Tech Corner

Tachyarrhythmia Suspicion and 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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Tachyarrhythmia Suspicion and Detection

The primary goal of an Implantable Cardioverter Defibrillator (ICD) is to preserve life by terminating life-threatening ventricular tachycardia (VT) or ventricular fibrillation (VF).

The secondary goal is to deliver therapy only when required and always in the least obtrusive manner.

The third goal is to deliver therapy as painless as possible by giving priority to ATP.

The challenge for any device 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 that is higher than the (programmable) VF cut-off rate (usually set to 200 bpm or higher).

However, appropriate detection of ventricular tachycardia requires a specific algorithm (arrhythmia discrimination) to discriminate ventricular tachycardia (VT) from supraventricular tachycardia (SVT) or sinus tachycardia (ST). The MicroPort core algorithms used for rhythms within the VT and Slow VT zones are called PARAD+ and PARAD¹.

PARAD stands for "**P** And **R** based Arrhythmia **D**iscrimination". PARAD+ is an enhancement of the PARAD algorithm providing an additional criterion to further reduce the incidence of inappropriate therapy in patients presenting with episodes of atrial fibrillation.

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

¹ PARAD+ is not available on the single chamber models



AVAILABILITY

This function is available on dual and triple chamber MicroPort ICDs.

PRINCIPLE OF TACHYARRHYTHMIA SUSPICION

For each and every ventricular complex (later on referred to as "beat by beat"), the device basically answers three questions:

I. What kind of ventricular cycle has occurred?

- 1. FIBRILLATION cycle
- 2. TACHYCARDIA cycle
- 3. SLOW cycle

II. What seems to be the ongoing rhythm?

- 1. Ventricular Fibrillation is suspected if a "majority" of ventricular cycles occurred within the VF zone.
- Tachycardia is suspected if a "majority" of ventricular cycles occurred within the VT zone. <u>Note</u>: The
 ongoing rhythm is not as yet classified as a ventricular Tachycardia. Finding out whether the
 tachycardia is of supraventricular or ventricular origin is the task of the PARAD(+) discrimination
 algorithm.²
- 3. The rhythm is classified as Slow Rhythm (SR) if a "majority" of ventricular cycles is not within the VT/VF zones
- The rhythm is classified as having "No majority" if none of the three "majorities" above can be attributed yet.

III. Is the ongoing rhythm becoming a persistent rhythm?

If the suspected ongoing rhythm is sustained for a pre-defined number of cycles (called persistence), the ongoing rhythm is confirmed.

- As soon as persistent VF is identified, VF therapy is initiated. Depending on the programmed settings of the VF detection zone, ATP on "Fast VT" may precede shock therapy. See more details under "Persistence definition" on page 8)
- As soon as a Tachycardia is suspected (Tachycardia majority is reached), the discrimination algorithm PARAD+3 is applied to determine whether the ongoing rhythm is a SVT/ST or a VT.
 - No therapy is given if persistent SVT/ST is diagnosed
 - VT therapy will be initiated if a diagnosis of persistent VT is made: the VT majority needs to be confirmed during each cycle of the persistence.

Note: No therapy is given in the absence of persistence of any type of rhythm.

³ PARAD+ is not available on the single chamber models



² PARAD+ is not available on the single chamber models

CYCLE DEFINITION

Although there are 4 therapy zones and slow rhythm zone in our current range of ICDs (Slow VT, VT, Fast VT and VF), be aware that the ICD itself only knows 3 types of cycles:

- FIBRILLATION cycle (F): any ventricular cycle with a coupling interval shorter than [60,000/VF cut-off rate] will be classified as a FIBRILLATION cycle. (FIBRILLATION zone = fast VT zone and VF zone)
- TACHYCARDIA cycle (T): any ventricular cycle with a coupling interval shorter than [60,000/VT cut-off rate]. (TACHYCARDIA zone = Slow VT zone and VT zone).
- SLOW cycle (S): any ventricular cycle with a coupling interval longer than [60,000/VT cut-off rate] (slow rhythm zone)

MAJORITY DEFINITION

Upon every ventricular event, MicroPort ICDs attribute one of the following "majorities" to the ongoing rhythm. These "majorities" are:

- VF majority (F)
- TACHYCARDIA majority (T). The discrimination algorithm PARAD(+)⁴ will be used to sort out whether the TACHYCARDIA is a Ventricular Tachycardia or a Sinus/Supra Ventricular Tachycardia.
- SLOW rhythm majority (S)
- NO majority (N) for as long as none of the above three majorities has been reached

The majority is by default 75% of the last 8 ventricular cycles⁵.

A "majority" label is attributed on every ventricular event.

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

⁵ 6 out of 8 is the default programming. The values 75% (X) and 8 (Y) are programmable values although they are (and should be) rarely reprogrammed.



⁴ PARAD+ is not available on the single chamber models

VF Majority

For a given rhythm to be labelled as a "VF majority" rhythm, at least 6 out of the last 8 ventricular cycles must have been classified as a "Fibrillation cycle".

Below is an example of a rhythm at the moment it reaches the VF majority.

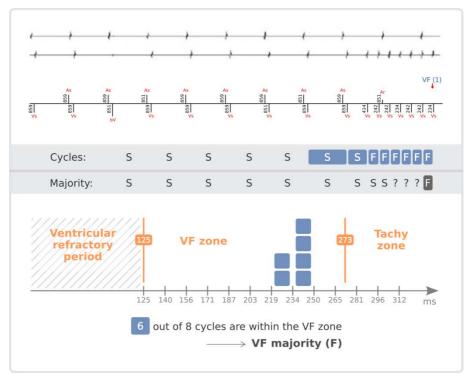


Figure 1: Onset of a fast VT in the "fast VT + VF zone" (here programmed at 273 ms = 220 bpm): more than 75% (6) out of the last 8 cycles have coupling intervals shorter than 273 ms (programmed zone). Therefore the ongoing rhythm is classified as having a "VF majority".

TACHYCARDIA Majority

For a given rhythm to be labelled as a "Tachycardia majority" rhythm, at least 6 out of the last 8 ventricular cycles must have been classified as a "Tachycardia cycle".

Below is an example of a rhythm at the moment it reaches a TACHYCARDIA majority.

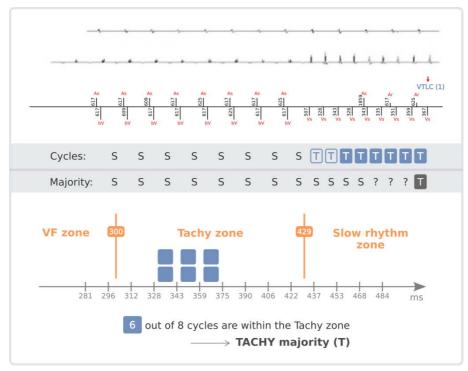


Figure 2: Onset of a tachycardia in the "Tachycardia zone" [here programmed between 300 ms (= 200 bpm) and 429 ms (= 140 bpm)]: more than 75% (6) out of the last 8 cycles have coupling intervals shorter than 429 ms (programmed zone). Therefore the ongoing rhythm is classified as having a "TACHYCARDIA majority".

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

SLOW Rhythm Majority

For a given rhythm to be classified as a "Slow majority" rhythm, at least 6 out of the last 8 ventricular cycles must have been classified as a "Slow cycle".

NO Majority

When none of the above majorities apply, the ongoing rhythm is labelled as having "No majority".



PERSISTENCE DEFINITION

What happens when the latest ventricular cycle results in or maintains VF Majority?

On the first ventricular cycle that the device reaches VF majority, it sets the "VF persistence counter" to 1. For each additional ventricular cycle that maintains this VF majority, the "VF persistence counter" is incremented by 1.

The as-shipped and nominal value for the "VF persistence" parameter is 6 (cycles). As soon as the "VF persistence counter" reaches the value to which the "VF persistence" parameter has been programmed, the system considers the VF as confirmed (it persists).

As soon as "VF persistence" is reached (i.e. VF is confirmed) and if the last cycle of the VF persistence is a VF cycle, therapy is initiated. The actual therapy (ATP on Fast VT and/or shock therapy) that will be initiated depends on the following situations:

- If the fast VT zone is NOT programmed, the device starts charging the capacitors.
- If a fast VT zone is programmed, the device will apply the fast VT criteria to determine whether it has to apply ATP (on Fast VT) or not.
 - If the criterion for Fast VT is set to "rate only" the device will apply (fast VT) ATP provided each of the last 4 cycles before reaching "VF persistence" was slower than the upper boundary of the Fast VT zone. If at least one of the last 4 cycles was faster than the upper boundary of the Fast VT zone, the device will immediately start charging the capacitors to the programmed energy of the first shock in the fast VT/VF zone.
 - If the criterion for Fast VT is set to "rate + stability" the device will apply (fast VT) ATP provided:
 - each of the last 4 cycles before reaching "VF persistence" was slower than the upper boundary of the Fast VT zone and
 - 6 out of the last 8 cycles before reaching "VF persistence" are within a stability window of 30 ms (30 ms is the shipped/nominal value).
 - However if at least one of the last 4 cycles was faster than the upper boundary of the Fast VT zone and/or if the rhythm is considered unstable, the device will immediately start charging the capacitors to the programmed energy of the first shock in the fast VT/VF zone.

If during the VF persistence counting process, the VF majority changes to a "No majority", the VF persistence counter is frozen (for as long as there is "No majority").

If during the VF persistence counting process, the VF majority changes to a Tachycardia majority (either due to a VT or an SVT/ST) or a Slow Rhythm (SR) majority, the VF persistence counter will be reset.



What happens during the charging process?

During the charging of the capacitors, the device continually monitors the rhythm:

- Charging continues for as long as the device finds a VF or a VT majority and no slow cycle is detected. As
 soon as the capacitors are charged to the programmed level, the shock will be delivered provided that the
 majority is still VF or VT and the last cycle before the shock is a VF or a VT cycle. The shock will be
 synchronised to the ventricular detection.
- Detection of a majority which is not a VT or a VF majority and/or detection of a slow cycle halts charging of the capacitors.

Notes:

- Charging is part of the shock therapy and once the device starts charging the capacitors it
 will never apply a less aggressive therapy (ATP or shock with a lower energy level) for the
 same episode.
- 2. For safety reasons if a transition from a VF majority to a VT majority occurs while charging the capacitors, a shock will be delivered if the shock therapy is ON in the VT zone and the programmed energy of the VT shock is equal or greater to the energy of the VF shock: the first confirmed rhythm was VF and if the majority after that changes to a VT majority, the device could be facing a VF rhythm which has slowed down into the VT zone or a VF with sensing dropout.

What happens when the latest ventricular cycle results in or maintains a Tachy Majority?

As soon as the device observes that the ongoing rhythm is reaching a tachycardia majority, it will try to find out whether the ongoing tachycardia is:

- 1. a sustained ventricular tachycardia or
- a sustained supra-ventricular or sinus tachycardia (SVT/ST).

PARAD/PARAD+ are MicroPort algorithms⁶ that discriminate rhythms into either VT or SVT/ST. They are described in detail in the PARAD+ Tech Corner article.

- If PARAD or PARAD+ confirms the ongoing rhythm is a sustained ventricular tachycardia, the device will initiate therapy (ATP and/or shock) if programmed ON.
- If PARAD or PARAD+ confirms the rhythm is a sustained SVT/ST no therapy will be initiated.

Note: If the rhythm is not sustained it will not be confirmed (by PARAD/PARAD+) and therefore no therapy will be initiated.

⁶ PARAD+ is not available on the single chamber models



What happens when PARAD/PARAD+ indicates that the Tachy Majority is "VT"?

On the first ventricular cycle whereby (1) the device has reached a tachycardia majority and (2) PARAD or PARAD+ discrimination indicates the rhythm to be "VT", the device sets both the VT and Slow VT persistence counters to 1. For each subsequent ventricular cycle for which PARAD or PARAD+ continues to indicate the Tachycardia rhythm to be "VT", both the VT and Slow VT persistence counters are incremented by 1.

The as-shipped and nominal value for both the VT and Slow VT persistence parameters is 12 cycles.

Some Physicians will program the Slow VT persistence parameter to a higher value than the VT persistence parameter since Slow VTs can (1) be asymptomatic and/or (2) terminate spontaneously.

The Slow VT persistence can never be programmed shorter than the VT persistence.

As soon as either the VT and/or the Slow VT persistence is reached (i.e. as soon as the VT or Slow VT is confirmed), therapy is initiated. The actual therapy (ATP and/or shock therapy) will be initiated depending on the following situations:

1. The VT persistence and Slow VT persistence parameters are set to the same value.

Upon reaching persistence the device calculates the "VT rate" by averaging the last 4 ventricular cycles:

- If the averaged rate is in the VT zone, the device initiates the first therapy programmed in the VT zone (most of the time ATP is programmed prior to shock) and the episode is labeled "VT".
- If the averaged rate is in the Slow VT zone the device initiates the first therapy programmed in the Slow VT zone (usually ATP) or do not apply any therapy if the Slow VT zone is set monitoring zone only. The episode is labeled "Slow VT".
- The Slow VT persistence parameter is programmed higher than the VT persistence parameter.

Upon reaching VT persistence the device calculates the "VT rate" by averaging the last 4 ventricular cycles (with a cycle length shorter than the Tachy Detection Interval):

- If the averaged rate is in the VT zone, the device initiates the first therapy programmed in the VT zone (most of the time ATP is programmed prior to shock) and the episode is labeled "VT".
- If the averaged rate is in the Slow VT zone the device continues (a) incrementing the Slow VT persistence and (b) averaging the ventricular rate. Upon reaching Slow VT persistence the device applies the first therapy programmed in the Slow VT zone (usually ATP). The episode is labeled "Slow VT". No therapy will be applied if the Slow VT zone is programmed as "monitoring zone" and as long as the averaged rate remains in the Slow VT zone.



If the ventricular rate increases to the VT zone before reaching Slow VT persistence, the device will
immediately initiate the first therapy programmed in the VT zone (the VT rhythm has already been
confirmed by the VT persistence).

If during the VT/Slow VT persistence counting process, the tachycardia majority changes into a "No majority", the VT/Slow VT persistence counters are frozen (for as long as there is "No majority").

If during the VT/Slow VT persistence counting process, PARAD or PARAD+ indicates the rhythm to be an SVT/ST or Slow Rhythm, the VT/Slow VT persistence counters will be reset.

What happens when PARAD/PARAD+ indicates that the Tachy Majority is "SVT/ST"?

On the first ventricular cycle whereby (1) the device has reached a tachycardia majority and (2) PARAD or PARAD+ discrimination indicates the rhythm to be "SVT/ST", the device sets the "SVT/ST persistence" counter to 1. For each subsequent ventricular cycle for which PARAD or PARAD+ continues to indicate the tachycardia rhythm to be "SVT/ST", the SVT/ST persistence counter" is incremented by 1.

As soon as the SVT/ST persistence counter reaches a value equal to the "VT persistence parameter", the system confirms the rhythm to be a SVT/ST. Consequently no therapy will be delivered.

Please note that there is not a separate programmable parameter called "SVT/ST persistence" this implies that the persistence required for SVT/ST equals the persistence required for VT (12 cycles as-shipped).

If the device obtains a VF majority, a VT majority or a SR (Slow Rhythm) majority while confirming SVT/ST, the SVT/ST persistence counter is reset to zero.

POST-THERAPY DETECTION

After therapy, **persistence counters are not reset.** After inefficient therapy the device needs to treat the rhythm as quickly as possible. Therefore the only requirement for a new therapy to be delivered is confirmation of majority (as explained hereafter).

After each therapy the device analyses the 'post therapy majority': it analyses the 6 to 8 cycles following therapy:

 If after the therapy 6 cycles (out of the last 8) are slow, the "post therapy majority" is considered to be Slow Rhythm majority. Therefore no additional therapy will be applied.



- If the majority (and persistence) was "VF" before therapy and:
 - the majority after therapy is still VF, the device will apply the next shock.
 - the majority after therapy is "VT" (see the PARAD+ Tech Corner article), the device will apply shock therapy as programmed in the VT zone with an energy level equal to or higher than the previous shock energy level. Therefore it is recommended to always program at least one maximum energy shock in the VT zone. This allows the device to provide therapy to a life threatening tachyarrhythmia when the ventricular rate decreases from a rate in the VF zone to a rate within the VT zone. Please note that the device will never apply a shock with lower energy than the previous energy during the same tachyarrhythmia.
 - If the majority after the therapy is SVT/ST (see the PARAD+ Tech Corner article), the device will
 not apply any therapy for as long as the majority is SVT/ST.
- If the majority (and persistence) was "VT" before therapy and:
 - the majority after the therapy is "VT" the device will apply the next therapy programmed in the VT zone (or Slow VT) zone.
 - the majority after the therapy is "VF" the device will increment the VF persistence and upon reaching VF persistence:
 - apply the first ATP of the fast VT zone if the rhythm is detected as fast VT and if no shock was delivered nor in progress in the VT zone
 - or apply a shock of the fast VT zone if the rhythm is detected as fast VT and if a shock was already delivered or in progress in the VT zone. In this case the shock energy delivered in the fast VT zone is equal or greater to the previous shock
 - ✓ or the first shock programmed in the VF zone with an energy level equal to or higher than the
 previous shock.
 - the majority after the (shock) therapy is "SVT/ST (see the PARAD/PARAD+ Tech Corner article) the device will not apply any therapy for as long as the majority is "SVT/ST".

Refer to the PARAD/PARAD+ Tech Corner article for detailed information on how PARAD and PARAD+ operate in the VT/Slow VT zones to discriminate VTs from other rhythms.

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

