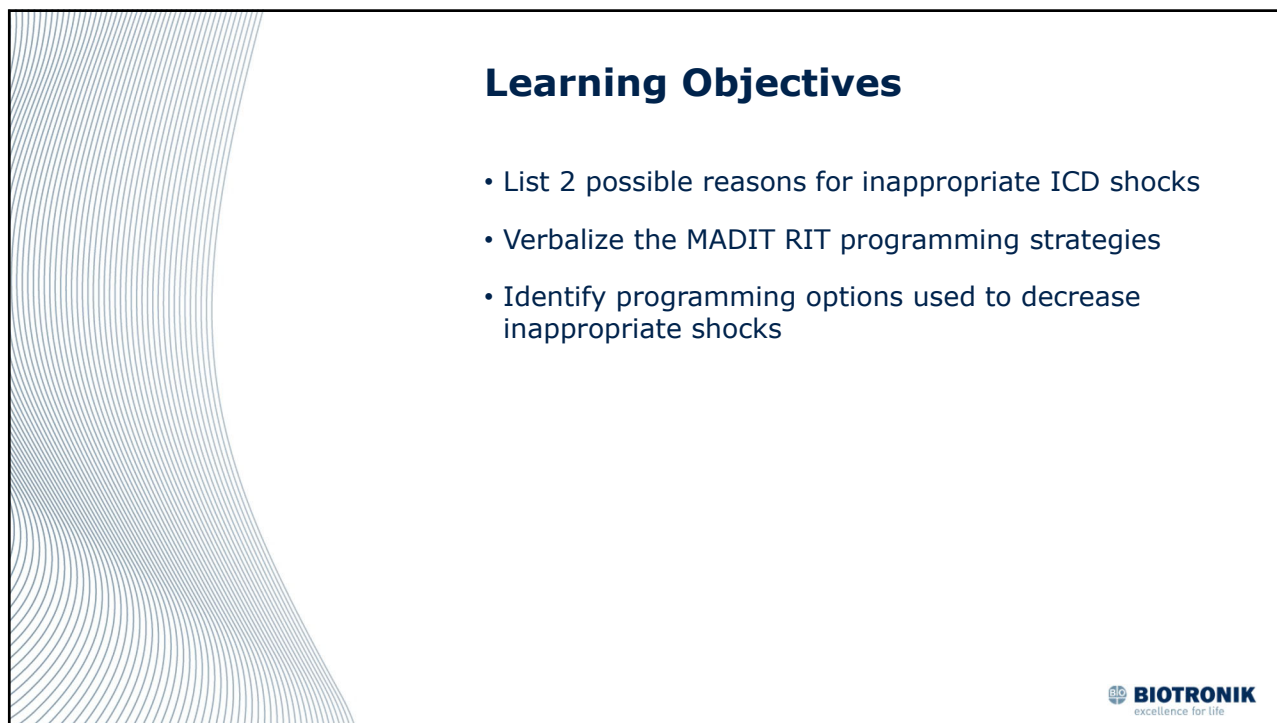


1



2

## 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.

## 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).

## Inappropriate Shocks

What is the impact on Patients?

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

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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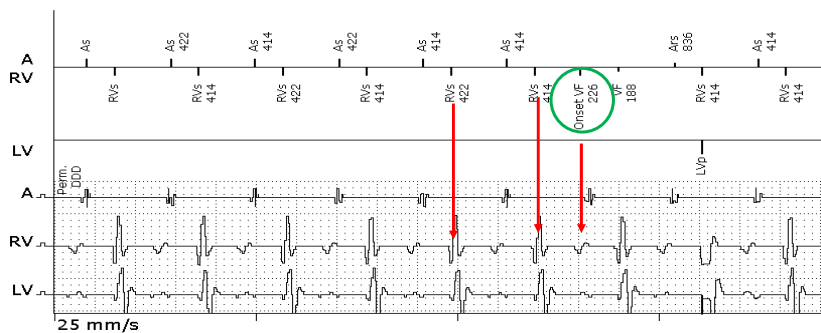
5

## 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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6

## Programming ASC Options

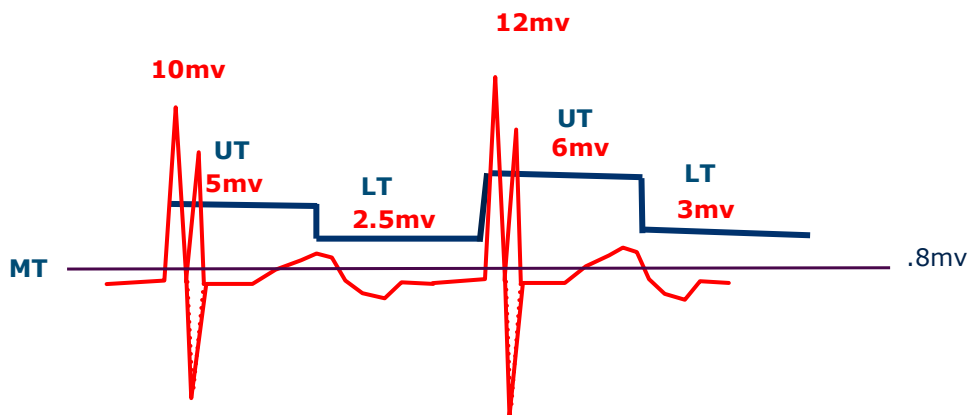
Parameter	Value	Unit
Mode	VDD	
Basic rate [bpm]	60	
CLS [bpm]	OFF	
Sensor/Rate fading [bpm]	120/OFF	
Upper rate [bpm]	130/WKB	
Mode switching [bpm]	160/VDIR	
AV delay [ms]	140/100	
Post-shock pacing	10 s	
Pulse amplitude [V]	3.5	
Pulse width [ms]	0.4	
Capture control	ON	
Sensing	Std.	Std.
Minimum threshold [mV]	0.4	0.8
Refractory period/Blanking	Std.	

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7

## Automatic Sensing Control (ASC)

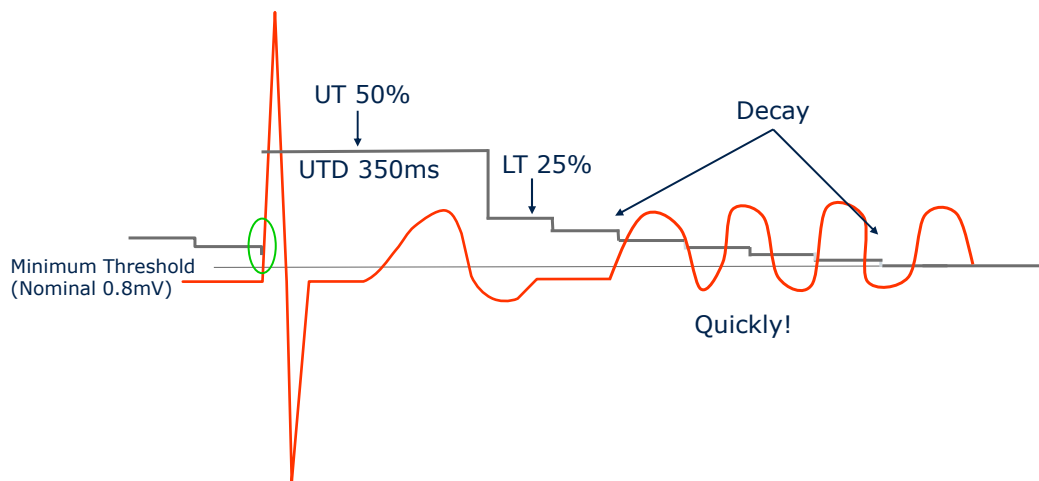
Beat-to-beat Sensitivity



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8

## The First Beat of VT/VF



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9

## Programming ASC Options

The screenshot shows a programming interface with several tabs: Tachycardia, Bradycardia, Home Monitoring, Diagnostics, Patient, and MRI. The 'Diagnostics' tab is active. A red arrow points from the text 'RV Extra Sensing Parameters' to a sub-window titled 'Show sensing expert parameters'. This sub-window has a 'Mode switching [bpm]' dropdown set to '160/VDIR'. Below it, 'AV delay [ms]' is set to '140/100' and 'Post-shock pacing' is set to '10 s'. The 'Sensing' section shows 'Minimum threshold [mV]' with 'Std.' values of '0.4' and '0.8', and 'Refractory period/Blanking' with a 'Std.' value. The BIOTRONIK logo is in the bottom right corner.

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10

## Programming ASC Options

The screenshot displays the Biotronik programming software interface. The main window shows 'Sensing' parameters for 'Mc', 'Ba', 'CL', and 'Se'. A 'Sensing RY' dialog box is open, showing 'Std.' and 'Close' buttons. Another 'Sensing' dialog box is open, showing 'A' and 'RV' tabs, 'Std.' and 'TWS' buttons, and a 'Help' button. The 'Sensing' dialog box contains the following parameters:

Parameter	Value
Upper threshold [%]	75
Mc Upper threshold duration after sens. [ms]	350
Ba Upper threshold duration after pacing [ms]	400
CL Lower threshold [%]	25
Se Post pace T-wave suppression	OFF
Mode switching [bpm]	160/VDIR
Minimum threshold [mV]	0.4 0.8
Refractory period/Blanking	Std.

The bottom of the interface shows a 'Program' button and a 'Program sets' menu.

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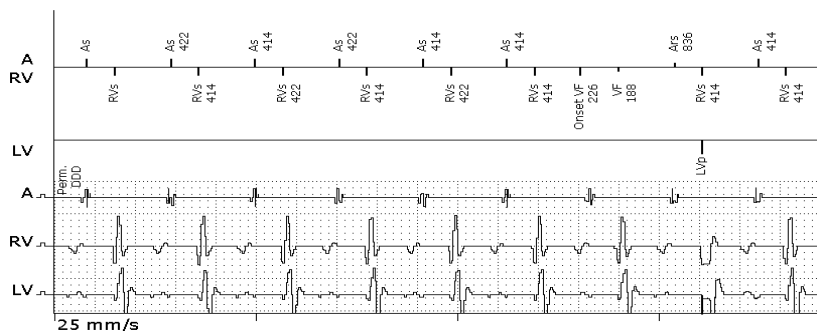
11

## 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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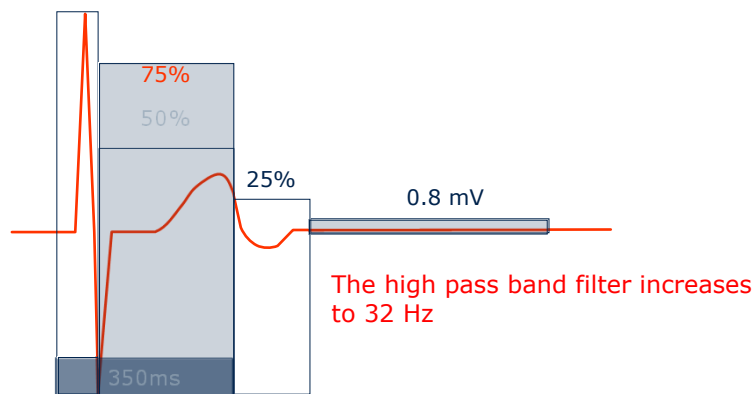
12

## ASC - Think In Segments!

TWS:

Increases the UT from 50% to 75%

Increases the High Pass band filter to 32 Hz



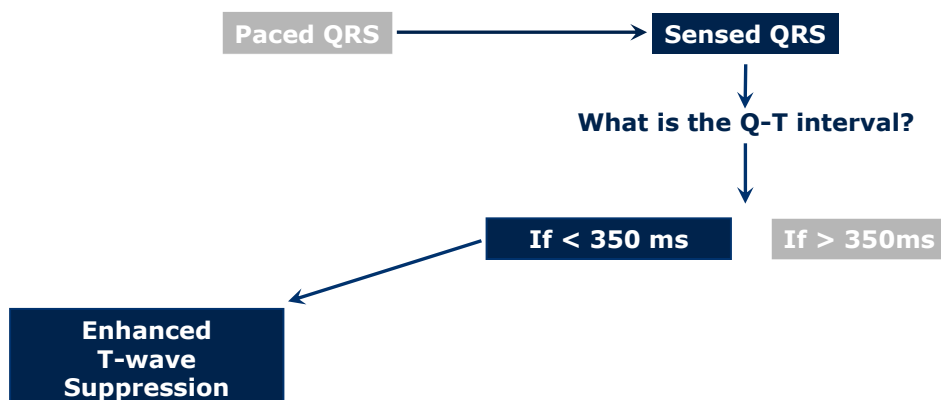
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## T-wave Over-sensing Decision Tree

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



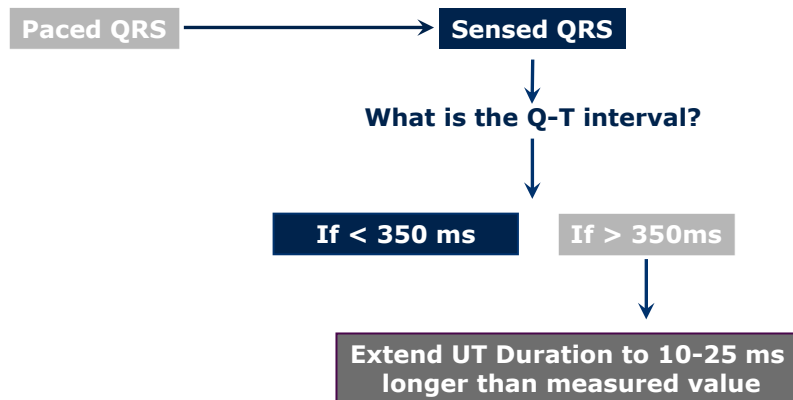
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## T-wave Over-sensing Decision Tree

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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17

## SMART® Detection

### Designed to:

- Increase Specificity of SVT discrimination
- Correct classification of SVTs
- Maintain Sensitivity of VT detection  
(\*ability to identify and treat all ventricular arrhythmias)

### SMART® Detection is

- Specificity = 94%<sup>1</sup>
- Sensitivity = 100%<sup>1</sup>

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

1. BIOTRONIK, data on file

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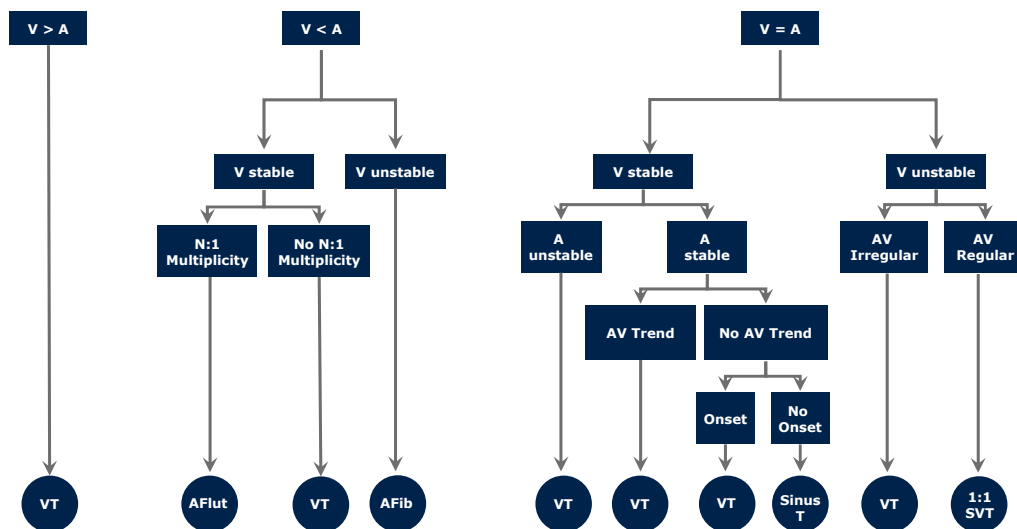
18

# SVT Discriminators SMART

The screenshot displays the 'SVT Discriminators SMART' configuration screen. It features a main table with columns for 'AT/AF', 'Rate (bpm)', '1st ATP', '2nd ATP', '1. shock[J]', '2. shock[J]', and '3.-nth[J]'. The table lists three detection modes: VT1 (182 bpm SMART), VT2 (200 bpm SMART), and VF (250 bpm, 18 out of 24). A 'Warnings' section at the bottom indicates 'WARNING! The state of tachycardia detection is unknown!'. A 'Parameters' sidebar on the right lists various settings like 'Rate [bpm]', 'Detection counter', and 'SMART detection'. A 'Warnings' dialog box is also visible, showing a table with columns for 'Rate (bpm)', 'Detection counter', 'Redetection counter', 'SMART detection', 'Onset [%]', 'Stability [%]', 'MorphMatch', and 'Sustained VT [min]'. The dialog shows values for 182, 200, and 250 bpm, with '18 out of 24' and '8 out of 12' for detection counters.

19

# SMART® Detection



20

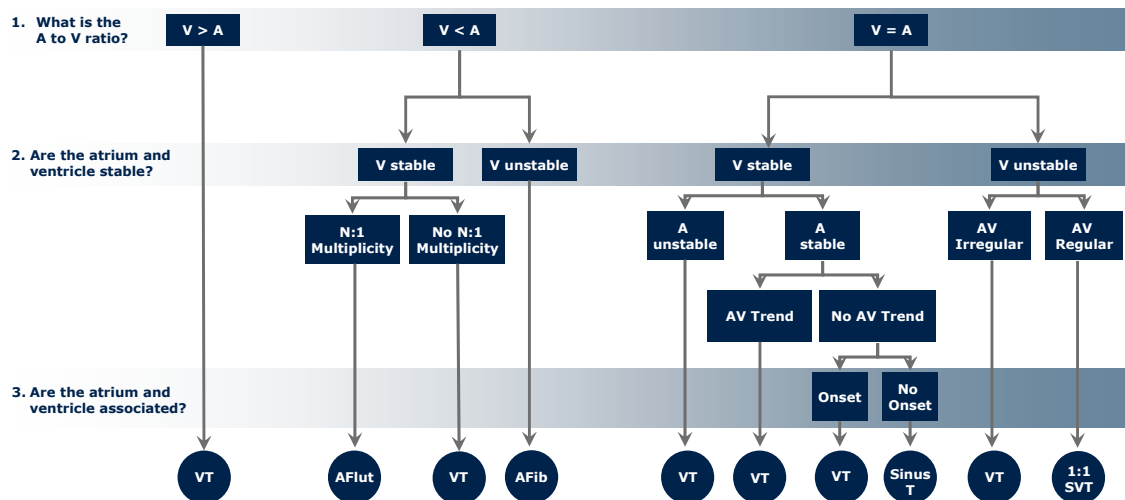
## SMART® Detection

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?

21

## SMART® Detection



22

## 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)

Zone	VT1	VT2	VF
Rate [bpm]	182	200	231
Detection counter	28	20	18 out of 24
Redetection counter	20	14	8 out of 12
SMART detection	OFF	OFF	
Onset [%]	20	20	
Stability [ms]	48	48	
MorphMatch	ON	ON	
Sustained VT [min]	OFF		

VT1	182 bpm Ons.-stab.	...	...	40	40	6*40 J
VT2	200 bpm Ons.-stab.	...	...	40	40	6*40 J
VF	231 bpm 18 out of 24	Burst	...	40	40	6*40 J

bpm    ms   ATP optimization   Shock details   Standard

**WARNING! The state of tachycardia detection is unknown!**

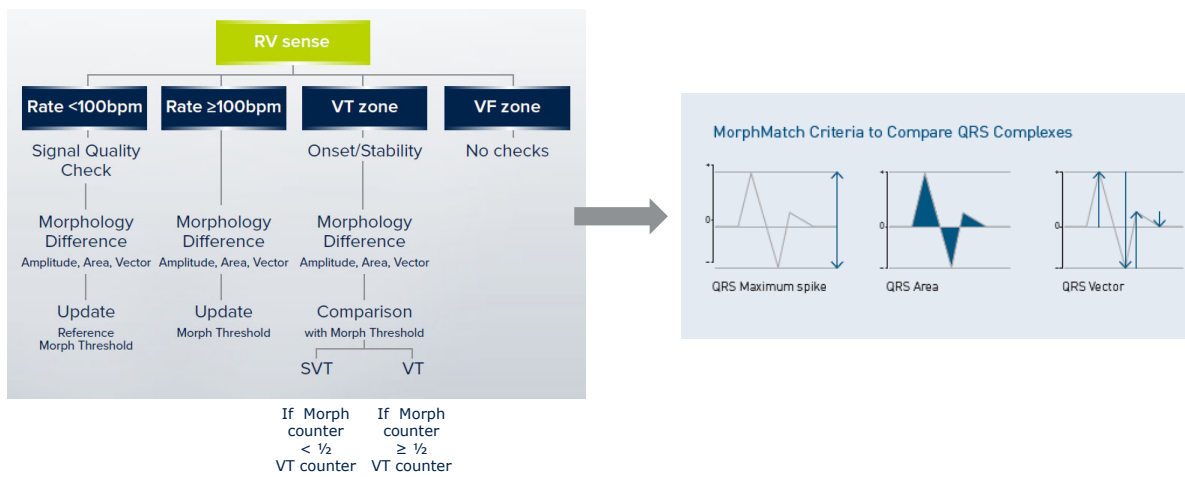
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25

## MorphMatch – Additional Enhancement

Discriminates SVT based on QRS morphology analysis



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26

## Inappropriate Shocks

Despite sophisticated device-detection algorithms, 8-40% of ICD therapies are inappropriate with adverse side effects.<sup>1</sup>

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

27

## Programming Recommendations Reducing Unnecessary Shocks

### MADIT-RIT<sup>1</sup>

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<sup>2</sup>

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

28

## Programming Recommendations Reducing Unnecessary Shocks

### MADIT-RIT<sup>1</sup>

High-rate cutoff >200 bpm or duration delay

### PREPARE<sup>2</sup>

- 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

29

## 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.<sup>1</sup>

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

30

## One Therapy Zone Arm

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

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

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31

## Three Therapy Zone Arm (Delayed)

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

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

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32



## Programming Recommendations Reducing Unnecessary Shocks

MADIT RIT programming for  
BIOTRONIK ICDs

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

The screenshot shows the 'Parameters' window for an ICD, specifically the 'Ventricular detection' section. A red circle highlights the 'Ventricular detection' window, which includes a table for rate zone cut-offs and detection counters. The table is as follows:

Zone	VT1	VT2	VF
Rate [bpm]	171	200	250
Detection counter	100	40	18 out of 24
Redetection counter	22	20	8 out of 12
SMART detection	ON	ON	
Onset [%]	20	20	
Stability [%]	12	12	
MorphMatch			
Sustained VT [min]			

Below the table, there are buttons for 'OK', 'Cancel', and 'Help'. The 'OK' button is highlighted with a red circle. The 'Parameters' button on the right sidebar is also highlighted with a red circle.

At the bottom of the window, there is a warning message: **WARNING! The state of tachycardia detection is unknown!**

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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).

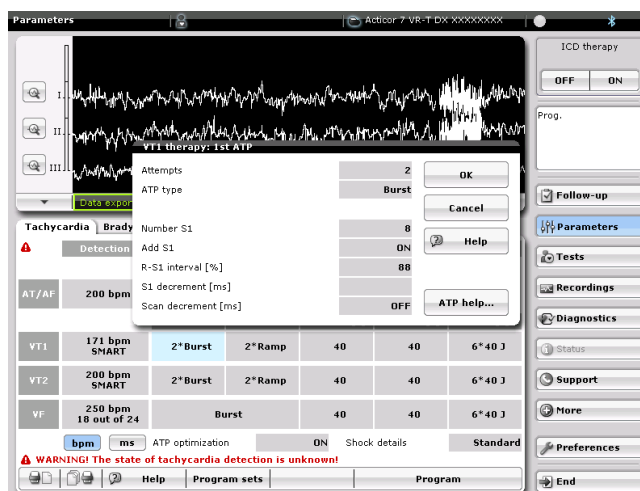
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35

## Programming Recommendations PainFree Rx II Study

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



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36

## 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%<sup>1</sup>**

**PainFree RX II ATP was effective in 229 of 284 episodes in ATP arm (72% adjusted)<sup>2</sup>**

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

37

## ICD Programming and Shock Reduction

38