

MultiSite Pacing

Technical Overview

smart solutions | **PROVEN TO LAST**

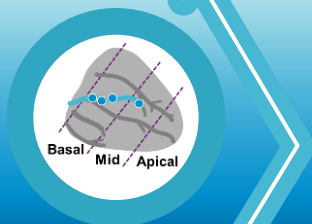
MultiSite Pacing within SmartCRT™

SmartCRT™ is Boston Scientific's approach to personalize CRT therapy by providing physicians with smart solutions to optimize **where**, **when**, and **how** to pace

Where

to pace

Site of latest
activation



ACUITY™ X4
VectorGuide

17 vectors, RV-LV delay

When

to pace

Maximize
global contractility



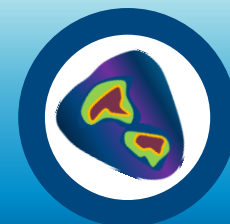
SmartDelay™

*Sensed and paced AV delay
BiV or LV-Only*

How

to pace

Options to
maximize response



MultiSite Pacing

Single Site or MultiSite pacing

Powered by

ENDURALIFE™
Battery Technology

*Labeled for up to 13.3 years¹
longevity with MultiSite Pacing ON*

1. Assumes: 2.0V RA, LV-only, 2.0V LVa, 2.0V LVb, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

□ Technology Overview

- Competitive Comparison
- Clinical Data
- Programming

- Only ~70% of CRT patients are responders¹
- Pacing from 2 LV vectors has been shown to achieve up to a 90% response rate²



Historical dual LV cathode Technology Challenges

Longevity impact (1-2 years)

Requires 2 viable vectors

Complicated to program

Boston Scientific's MultiSite Pacing (MSP) Solution

EnduraLife battery is labeled up to **13.3 years³** even with MultiSite Pacing turned ON

We have **17 pacing vectors** with **216 MultiSite pacing vector combinations**

SmartVector offers **simple, automated** programming recommendations

1. Daubert JC et al. Heart Rhythm 2012.

2. Zanon, et. All. JACC April 5, 2016. Volume 16, Issue 13.

3. Assumes: 2.0V RA, LV-only, 2.0V LVa, 2.0V LVb, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

MultiSite Pacing Technology Overview

Single site LV pacing: 2 ventricular pacing pulses, separated by an optional offset

MultiSite LV Pacing: 3 ventricular pacing pulses, separated by optional offsets

Single Site Pacing

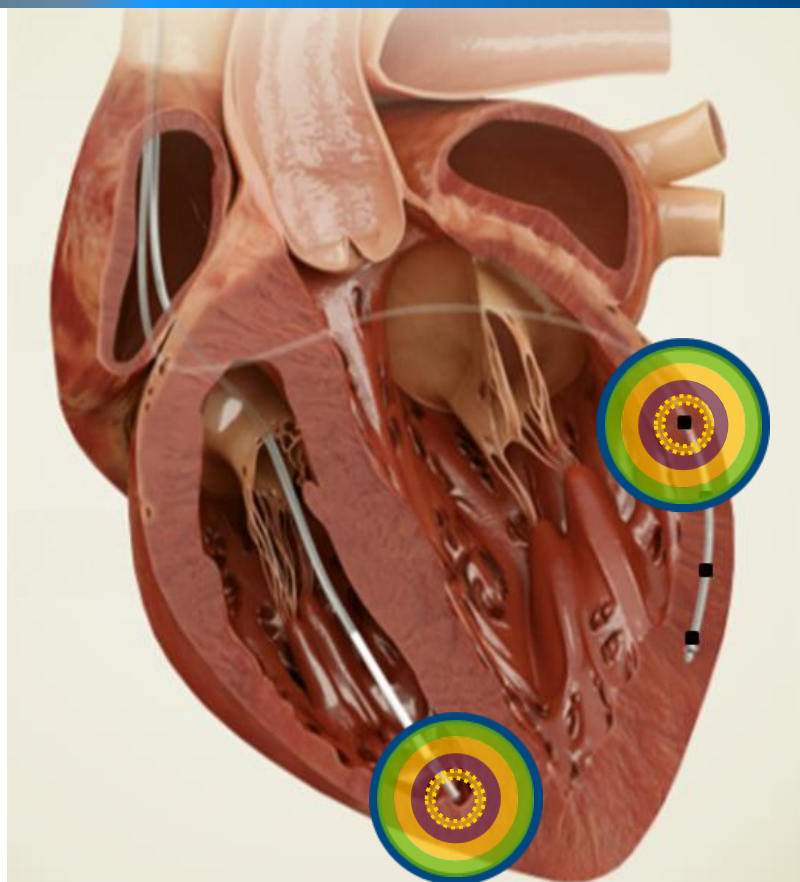
LV Pace



LV Offset



RV Pace



Example 1:
Offset = 0ms

MultiSite Pacing Technology Overview

Single site LV pacing: 2 ventricular pacing pulses, separated by an optional offset

MultiSite LV pacing: 3 ventricular pacing pulses, separated by optional offsets

Single Site Pacing

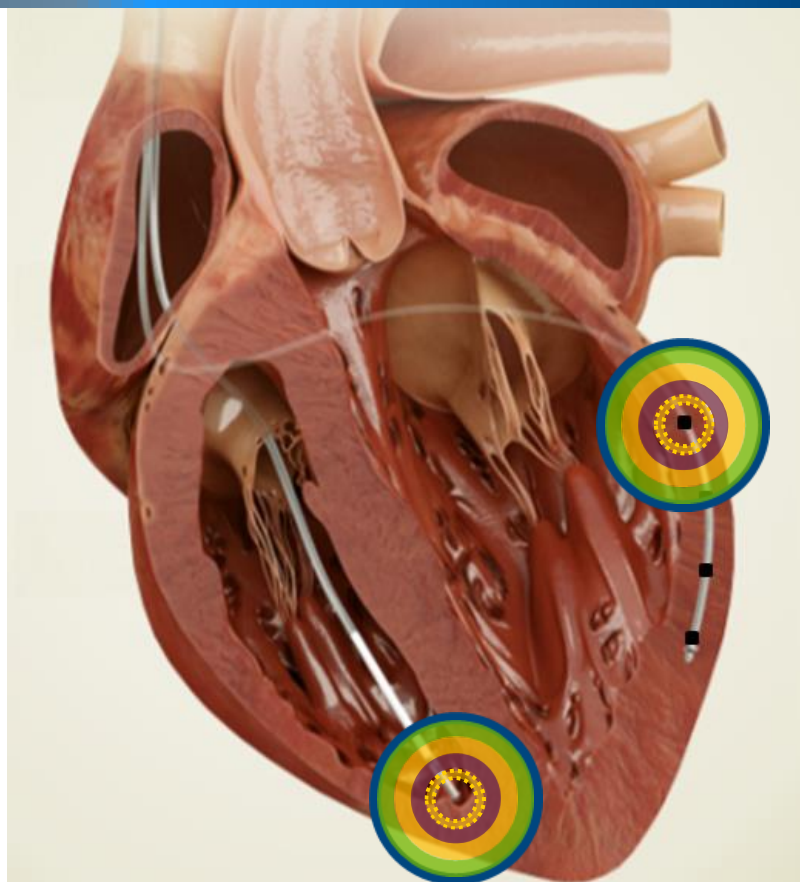
LV Pace



LV Offset



RV Pace



Example 2:
Offset = 40ms

MultiSite Pacing Technology Overview

Single site LV pacing: 2 ventricular pacing pulses, separated by an optional offset

MultiSite LV pacing: 3 ventricular pacing pulses, separated by optional offsets

MultiSite Pacing

1st LV Pace (LVa)



LVa ▶ LVb Offset



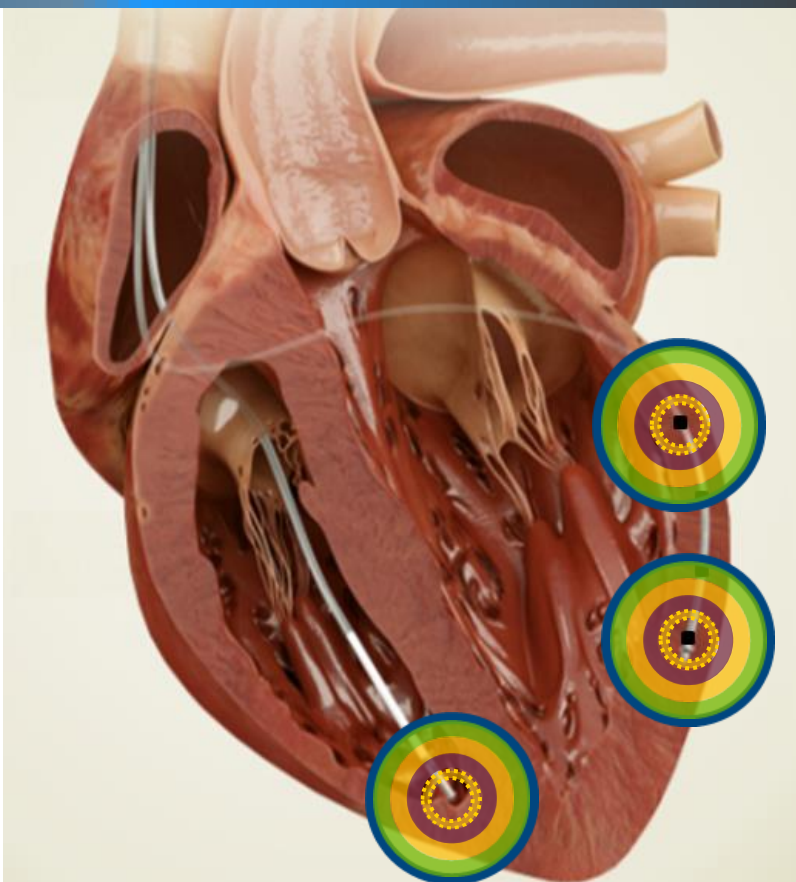
2nd LV Pace (LVb)



LVb ▶ RV Offset



RV Pace



Example 1:
No Offset
“simultaneous pacing”

MultiSite Pacing Technology Overview

Single site LV pacing: 2 ventricular pacing pulses, separated by an optional offset

MultiSite LV pacing: 3 ventricular pacing pulses, separated by optional offsets

MultiSite Pacing

1st LV Pace (LVa)



LVa ▶ LVb Offset



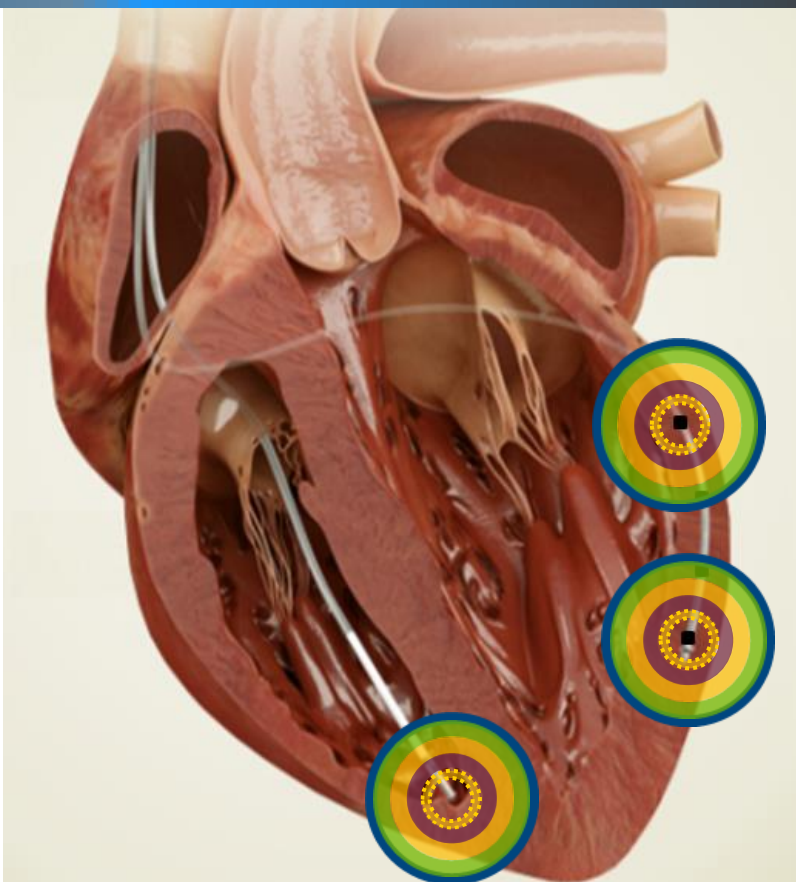
2nd LV Pace (LVb)



LVb ▶ RV Offset



RV Pace



Example 2:

10ms LVa→LVb Offset

10ms LVb→RV Offset

“sequential pacing”

- Technology Overview

Competitive Comparison

- Clinical Data
- Programming

Competitor Comparison

	Boston Scientific MultiSite Pacing	St. Jude Multipoint Pacing ¹	Medtronic Multiple Point Pacing ²	Biotronik MultiPole Pacing ³
Battery Capacity	1.8 Ah	1.4 Ah	1.0 Ah	1.6 Ah
Standard Vectors	17	10	16	12
Multisite Vectors	216	60	5	106
LVa ▶ LVb Timing Offsets	Independent Cathodes 0-100ms	Independent Cathodes 5-80ms offsets	Tied Cathodes No offsets	Independent Cathodes 0-50ms
Automatic Programming Recommendation	Yes SmartVector algorithm automatically recommends settings	Yes Options for choosing based on RV-LV or widest spacing	None	None
Pacing Configurations	Bi-V LV-only	Bi-V	Bi-V LV-only	Bi-V

Boston Scientific will offer the most options for vectors and offsets
EnduraLife battery allows you to optimize the patient, not the battery

¹ CE Mark and FDA approved. Information for Quadra Assura MP excerpted from the U.S. technical manual published by St. Jude Medical.

² CE Mark. Not FDA approved. Information for Claria excerpted from the EU technical manual published by Medtronic. Information based on available knowledge and could change.

³ CE mark. Not FDA approved. Information for Intica 5/7 excerpted from the EU technical manual published by Biotronik. Information based on available knowledge and could change.

We've addressed three main barriers to dual LV cathode pacing:

1 Longevity	2 Flexibility	3 Automatic Recommendations
Our EnduraLife battery supports up to 13.3 years¹ projected longevity even with MultiSite pacing turned ON	We have 17 pacing vectors with 216 MultiSite pacing configurations	Our SmartVector algorithm provides simple recommendations with the click of a button, in < 5 seconds

1. Assumes: 2.0V RA, LV-only, 2.0V LVa, 2.0V LVb, 700Ω, No LATITUDE, No Respiratory Rate Sensor, No Heart Failure Sensor Suite.

- Technology Overview
- Competitive Comparison

☐ **Clinical Data**

- Programming

Patients who received electrical delay optimization plus dual LV cathode pacing achieved **90% response rate**

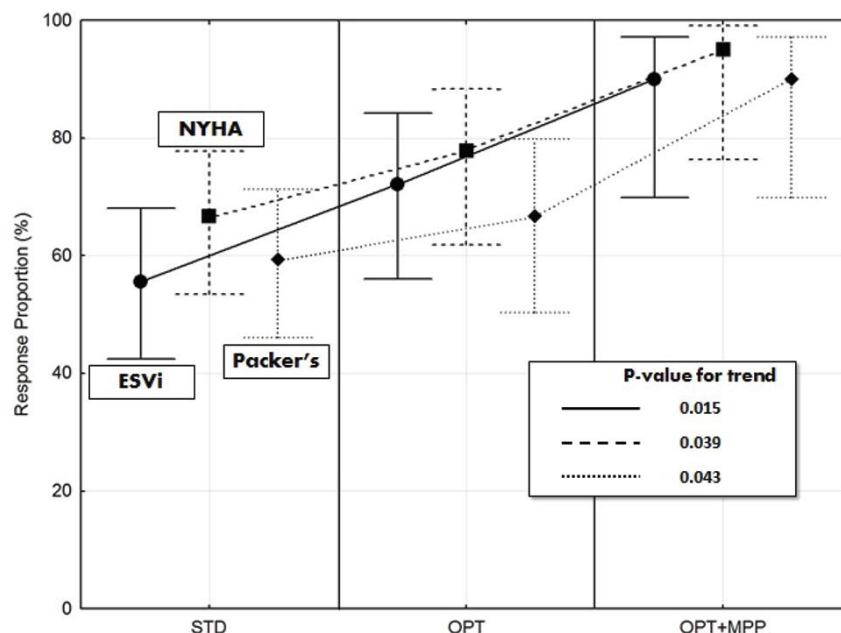
Zanon 2016

Tomassoni 2016

Other Studies

Future Studies

ACUTE OPTIMIZATION OF LEFT VENTRICULAR PACING SITE PLUS MULTIPOINT PACING IMPROVE REMODELING AND CLINICAL RESPONSE OF CRT AT ONE YEAR FOLLOW UP



110 patients treated for 1 year

Results: multipoint pacing achieved a **90% response rate**

Therapy	Response Rate
Standard (single-site)	55.6%
Electrical delay optimization (single site)	72.2%
Electrical delay optimization plus multipoint pacing	90.0%

Programming is important:

Overall multipoint pacing showed no benefit, but patients who were programmed with wide electrical spacing & short timing offset achieved an **87% response rate**

Zanon 2016

Tomassoni 2016

Other Studies

Future Studies

Safety and Efficacy of MultiPoint Pacing in CRT Therapy: The MPP IDE Trial

- 455 patients assessed for clinical composite score.
- **Overall Results:** Multipoint pacing is non-inferior to conventional CRT.
- **Sub-analysis:** **87% response rate** achieved in patients who were programmed to > 30 mm separation and 5 ms offset.

Sub-analysis Results	n	Response
< 30 mm separation	115	63%
> 30 mm separation and TD > 5 Msec	32	69%
> 30 mm separation and TD @ 5 Msec	52	87%
Total / Response	199	70%

In total, more than **31 manuscripts** and **> 60 abstracts** have been published

Zanon 2016

Tomassoni 2016

Other Studies

Future Studies

Study	Size	Results
IRON-MPP 2016	507 patients 76 centers	Compared with conventional CRT, multipoint pacing improved ejection fraction (34.7% vs. 39.0%, p=0.001)
Pappone 2015	44 patients Single center	After 12 months: 76% responder rate with MPP vs 57% responder rate with BiV

Boston Scientific is committed to studying the clinical benefits of MultiSite pacing

Zanon 2016

Tomassoni 2016

Other Studies

Future Studies

Study	Study Objective	Estimated Enrollment	Estimated Study Start Date
SMART Registry	This registry will explore how physician practices and BSC device optimization may be associated with improving clinical outcomes	2000	March 2017
SMART MSP	To evaluate the safety and effectiveness of the MultiSite pacing feature in CRT non-responder patients	450	December 2017

- Technology Overview
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- Clinical Data

□ Programming

» ***Programming Overview***

- » Manual Programming (step-by-step)
- » SmartVector and SmartOffset Algorithms
- » Error Messages and Interactive Limits

All Patients



Acuity X4 Family of Leads

Where to Pace

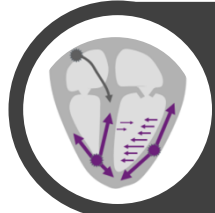
- Designed to optimize non-apical pacing
- 17 vectors allow programming flexibility



VectorGuide™

Where to Pace

- Test all vectors for RV-LV, Ω , PNS, and LV Quick Capture
- Note: Full LV threshold test is not necessary



SmartDelay

When to Pace

- Sensed and Paced AV delay
- Pacing Mode: BiV or LV only

Sub-optimal Responders



MultiSite Pacing

How to Pace

- Choose 2 pacing vectors (LVa & LVb)
- Program timing offsets

Note: After programming MultiSite pacing On, consider running SmartDelay again if LVa was changed to a different vector, or if the timing offsets were modified.

Programming Objectives

Clinical data suggests the following approach to programming¹

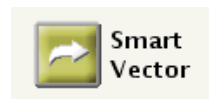
Programming Options

Automatic

Manual

Vectors

- Eliminate vectors poor threshold, out-of-range Ω , and PNS
- 1 Pace 1st vector from site of latest activation (longest RV-LV delay)
 - 2 Choose 2nd vector to achieve wide anatomical spacing



1-click

216
Vector
combinations

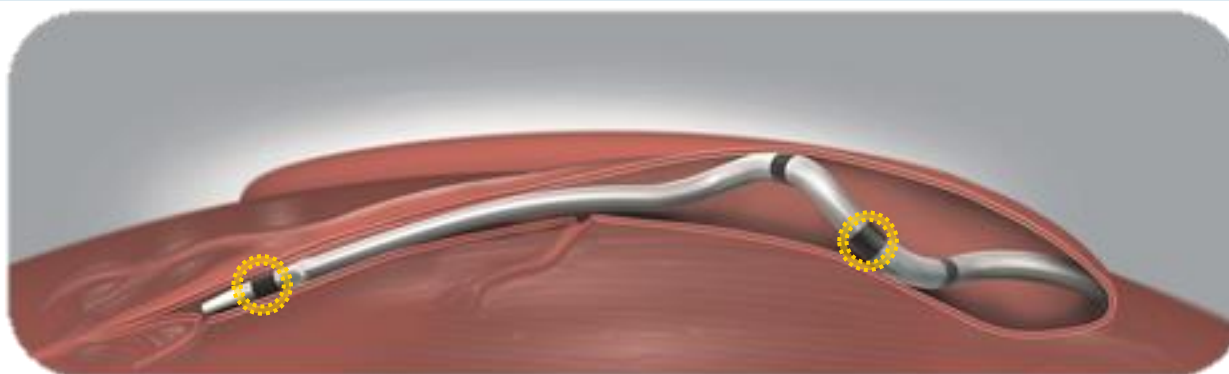
Offsets

- Shorter spacing (0ms or 5ms) is generally better
- Longer spacing may be beneficial to certain patient subgroups (ex. Wide RV-LV spacing between electrodes due to scar pattern or enlarged left ventricle)



1-click

0-100ms



Programming Overview

How to Program

Boston Scientific

Tachy Mode Ventricular: Monitor + Therapy

RESONATE HF CRT-D CRT Defibrillator

Lead-III

A Rate 60

RV Rate 60

LV Rate 60

AS RVP AS RVP AS RVP AS RVP AS RVP AS RVP AS RVP AS RVP AS RVP AS RVP

SETTINGS - NORMAL BRADY/CRT

PARAMETERS

Mode DDD

Lower Rate Limit 45 min⁻¹

Maximum Tracking Rate 130 min⁻¹

Maximum Sensor Rate min⁻¹

Paced AV Delay 180-180 ms

Sensed AV Delay 120-120 ms

A-Refractory (PVARP) 210-280 ms

RV-Refractory (RVRP) 230-250 ms

LV-Refractory (LVRP) 250 ms

Ventricular Pacing Chamber BiV

LV Offset 0 ms

Timing, Rate Enhancements, Noise

SmartDelay™ optimization

PACING AND SENSING

Amplitude Pulse Width Sensitivity

A 3.5 V@ 0.4 ms AGC 0.25 mV

RV 3.5 V@ 0.4 ms AGC 0.6 mV

LV 5.0 V@ 0.4 ms AGC 1.0 mV

Pacing and Sensing Details

LV MultiSite Pacing Off

LEADS

A Pace/Sense

RV Pace/Sense

LV Pace/Sense

RATE ADAPTIVE PACING

Minute Ventilation

Accelerometer

Passive

Utilities Reports Interrogate View Changes Program OK End Session

Select LV MultiSite Pacing from Normal Brady screen

Step 1: Run LV VectorGuide

- Test RV-LV delay, Ω , PNS, and Quick Capture for all 17 vectors
- Full LV threshold test is not required

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:

Step 2a: Program Vectors

- SmartVector – 1 click recommendation
- OR
- User programmable

Step 2b: Program Offsets

- SmartOffset – 1 click recommendation
- OR
- User programmable

Pace Vector	V RVS-LV Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	805 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	880 Ω	No PNS 7.5V @ 0.4 ms	No Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector ☐ Pacing Order/Off ☐ Off

Smart Offset ☐ Smart Offset values are not available when LV MultiSite Pacing is Off.

Pace Vector: LVRing2>>RV, Amplitude: 3.0 V @ 0.4 ms

LVa: V @ ms, LVb: V @ ms

Utilities Reports Interrogate View Changes Program OK End Session

- Technology Overview
- Competitive Comparison
- Clinical Data

□ Programming

- » Programming Overview
- » ***Manual Programming (step-by-step)***
- » SmartVector and SmartOffset Algorithms
- » Error Messages and Interactive Limits

Manual Programming (step-by-step)

Program Vectors

Boston Scientific Tachy Mode Ventricular: Monitor + Therapy RESONATE HF CRT-D CRT Defibrillator

Lead-III A RV LV

A Rate 60 RV Rate 60

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:

Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	580 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector Pacing Order/Off Off

Smart Offset Smart Offset values are not available when LV MultiSite Pacing is Off.

Pace Vector Amplitude Pulse Width

LVa LVRing2>>RV 3.0 V @ 0.4 ms

LVb V @ ms

Utilities Reports Interrogate View Changes Program OK End Session

Manual Programming (step-by-step)

Program Vectors – Pacing Order

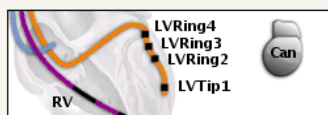
Boston Scientific Tachy Mode Ventricular: Monitor + Therapy RESONATE HF CRT-D CRT Defibrillator

Lead-III A RV LV

A Rate 60 RV Rate 60

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:



Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	821 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms		No PNS 7.5V @ 0.4 ms	No Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector Pacing Order/Off Off

Smart Offset Smart Offset val

Pace Vector Amplitude Pulse Width

LV MultiSite Pacing Order

Off LVa→LVb

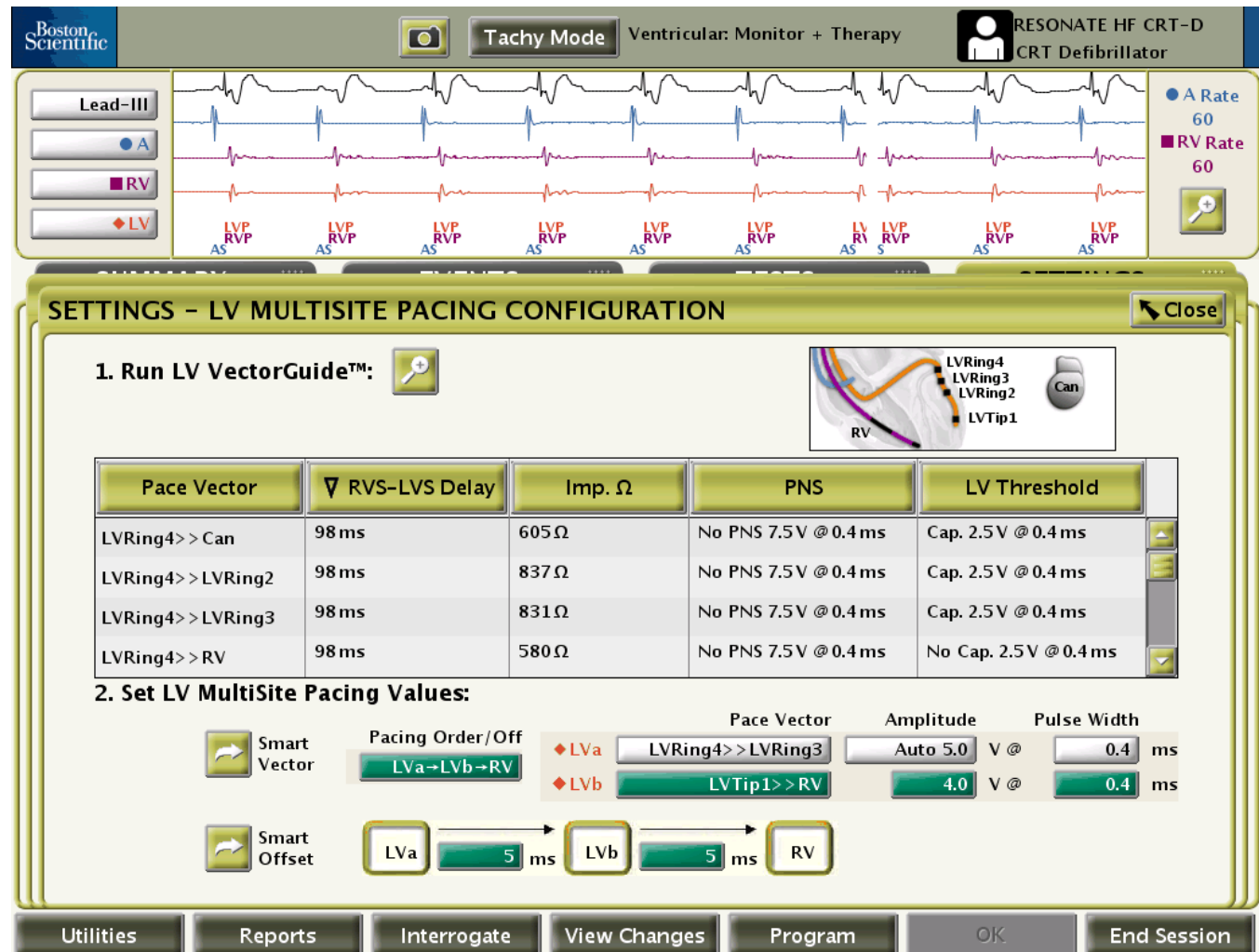
LVa→LVb→RV RV→LVa→LVb Off.

Utilities Reports Interrogate View Changes Program OK End Session

RVa→LVa→LVb pacing configuration only available OUS.


NOTE:

Selecting a Pacing Order turns MultiSite Pacing ON and allows you to program **LVb vector** and timing offsets



SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:



Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	580 Ω	No PNS 7.5V @ 0.4 ms	No Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector: **Pacing Order/Off** **LVa→LVb→RV**

Smart Offset: **LVa** 5 ms **LVb** 5 ms **RV**

Amplitude and Pulse Width settings:

Pace Vector	Amplitude	Pulse Width
LVa: LVRing4>>LVRing3	Auto 5.0 V @	0.4 ms
LVb: LVTip1>>RV	4.0 V @	0.4 ms

Buttons at the bottom: Utilities, Reports, Interrogate, View Changes, Program, OK, End Session

Program Vectors – Pace Vectors

NOTE:

LVa and LVb cannot share the same pacing cathode

RESONATE HF CRT-D CRT Defibrillator

Tachy Mode Ventricular: Monitor + Therapy

Lead-III

● A
■ RV

● A Rate 60
■ RV Rate 60

LV MultiSite Pacing Leads LVb-Pace

Select a pace vector from the table

		Anode (+)				
		LVRing2	LVRing3	LVRing4	RV	Can
Cathode (-)	LVTip1	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
	LVRing2	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	LVRing3	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	LVRing4	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Accept Cancel

Pace Vector

2. Set LV MultiSite Pacing Values:

Smart Vector Pacing Order/Off

Smart Offset

LVa → LVb → RV

LVa 5 ms → LVb 5 ms → RV

Pace Vector Amplitude Pulse Width

LVa LVRing4 >> LVRing3 Auto 5.0 V @ 0.4 ms

LVb LVTip1 >> RV 4.0 V @ 0.4 ms

Utilities Reports Interrogate View Changes Program OK End Session

Manual Programming (step-by-step)

Program Vectors – Amplitude

NOTE:

Auto amplitude can only be programmed on **LVa vector**

Normal Brady LV-Amplitude

Select a manual pace amplitude, or Auto to use an amplitude from the PaceSafe™ LV automatic threshold feature. Select Daily Trend to passively collect the PaceSafe™ LV automatic threshold test results as a daily trend when a manual pace amplitude is selected.

Daily Trend Enabled

	Auto	1.0	2.0	3.0	6.0
0.1	1.1	2.1	3.1	6.5	
0.2	1.2	2.2	3.2	7.0	
0.3	1.3	2.3	3.3	7.5	
0.4	1.4	2.4	3.4		
0.5	1.5	2.5	3.5		
0.6	1.6	2.6	4.0		
0.7	1.7	2.7	4.5		
0.8	1.8	2.8	5.0		
0.9	1.9	2.9	5.5		

Amplitude

Amplitude Pulse Width

Auto 5.0 V @ 0.4 ms

4.0 V @ 0.4 ms


Boston Scientific **Tachy Mode** Ventricular: Monitor + Therapy **RESONATE HF CRT-D CRT Defibrillator**

Lead-III
● A
■ RV
◆ LV

A Rate 60
RV Rate 60

SETTINGS - LV MULTISITE PACING CONFIGURATION **Close**

1. Run LV VectorGuide™:



Pace Vector	▽ RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω		
LVRing4>>RV	98 ms	580 Ω		

2. Set LV MultiSite Pacing Values:

Smart Vector **Pacing Order/Off** **LVa→LVb→RV** **LVa** **LVb**

Smart Offset **LVa** **5 ms** **LVb**

Normal Brady LV-Pulse Width

0.1	0.6	1.1	1.6
0.2	0.7	1.2	1.7
0.3	0.8	1.3	1.8
0.4	0.9	1.4	1.9
0.5	1.0	1.5	2.0

Pulse Width 0.4 ms

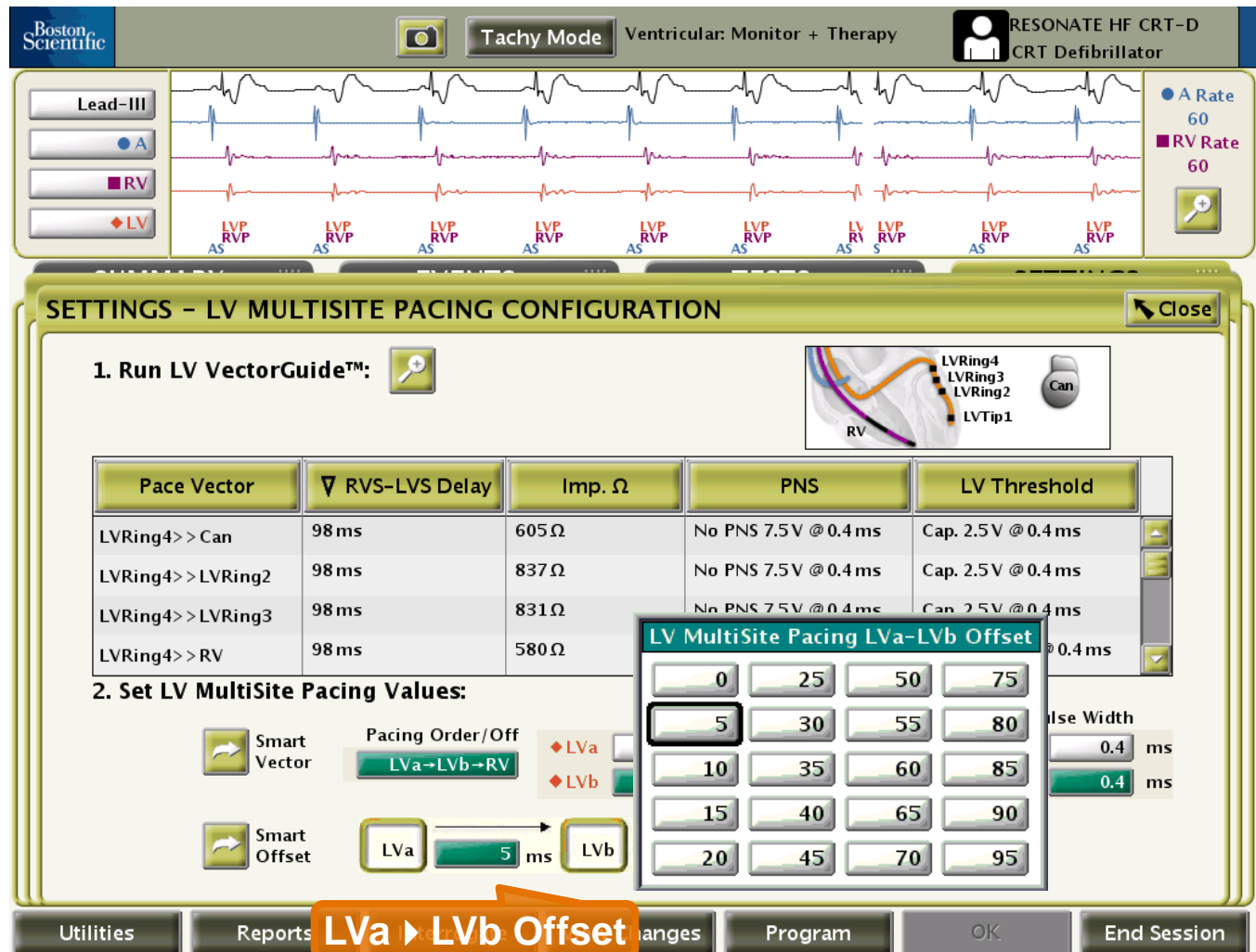
Utilities **Reports** **Interrogate** **View Changes** **Program** **OK** **End Session**

Pulse Width

Pulse Width
0.4 ms

NOTE:

- The traditional LV Offset field used in single site pacing will be disabled during MultiSite pacing
- For reference, the traditional LV Offset equals the sum of LVa ▶ LVb Offset + LVb ▶ RV Offset



SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:

Pace Vector	▽ RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	580 Ω		

2. Set LV MultiSite Pacing Values:

Smart Vector: Pacing Order/Off: LVa → LVb → RV

Smart Offset: LVa 5 ms LVb

LV MultiSite Pacing Lva-LVb Offset

0	25	50	75
5	30	55	80
10	35	60	85
15	40	65	90
20	45	70	95

Utilities Reports **LVa ▶ LVb Offset** Changes Program OK End Session

Manual Programming (step-by-step)

Program Offsets – LVb ▶ RV

RESONATE HF CRT-D CRT Defibrillator

Tachy Mode Ventricular: Monitor + Therapy

Lead-III
● A
■ RV
◆ LV

A Rate 60
RV Rate 60

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:

Pace Vector	▽ RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	580 Ω	No PNS 7.5V @	Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector Pacing Order/Off: LVa→LVb→RV

Smart Offset: LVa 5 ms → LVb 5 ms → RV

Pace Vector:
◆ LVa LVRing4>>LVRing3
◆ LVb LVTip1>>RV

LV MultiSite Pacing LVb-RV Offset

5	30	55	80
10	35	60	85
15	40	65	90
20	45	70	95
25	50	75	100

LVb ▶ RV Offset

Utilities Reports Interrogate OK End Session

Manual Programming (step-by-step)

Final Step – Press Program


Boston Scientific Tachy Mode Ventricular: Monitor + Therapy RESONATE HF CRT-D CRT Defibrillator

Lead-III A RV LV

A Rate 60 RV Rate 60

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:



Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVRing4>>Can	98 ms	605 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing2	98 ms	837 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>LVRing3	98 ms	831 Ω	No PNS 7.5V @ 0.4 ms	Cap. 2.5V @ 0.4 ms
LVRing4>>RV	98 ms	580 Ω	No PNS 7.5V @ 0.4 ms	No Cap. 2.5V @ 0.4 ms

2. Set LV MultiSite Pacing Values:

Smart Vector Pacing Order/Off LVa→LVb→RV

Smart Offset LVa 5 ms LVb 5 ms

Pace Vector Amplitude Pulse Width

LVa LVRing4>>LVRing3 Auto 5.0 V @ 0.4 ms

LVb LVRing4>>LVRing3 1.0 V @ 0.4 ms

Final Step Press Program

Utilities Reports Interrogate View Changes Program OK End Session

- Technology Overview
- Competitive Comparison
- Clinical Data

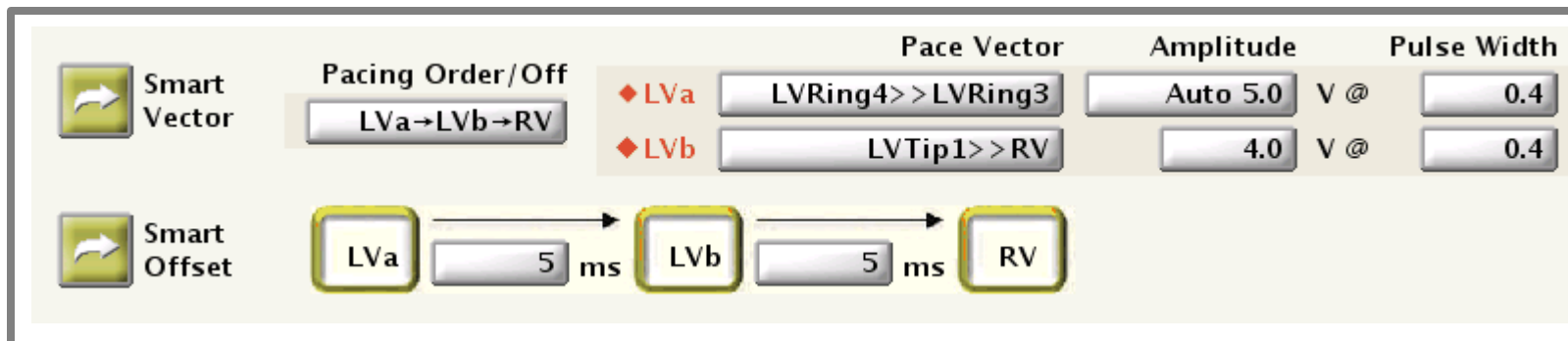
□ Programming

- » Programming Overview
- » Manual Programming (step-by-step)
- » ***SmartVector and SmartOffset Algorithms***
- » Error Messages and Interactive Limits

In total, Boston Scientific offers **216 vector combinations**:

SmartVector and SmartOffset can be used to facilitate programming by providing a recommendation with the click of a button.

- **SmartVector** provides recommendations for the LV MSP pacing sequence, pacing vectors, and pacing characteristics (amplitude and pulse width) based on RVS-LVS delay and electrode separation distance.
- **SmartOffset** provides recommendations for the programmed delays between the ventricular paces.



The screenshot displays two programming sections: Smart Vector and Smart Offset.

Smart Vector Section:

- Pacing Order/Off:** A button labeled "LVa→LVb→RV".
- Pace Vector:**
 - For **LVa** (indicated by a red diamond), the vector is "LVRing4>>LVRing3".
 - For **LVb** (indicated by a red diamond), the vector is "LVTip1>>RV".
- Amplitude:**
 - For LVa, it is "Auto 5.0".
 - For LVb, it is "4.0".
- Pulse Width:** Both LVa and LVb are set to "0.4".

Smart Offset Section:

- A sequence diagram showing the timing between LVa, LVb, and RV. LVa is followed by a 5 ms delay to LVb, which is followed by a 5 ms delay to RV.

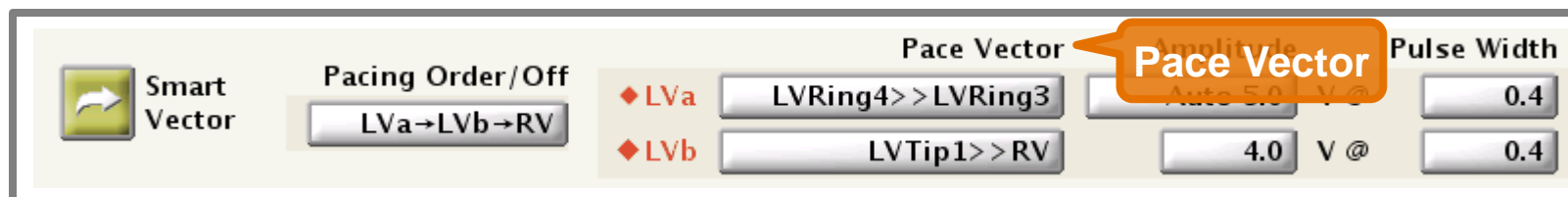
1 click will recommend Pacing Order



The interface shows the 'Smart Vector' section with a 'Pacing Order/Off' button set to 'LVa→LVb→RV'. An orange callout bubble points to this button with the text 'Pacing Order'. To the right, the 'Pace Vector' section shows 'LVa' (red diamond) with 'LVRing4>>LVRing3' and 'LVb' (red diamond) with 'LVTip1>>RV'. The 'Amplitude' is set to 'Auto 5.0' and '4.0', and the 'Pulse Width' is set to '0.4' for both channels.

Pacing Order Algorithm		
Normal Brady Programming	VectorGuide RV-LV Results	Recommendation
Ventricular Pacing Chamber <input type="button" value="BiV"/>	≥ -20 ms	<input type="button" value="LVa→LVb→RV"/>
	< -20 ms	<input type="button" value="RV→LVa→LVb"/>
Ventricular Pacing Chamber <input type="button" value="LV Only"/>	N/A	<input type="button" value="LVa→LVb"/>

1 click will recommend Pace Vector



Pace Vector Algorithm

Eliminates all vectors with PNS, Ω out of range, LV threshold > 4.5 V, missing data

LVa

- Select cathode with Longest RV-LV
- If RV-LV is a tie, prioritize best LV threshold
- If LV threshold is a tie, prioritize
 - Cathode: most basal electrode
 - Anode: RV>4>3>2>Can

LVb

- Select cathode with widest anatomical distance from LVa
(note: this algorithm is optimized for BSC spiral leads)
- Select anode with lowest LV threshold

1 click will recommend Amplitude

The screenshot shows the SmartVector control interface. On the left is the 'Smart Vector' logo. In the center is the 'Pacing Order/Off' section with a button labeled 'LVa→LVb→RV'. To the right are two rows of controls for LVa and LVb. Each row has a red diamond icon, a label (LVa or LVb), a 'Pace Vector' dropdown menu (showing 'LVRi' for LVa and 'LVTip1>>RV' for LVb), an 'Amplitude' button (highlighted with an orange callout), an 'Amplitude' value field (showing 'Auto 5.0' for LVa and '4.0' for LVb), a 'V @' label, and a 'Pulse Width' button (showing '0.4' for both).

Amplitude Algorithm

LVa

- Automatic Threshold (PaceSafe)

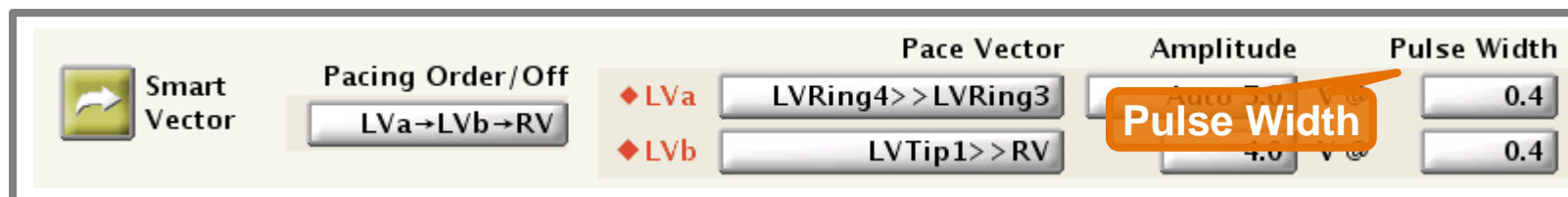
LVb

- VectorGuide results +1.5V
- Automatic threshold is not available for LVb

Example:

VectorGuide LV Threshold	Programmed Amplitude
1.1V	2.6V
Cap. 2.5V	4.0V

1 click will recommend Pulse Width



Pulse Width Algorithm

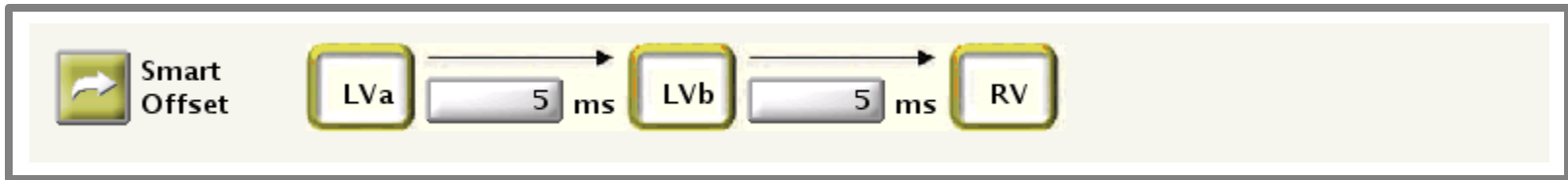
LVa

Choose whatever pulse width was tested during VectorGuide test

LVb

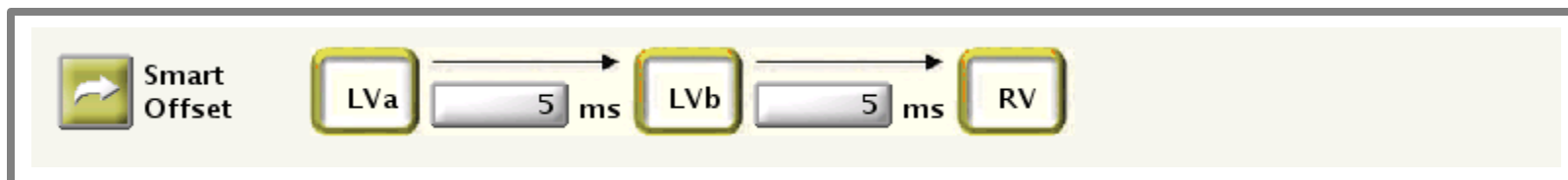
Choose whatever pulse width was tested during VectorGuide test

1 click will recommend LVa ▶ LVb Offset and LVb ▶ RV Offset



SmartOffset utilizes the SmartDelay algorithm combined with VectorGuide test results to recommend MultiSite Pacing offsets with the click of a button.

1 click will recommend LVa ▶ LVb Offset and LVb ▶ RV Offset



SmartOffset Algorithm

LVa ▶ LVb Offset SmartOffset runs a lite version SmartDelay twice, to determine the optimal A→LV delay for both LV vectors

LVb ▶ RV Offset is always set to 5ms. This is the minimum value and therefore recommended to achieve simultaneous RV and LV contraction.

RV-LV Delay Difference (difference between LVa and LVb)	LVa ▶ LVb Offset	LVb ▶ RV Offset
0-19ms	0	5
20-39ms	5	5
40-119ms	10	5
119-159ms	15	5

- Technology Overview
- Competitive Comparison
- Clinical Data

□ Programming

- » Programming Overview
- » Manual Programming (step-by-step)
- » SmartVector and SmartOffset Algorithms
- » ***Error Messages and Interactive Limits***

SmartVector will be unable to make a recommendation in the following circumstances:

- If there is insufficient or missing data, a message appears to suggest that the user assess additional vectors or complete all tests for the selected vectors.
- If no acceptable combination of two pacing vectors is available, a message appears to suggest the user re-run vectors with a lower PNS Threshold or higher Quick Capture Threshold.

SmartOffset will be unable to make a recommendation in the following circumstances:

- If RVS-LVS Delay tests have not been run for the selected vector(s), a message appears to suggest that the user complete the RVS-LVS Delay test for the vectors chosen.
- If the RVS-LVS Delay measurement for the selected vectors is invalid, a message appears to suggest the user re-run the RVS-LVS Delay tests again for the vectors chosen, or manually select offsets.

NOTE:

Pacing Chamber and Pacing Order must be compatible.

The screenshot displays the Boston Scientific RESONATE HF CRT-D CRT Defibrillator programming interface. The main window is titled "PARAMETER INTERACTIONS" and shows a "Brady" program. A warning message states: "Ventricular Pacing Chamber and LV MultiSite Pacing Order have been set to incompatible values. If a new LV MultiSite Pacing Order is chosen to fix this incompatibility, use the LV MultiSite Pacing Screen to review settings and adjust if needed." The current settings are "LV MultiSite Pacing Order" set to "LVa→LVb" and "Normal Brady Ventricular Pacing Chamber". The interface also shows "SETTINGS - NORMAL BRADY/CRT" on the left, with parameters like Mode (DDD), Lower Rate Limit (45 ppm), and Maximum Tracking Rate (130 ppm). A large orange callout bubble with the text "Interactive limit must be resolved before programming" is overlaid on the right side of the screen. The bottom of the screen features a "WARNING" button and an "End Session" button.

SETTINGS - NORMAL BRADY/CRT

PARAMETERS

- Mode: DDD
- Lower Rate Limit: 45 ppm
- Maximum Tracking Rate: 130 ppm
- Maximum Sensor Rate: 130 ppm
- Paced AV Delay: 210 ms
- Sensed AV Delay: 200 ms
- A-Refractory (PVARP): 240 ms
- RV-Refractory (RVRP): 230 ms
- LV-Refractory (LVRP): 250 ms
- Ventricular Pacing Chamber: LV Only
- LV Offset: ms

PARAMETER INTERACTIONS

Program

Brady

Ventricular Pacing Chamber and LV MultiSite Pacing Order have been set to incompatible values.

If a new LV MultiSite Pacing Order is chosen to fix this incompatibility, use the LV MultiSite Pacing Screen to review settings and adjust if needed.

LV MultiSite Pacing Order: LVa→LVb

Normal Brady Ventricular Pacing Chamber

Interactive limit must be resolved before programming

WARNING

End Session

NOTE:

An interactive limit will occur if the 2 LV vectors share the same cathode

The screenshot displays the Boston Scientific RESONATE X4 CRT-D CRT Defibrillator interface. At the top, the status bar shows 'Tachy Mode' and 'Ventricular: Off'. The main display area shows a heart rhythm strip with various waveforms and labels like 'LVP', 'RV', 'AP', and 'RVP'. On the right, the 'A Rate' and 'RV Rate' are both set to 45. Below the rhythm strip, the 'SETTINGS - LV MULTISITE PACING CONFIGURATION' window is open. This window contains two main sections: '1. Run LV VectorGuide™' and '2. Set LV MultiSite Pacing Values:'. The 'Run LV VectorGuide™' section includes a diagram of the heart with cathodes labeled 'LVRing4', 'LVRing3', 'LVRing2', 'LVRing1', and 'RV'. The 'Set LV MultiSite Pacing Values:' section includes a table for 'Pace Vector', 'RVS-LVS Delay', 'Imp. Ω', 'PNS', and 'LV Threshold'. The 'Pace Vector' table shows four rows: 'LVTip1>>Can', 'LVTip1>>LVRing2', 'LVTip1>>LVRing3', and 'LVTip1>>LVRing4'. Below the table, there are controls for 'Smart Vector' and 'Smart Offset'. The 'Smart Vector' section shows 'Pacing Order/Off' as 'LVa→LVb→RV' and 'Pace Vector' as 'LVa→LVRing2>>RV' and 'LVb→LVRing2>>LVRing4'. The 'Smart Offset' section shows 'LVa' at 0 ms and 'LVb' at 5 ms. At the bottom of the interface, there are buttons for 'Utilities', 'Reports', 'Interrogate', 'View Changes', 'Program', a 'WARNING' indicator, and 'End Session'.

SETTINGS - LV MULTISITE PACING CONFIGURATION

1. Run LV VectorGuide™:

RV, LVRing4, LVRing3, LVRing2, LVRing1, Can

Δ Pace Vector	RVS-LVS Delay	Imp. Ω	PNS	LV Threshold
LVTip1>>Can				
LVTip1>>LVRing2				
LVTip1>>LVRing3				
LVTip1>>LVRing4				

2. Set LV MultiSite Pacing Values:

Smart Vector: Pacing Order/Off: LVa→LVb→RV

Pace Vector: LVa → LVRing2>>RV, LVb → LVRing2>>LVRing4

Amplitude: 3.5 V @, Pulse Width: 0.4 ms

Smart Offset: LVa → 0 ms, LVb → 5 ms, RV

Utilities Reports Interrogate View Changes Program WARNING End Session

DISCLAIMER

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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