heart Lung*. 2005;34:169-78.

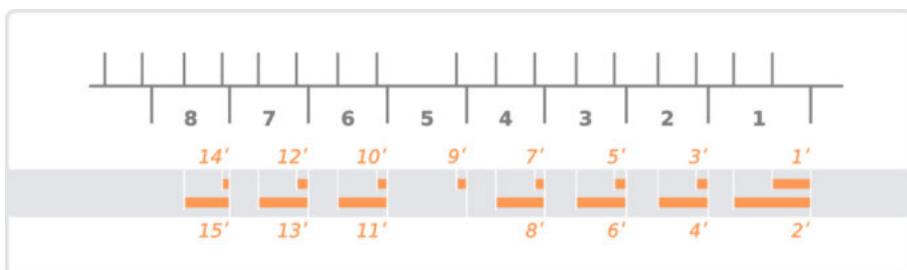
12. Heller SS, Ormont MA, Lidagoster L, et al. Psychosocial outcome after ICD implantation: a current perspective. *Pacing Clin Electrophysiol*. 1998;21:1207-15.
13. Whang W, Albert CM, Sears SF Jr, TOVA Study Investigators Depression as a predictor for appropriate shocks among patients with implantable cardioverter-defibrillators: results from the Triggers of Ventricular Arrhythmias (TOVA) study. *J Am Coll Cardiol*. 2005;45:1090-5.
14. Glikson M, Lipchenca I, Viskin S, et al. Long-term outcome of patients who received implantable cardioverter defibrillators for stable ventricular tachycardia. *J Cardiovasc Electrophysiol*. 2004;15:658-64.
15. Hreybe H, Ezzeddine R, Barrington W, et al. Relation of advanced heart failure symptoms to risk of inappropriate defibrillator shocks. *Am J Cardiol*. 2006;97:544-6.

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

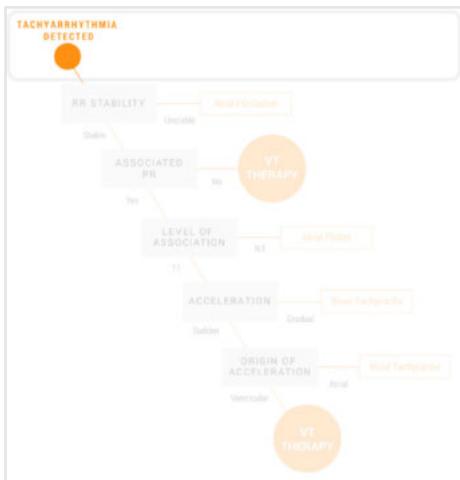
ANNEX 1

The annex 1 explains the first steps of the PARAD/PARAD+ analysis (Tachy majority, RR stability, PR association) of the example shown in the figure 11. Then the analysis of the "Level of association" is explained and detailed in the article, under the section "Association Level N:1".

In this example, each primed number represents the PR interval (in orange) between the P wave detection and the following R wave detection. We can see 8 RR intervals (from 1 to 8) and 15 PR intervals (from 1' to 15').



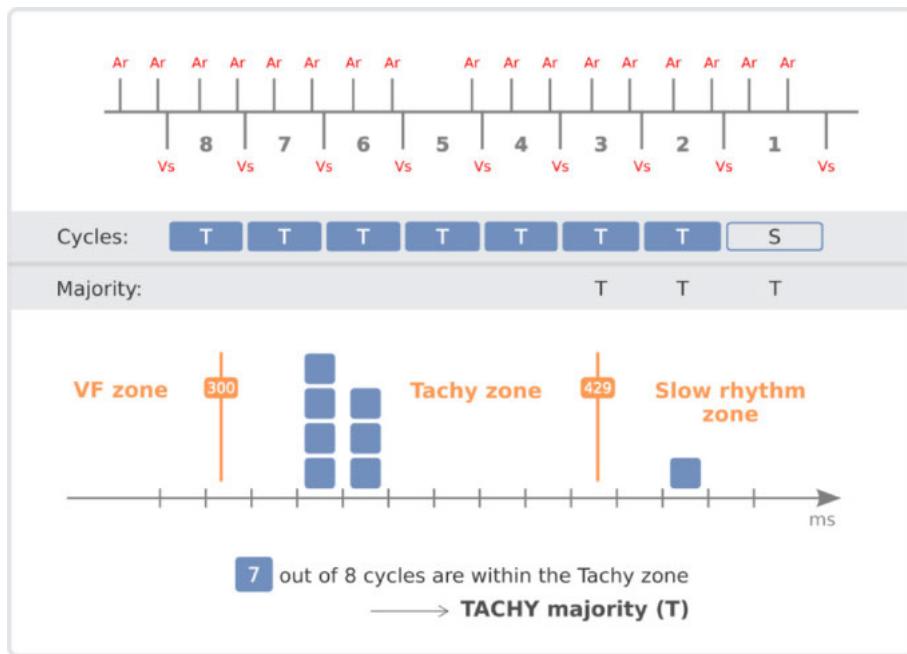
Majority detection



Reminder: Upon each and every ventricular complex, the device classifies the ventricular cycle according to its coupling interval (F: Fibrillation, T: Tachycardia, S: Slow rhythm).

To reach a majority, at least 6 out of the last 8 ventricular cycles (75%, programmable) must be classified within the same detection zone (VF, Tachy, Slow rhythm).

In our example we have 7 out of the last 8 ventricular cycles within the Tachy zone (from 2 to 8): the majority of 75% is reached, therefore the ongoing rhythm is classified as a "TACHYCARDIA majority".

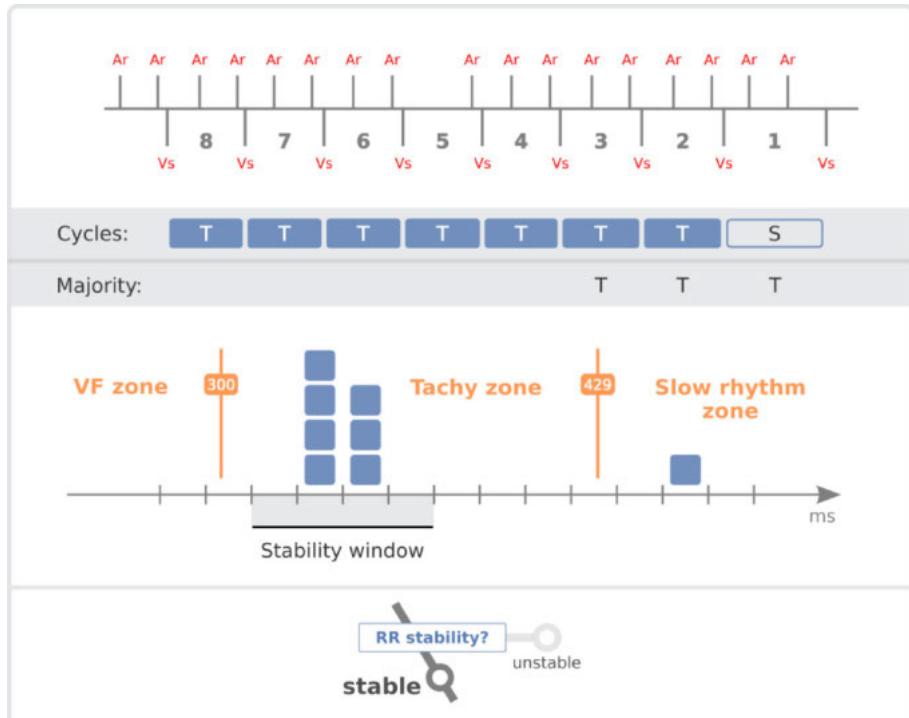


Stability analysis



Reminder: A rhythm with a Tachy majority is considered “stable” if at least 75% (programmable value) of the cycles in the Tachy zone are stable.

In our example, the 7 cycles (which are in the Tachycardia zone) fit within the stability window: the majority of 75% is reached ($7/8 \geq 75\%$): the rhythm is stable and PARAD/PARAD+ analysis will continue to identify the ongoing rhythm.



Out of the 8 ventricular cycles, there are 7 stable RR intervals (from 2 to 8): the majority for ventricular stability is reached ($7/8 \geq 75\%$): the rhythm in the ventricle is stable.

PR association analysis

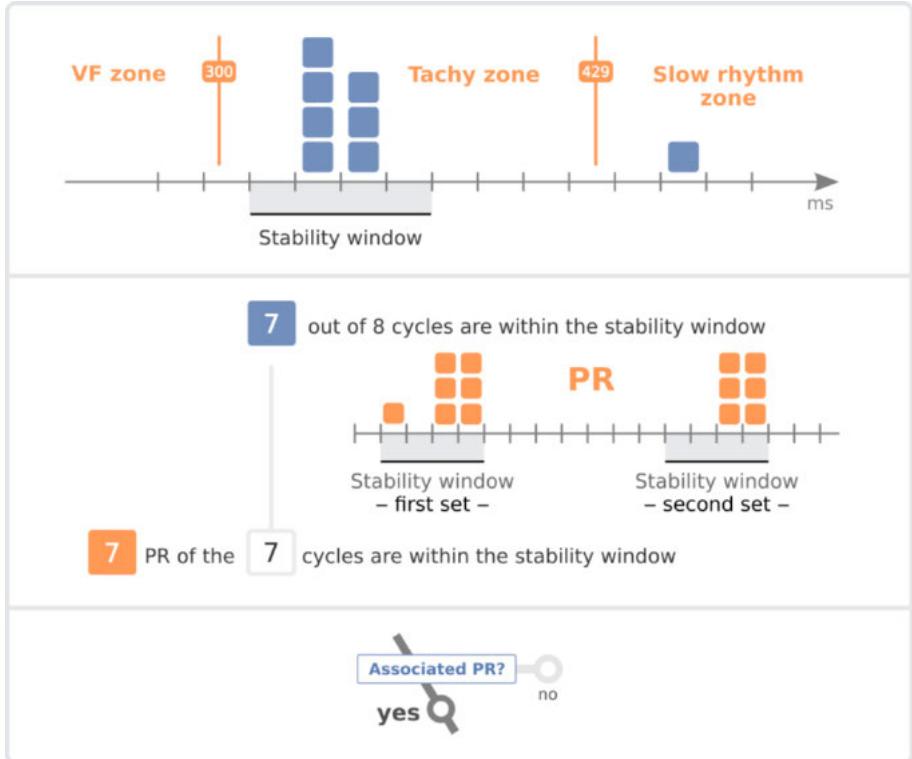


Reminder: A PR association is reached if at least 75% of the stable cycles have a PR interval fitting within a stability window.

In our example, we have 7 stable RR intervals (from 2 to 8, see above), and a total of 13 PR intervals (3' to 15'). The PR intervals are ranging as follow:

- 3', 5', 7', 9', 10', 12' and 14' in the first set (7 stable PR intervals),
- 4', 6', 8', 11', 13' and 15' in the second set (6 stable PR intervals).
- 1' and 2' are excluded because the associated ventricular cycle (cycle 1) is a slow cycle (and therefore not part of the stable RR intervals)

The majority for PR association is reached: 7 stable PR intervals out of 7 stable RR intervals ($7/7 \geq 75\%$).

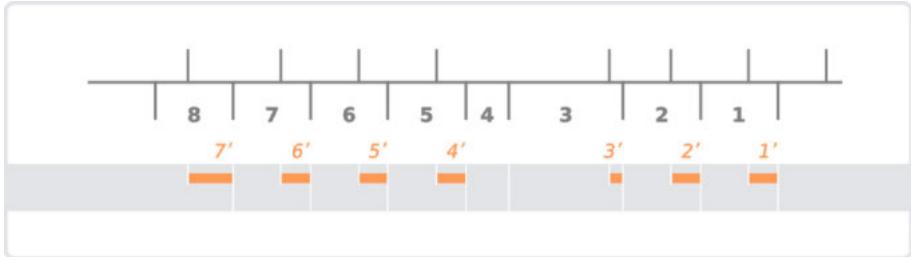


The PR intervals of the 7 stable RR intervals are analysed: the highest number of PR intervals fitting within the stability window is 7 (first set): the majority is reached ($7/7 \geq 75\%$), the PR association is confirmed.

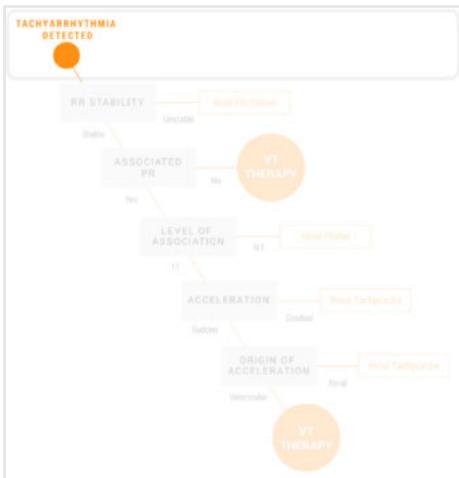
ANNEX 2

The annex 2 explains the first steps of the PARAD/PARAD+ analysis (Tachy majority, RR stability, PR association) of the example shown in the figure 12. Then the analysis of the “Level of association” is explained and detailed in the article, under the section “[Association Level 1:1](#)”.

In this example, each primed number represents the PR interval (in orange) between the P wave detection and the following R wave detection. We can see 8 RR intervals (from 1 to 8) and 7 PR intervals (from 1' to 7').



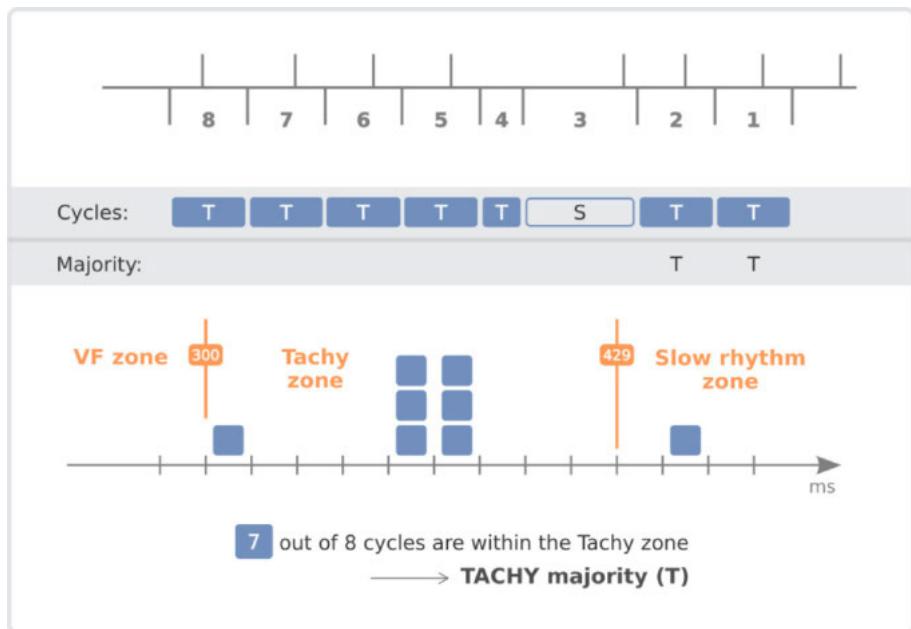
Majority detection



Reminder: Upon each and every ventricular complex, the device classifies the ventricular cycle according to its coupling interval (F: Fibrillation, T: Tachycardia, S: Slow rhythm).

To reach a majority, at least 6 out of the last 8 ventricular cycles (75%, programmable) must be classified within the same detection zone (VF, Tachy, Slow rhythm).

In our example we have 7 out of the last 8 ventricular cycles within the Tachy zone (1, 2, 5, 6, 7, 8): the majority of 75% is reached, therefore the ongoing rhythm is classified as a “TACHYCARDIA majority”.

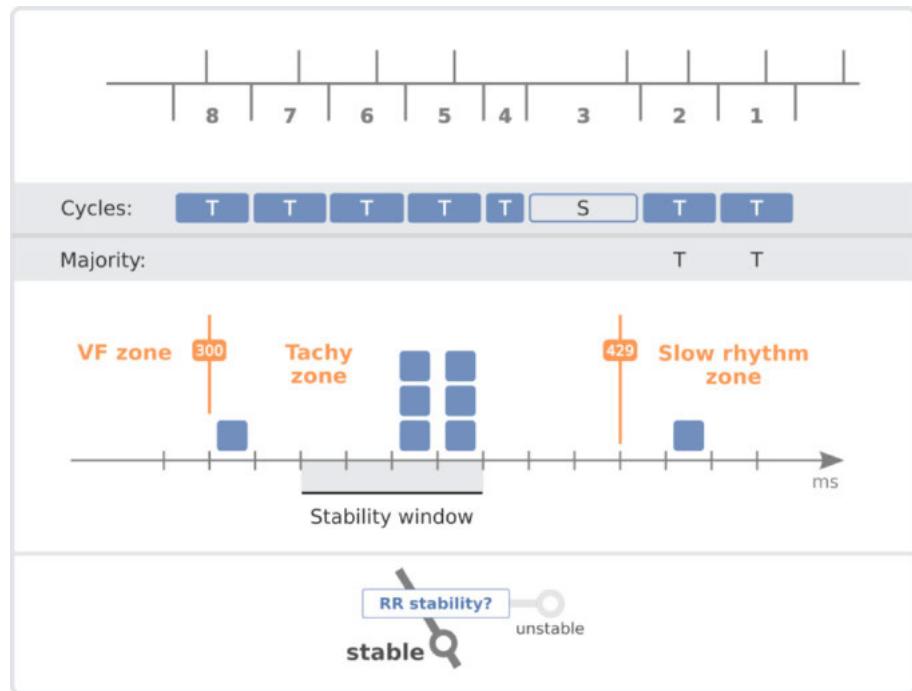


Stability analysis



Reminder: A rhythm with a Tachy majority is considered “stable” if at least 75% (programmable value) of the cycles in the Tachy zone are stable.

In our example, out of the 8 ventricular cycles, there are 6 stable RR intervals (cycles 1, 2, 5, 6, 7 and 8): the majority for ventricular stability is reached ($6/8 > 75\%$): the rhythm in the ventricle is stable.



Out of the 8 ventricular cycles, there are 6 stable RR intervals: the majority for ventricular stability is reached ($6/8 \geq 75\%$): the rhythm in the ventricle is stable.

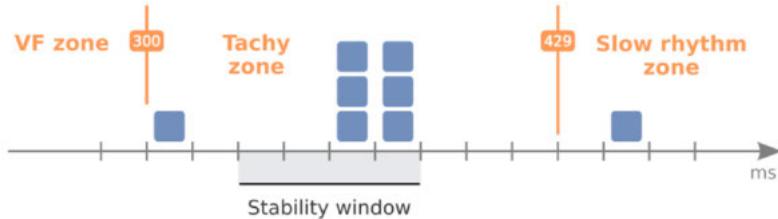
PR association analysis



Reminder: A PR association is reached if at least 75% of the stable cycles have a PR interval fitting within a stability window.

In our example, we have 6 stable RR intervals (1, 2, 5, 6, 7, 8), and a total of 6 PR intervals: 1', 2', 4', 5', 6' and 7'.

Among the 6 PR intervals, 5 PR are stable (1', 2', 4', 5' and 6'): the majority for the PR association is reached ($5/6 \geq 75\%$): the ventricular rhythm is associated to the atria.



6 out of 8 cycles are within the stability window



5 PR of the **6** cycles are within the stability window



The PR intervals of the 6 stable RR intervals are analysed: the highest number of PR intervals fitting within the stability window is 5: the majority is reached ($5/6 \geq 75\%$), the PR association is confirmed.