ICD Programming and Shock Reduction

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Learning Objectives

- List 2 possible reasons for inappropriate ICD shocks
- Verbalize the MADIT RIT programming strategies
- Identify programming options used to decrease inappropriate shocks

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What is an Inappropriate Shock?

An **inappropriate ICD shock** is one that is not precipitated by accurate detection of a malignant ventricular arrhythmia, ventricular tachycardia (VT), or ventricular fibrillation (VF).

... **Inappropriate ICD shocks** can be mostly attributed to atrial fibrillation, supraventricular tachycardia, abnormal sensing (i.e., T-Wave double counting) and noise.

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What is an Inappropriate Shock?

Other causes for inappropriate shocks could also be attributed to other SVTs such as Atrial flutter with fast conduction, under-sensing of P waves or double counting of R waves, and an artifact from lead fractures or electromagnetic interference (EMI).

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Inappropriate Shocks

What is the impact on Patients?

…" there is evidence that ICD shocks can lead to myocardial dysfunction[7] and heart failure progression.[8] ICD shocks have been associated with increased mortality.[9] The psychological effect of ICD shocks on patients can be significant, even when such therapy is appropriate.[10]."

Quoted from Delaughter, MC. Review of Reduction in Inappropriate Therapy and Mortality with ICD Programming (MADIT-RIT), Feb 15, 2013. Accessed Mar 14, 2024, https://www.acc.org/latest-in-cardiology/articles/2014/07/18/17/42/review-of-reduction-in-inappropriate-therapy-and-mortality-with-icd-programming
7. Xie J, Weil MH, Sun S, et al. High-energy defibrillation increases the severity of post resuscitation myocardial dysfunction. Circulation 1997; 96:683-8.
8. Tereshchenko LG, Faddis MN, Fetics BJ et al. Transient local injury current in right ventricular electrogram after implantable cardioverter-defibrillator shock predicts heart failure progression. J Am Coll Cardiol 2009;54:822-8.
9. Poole JE, Johnson GW, Hellkamp AS et al. Prognostic importance of defibrillator shocks in patients with heart failure. N Engl J Med 2008; 359:1009-17.
10. Sears SF and Conti JB. Quality of life and psychological functioning of ICD patients. Heart 2002; 87:488-93.

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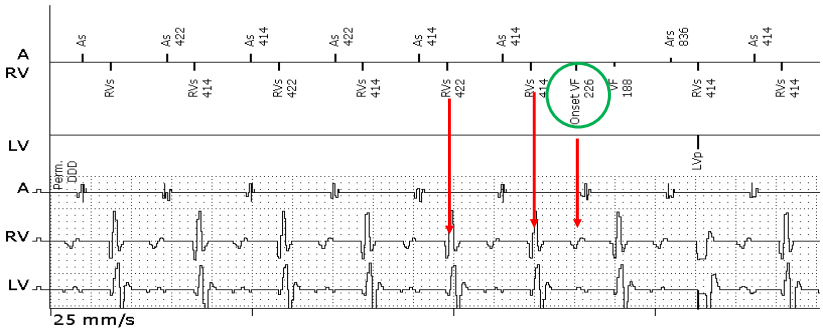
Inappropriate Shocks

Over-sensing:

How to Identify over-sensing:

- Use the marker channels
- Line up V-markers
- Measure interval between V event and over-sensed event
  - Example 226 ms



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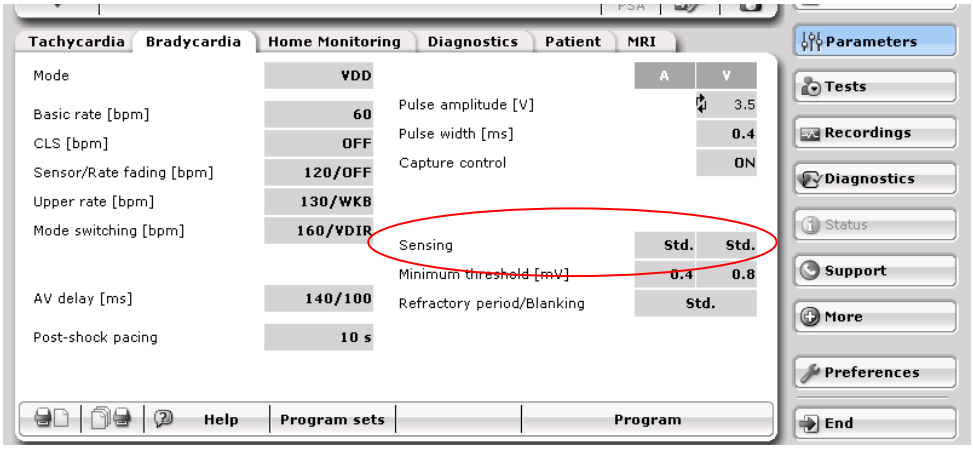
Programming ASC Options



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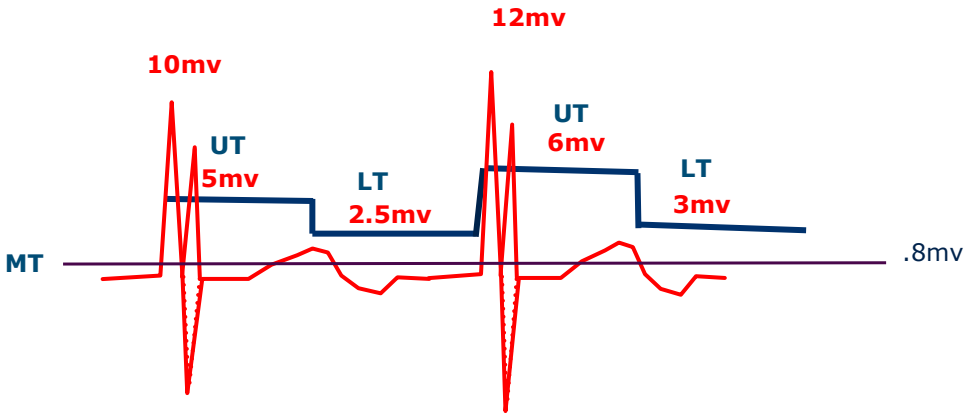
Automatic Sensing Control (ASC)

Beat-to-beat Sensitivity



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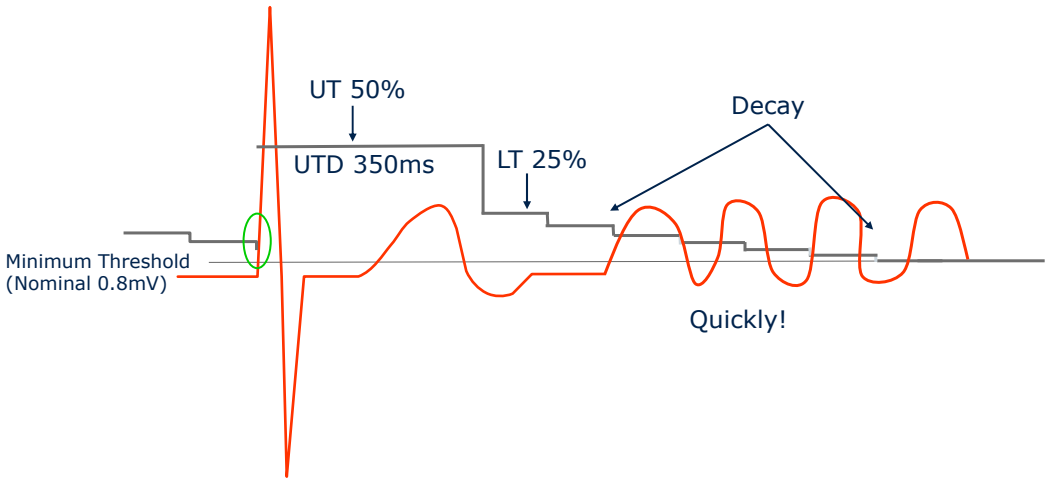
The First Beat of VT/VF



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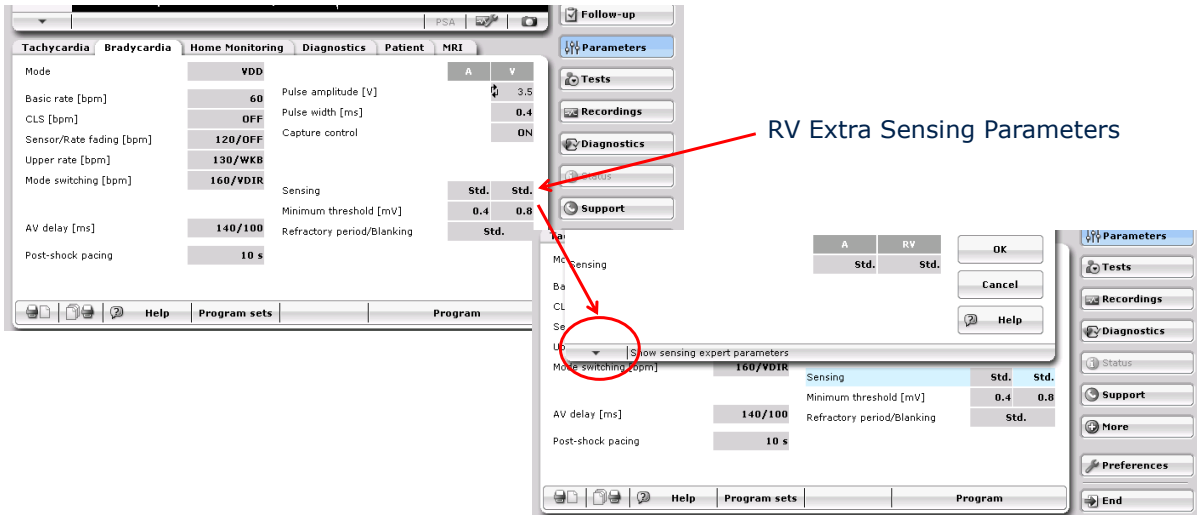
Programming ASC Options



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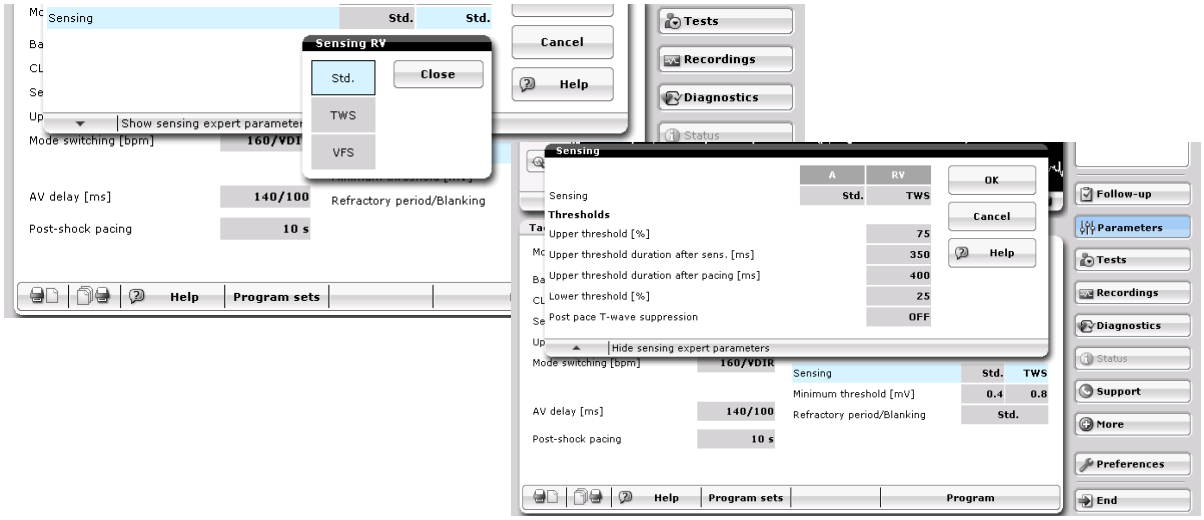
Programming ASC Options



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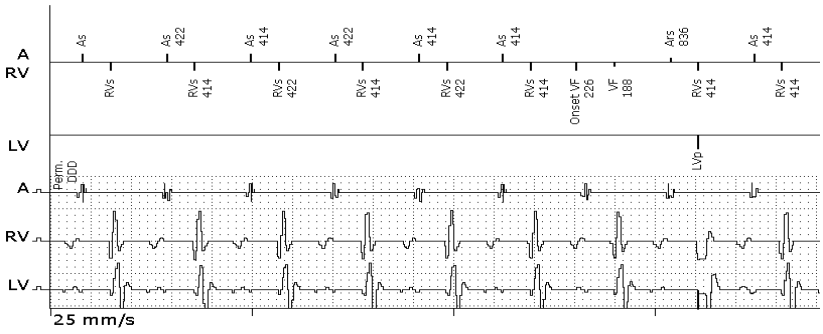
Inappropriate Shocks

Over-sensing:

How to Identify Long-T over-sensing:

- Measure interval between R and T events
- If measurement is greater than 350 ms go back to STD and increase UTD



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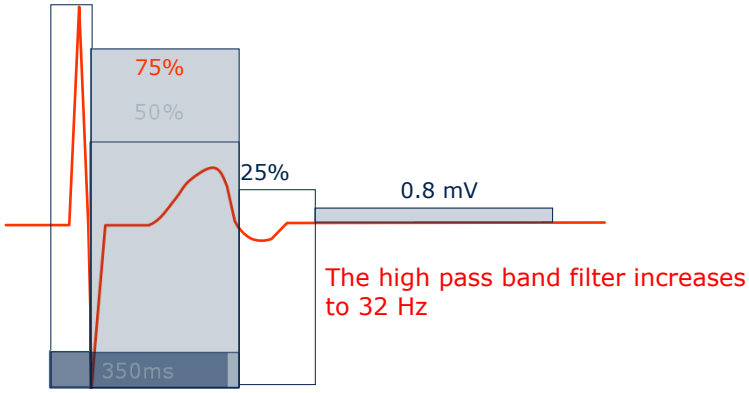
ASC - Think In Segments!

TWS:

Increases the UT from 50% to 75%

Increases the High Pass band filter to 32 Hz



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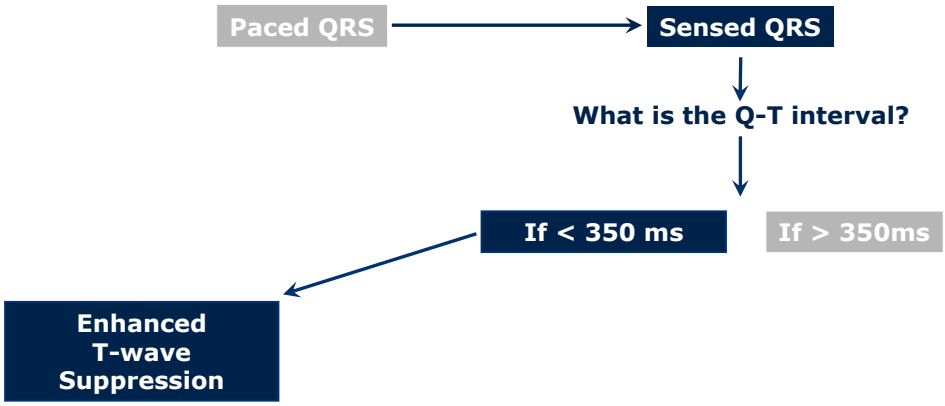
T-wave Over-sensing Decision Tree

Is the over-sensing associated with a V sense event?



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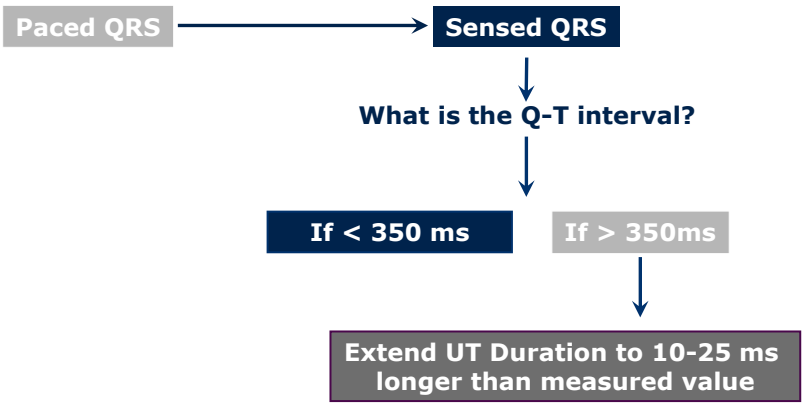
T-wave Over-sensing Decision Tree

Is the over-sensing associated with a V sense event?



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Inappropriate Shock

SVT's Discriminators

1. **Ventricular-Only detection (SMART® = OFF)**
   - "Standard" detection
   - Based on rate
   - Detection enhancements (Stability and Onset)
2. **MorphMatch**
3. **SMART® Detection**
   - AV Discrimination algorithm based on SMART® decision tree

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SMART® Detection

Appropriately delivers therapy for (Sensitivity)

- Ventricular tachycardia
- Ventricular tachycardia that develops during atrial fibrillation or atrial flutter (concurrent arrhythmias)

Appropriately inhibits therapy for (Specificity)

- Atrial flutter
- Atrial fibrillation
- Exercise induced sinus tachycardia

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SMART® Detection

Designed to:

- Increase Specificity of SVT descrimination
- Correct classification of SVTs
- Maintain Sensitivity of VT detection

  (*ability to identify and treat all ventricular arrhythmias)

SMART® Detection is

- Specificity = 94%[1]
- Sensitivity = 100%[1]

*Source: Sinha, et al. J Cardiovasc Electrophys, 15: 646-652, 2004.

1. BIOTRONIK, data on file

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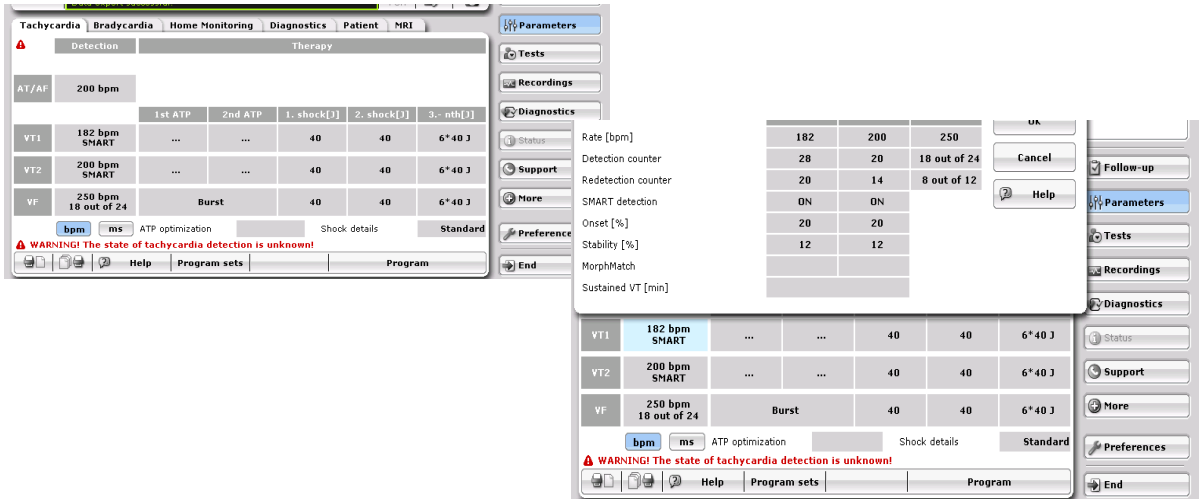
SVT Discriminators SMART



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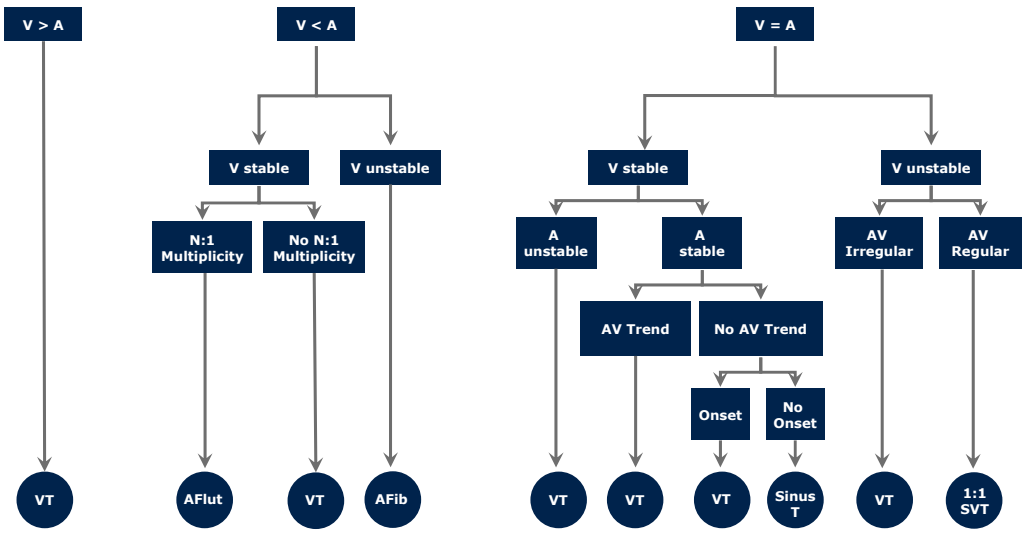
SMART® Detection



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SMART® Detection

SMART® asks three questions:

1. What are the V & A rates?
2. Are the Atrium and Ventricle stable?
3. What is the relationship of A to V?

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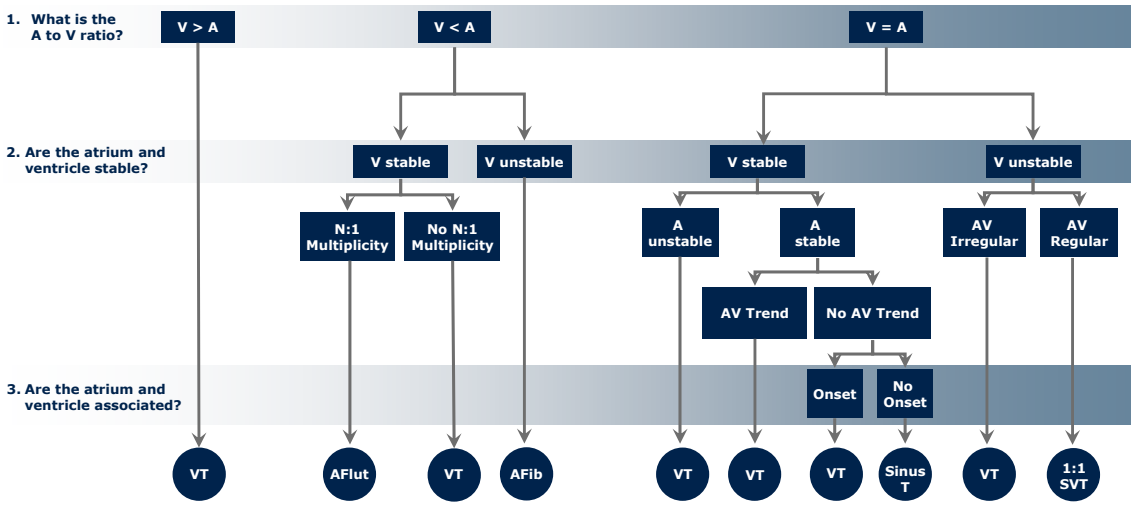
SMART® Detection



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SMART® Detection

SMART® Detection Counter

Up/down counter based on interval length and SMART® Detection decision criteria

- +1 for interval in VT zone and meets SMART® detection criteria
- - 1/4 for ST or 1:1 interval in the VT zone
- - 4 for Afib interval in the VT zone
- - 1 for Aflutter interval in the VT zone
- -1 for Sinus interval
- The VT zone count freezes when a VF interval is binned

Why? SMART® is not active in the VF zone!

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Inappropriate Shock

SVT's Discriminators

1. Ventricular-Only detection (SMART® = OFF)
   - "Standard" detection
   - Based on rate
   - Detection enhancements (Stability and Onset)

2. SMART® Detection
   - AV Discrimination algorithm based on SMART® decision tree

3. MorphMatch

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Inappropriate Shock

SVT Discriminator – MorphMatch *(note: SMART is OFF)*

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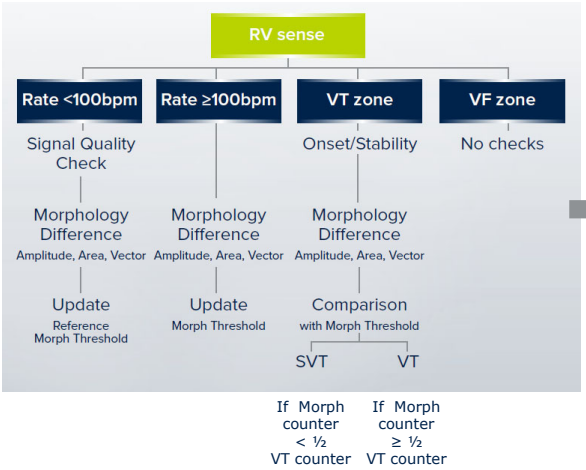
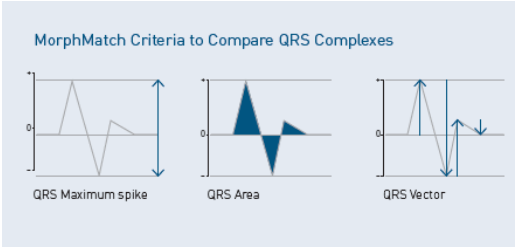
MorphMatch – Additional Enhancement

Discriminates SVT based on QRS morphology analysis





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Inappropriate Shocks

Despite sophisticated device-detection algorithms, 8-40% of ICD therapies are inappropriate with adverse side effects.[1]

Analysis of the MADIT II trial data revealed that 11.5% of the ICD patients received inappropriate ICD shocks and that 31.2% of all ICD shocks were deemed inappropriate.

Today, we have clinical data to guide ICD programming…

1. Daubert JP, Zareba W, Cannom DS, et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. J Am Coll Cardiol 2008;51:1357-1365

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Programming Recommendations Reducing Unnecessary Shocks

MADIT-RIT [1]

Question: can ICD devices be reprogrammed to reduce inappropriate therapies?

The MADIT RIT study has showed that high-rate shock box programming or delayed therapy programming reduced the risk of inappropriate therapy by 76-79%, and reduced mortality risk by 44-55%.

PREPARE [2]

Strategically chosen VT/VF detection and therapy options targeting primary prevention patients can safely reduce the morbidity related to ICD therapy

- 62% reduction in Morbidity Index.
- 63% reduction in shocked episodes.

1. Large majority of ICD implants are for primary prevention.
2. Most ICD patients receive too many shocks.
3. Using strategic PREPARE programming to treat sustained and fast tachycardias with ATP before shocks should safely reduce ICD morbidity.

1. Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283
2. B.L. Wilkoff, R. Stern, B. Williamson, et al., Design of the Primary Prevention Parameters Evaluation (PREPARE) trial of implantable cardioverter defibrillators to reduce patient morbidity, J am Coll Cardiol 2008;52:541-50

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Programming Recommendations Reducing Unnecessary Shocks

MADIT-RIT[1]

High-rate cutoff >200 bpm or duration delay

PREPARE[2]

- Longer Detection Durations
- ATP for FVT's 330-240 ms *(181-250 bpm)*
- Maximum output for all VF therapy and FVT
- Tachycardia detection at 330 ms
- VT Monitor zone for slow VTs
- Longer detection duration

1. Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283
2. B.L. Wilkoff, R. Stern, B. Williamson, et al., Design of the Primary Prevention Parameters Evaluation (PREPARE) trial of implantable cardioverter defibrillators to reduce patient morbidity, J am Coll Cardiol 2008;52:541-50

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MADIT RIT Programming in Iperia and Newer ICDs

The MADIT RIT study has showed that **high rate shock box programming or delayed therapy programming reduced the risk of inappropriate therapy by 76-79%, and reduced mortality risk by 44-55%.** Your customer may have questions about how BIOTRONIK devices can be programmed to reduce unnecessary therapy.[1]

On the next two slides are two scenarios for programming the BIOTRONIK ICD to function similarly to the MADIT RIT recommendations.

1 Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283

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One Therapy Zone Arm

	VF Zone	VT1 Zone
Rate	200 bpm	171 bpm
Counter	18 out of 24	Detection Count: 26 Redetection count: 20
Detection	X out of Y	Smart Detection®
Therapy	ATP One-shot + Shock	Monitor Zone

1 Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283

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Three Therapy Zone Arm (Delayed)

	VF Zone	VT2 Zone	VT1 Zone
Rate	250 bpm	200 bpm	171 bpm
Counter	18 out of 24	Detection Count: 40 Redetection count: 20	Detection Count: 100 Redetection count: 22
Detection	X out of Y	Smart Detection®	Smart Detection®
Therapy	ATP One-shot + Shock	ATP + Shock	ATP + Shock

1 Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283

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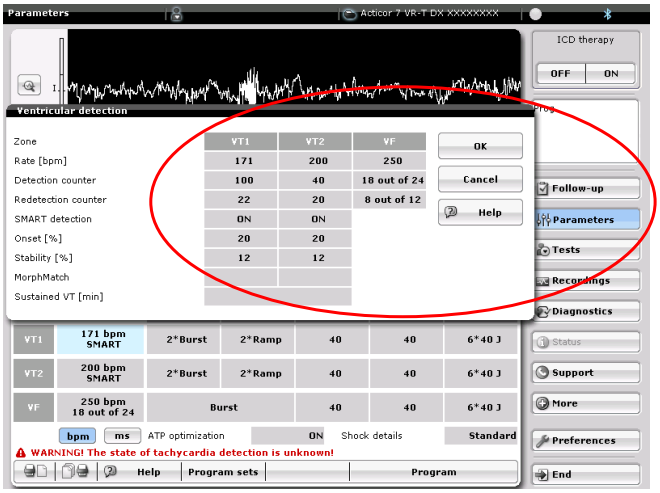
Programming Recommendations Reducing Unnecessary Shocks

MADIT RIT programming for BIOTRONIK ICDs

- Rate Zone cut-offs
- Detection counter
- SMART On



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PainFree Rx II Study

Purpose

In implantable cardioverter-defibrillator (ICD) patients, anti-tachycardia pacing (ATP) can terminate ventricular tachycardia (VT) up to 250 bpm without the need for painful shock therapy. However, fast VT (FVT) is mostly treated with shocks due to safety concerns. This *prospective, multicenter, randomized* trial compares the safety and efficacy of empirical ATP to treatment with shock therapy.

Methods

To assess safety, the primary objective was to determine if FVT episodes initially treated with ATP lasted no greater than 6 seconds longer than those treated by shocks. This study randomized 634 patients in 2 treatment arms (standardized empirical ATP or shock therapy) spanning 42 U.S. centers. The devices were programmed as follows, where Burst ATP is programmed with S1= 8 and R-S1= 88%:

Wathen M et al. Circulation. 2004, 110(17).

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PainFree Rx II Study-Programming

Therapy Zone	Detection Rate	Detection Count	Therapy
VT	167 bpm	20	3* Burst, DFT+10 J shock, max shocks
FVT (or VT2)	188 bpm	18	ATP arm: 1*Burst, DFT+10 J shock, max. shocks Shock arm: DFT+10 J shock, max. shocks
VF	250 bpm	18 out of 24	DFT +10J, max shocks

Findings:
ATP was effective in 229 of 284 episodes in the ATP arm (72% adjusted). Acceleration, episode duration, syncope, and sudden death were similar between the treatment arms. The median fast VT episode duration was 10 seconds in the ATP arm and 9.7 seconds in the shock arm, satisfying the primary objective of this trial. The results suggest empirical ATP for fast VT is effective, equally safe and improves quality of life compared to shock therapy. Note: The PainFree Rx II Study included no BIOTRONIK devices.

Wathen M et al. Circulation. 2004, 110(17).

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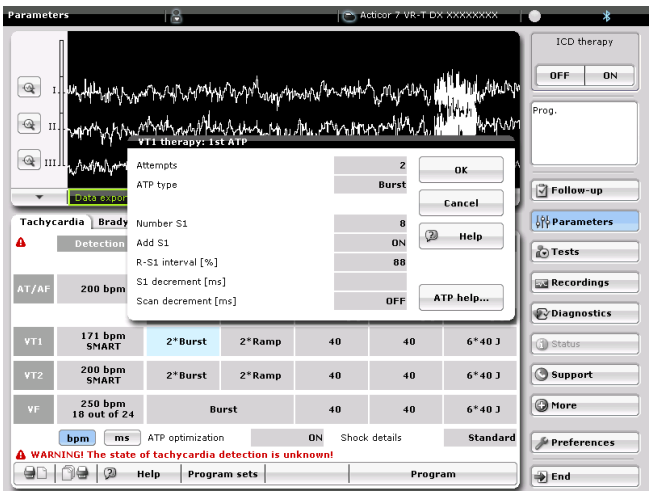
Programming Recommendations PainFree Rx II Study

ATP was effective in 229 of 284 Episodes (72% adjusted)



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Summary

Common reasons for inappropriate shocks:

- SVT's
- Device over-sensing
- EMI

Programming to reduce shocks

- Increase rate zone cut-offs
- Increase detection counts
- Detection Enhancements (SMART and MorphMatch)

MADIT RIT Programming reduces mortality 44-55%[1]

PainFree RX II ATP was effective in 229 of 284 episodes in ATP arm (72% adjusted)[2]

1 Reduction in Inappropriate Therapy and Mortality through ICD Programming. N Engl J Med 2012; 367:2275-2283.
2 Wathen M et al. Circulation. 2004, 110(17).

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ICD Programming and Shock Reduction

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