Boston Scientific
Advancing science for life™

LV VectorGuide™

Technical Training

smart solutions | **PROVEN TO LAST**

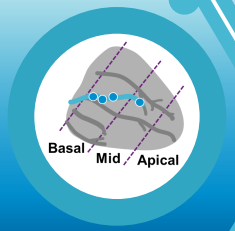
SmartCRT™

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

SmartCRT™

Where
to pace

Site of latest activation



ACUITY™ X4

VectorGuide™
17 vectors, RV-LV delay

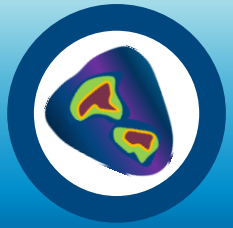
When
to pace

Maximize global contractility

SmartDelay™
Sensed and paced AV Delay
BiV or LV Only

How
to pace

Maximize ventricular contractility



MultiSite Pacing
Single Site or MultiSite Pacing

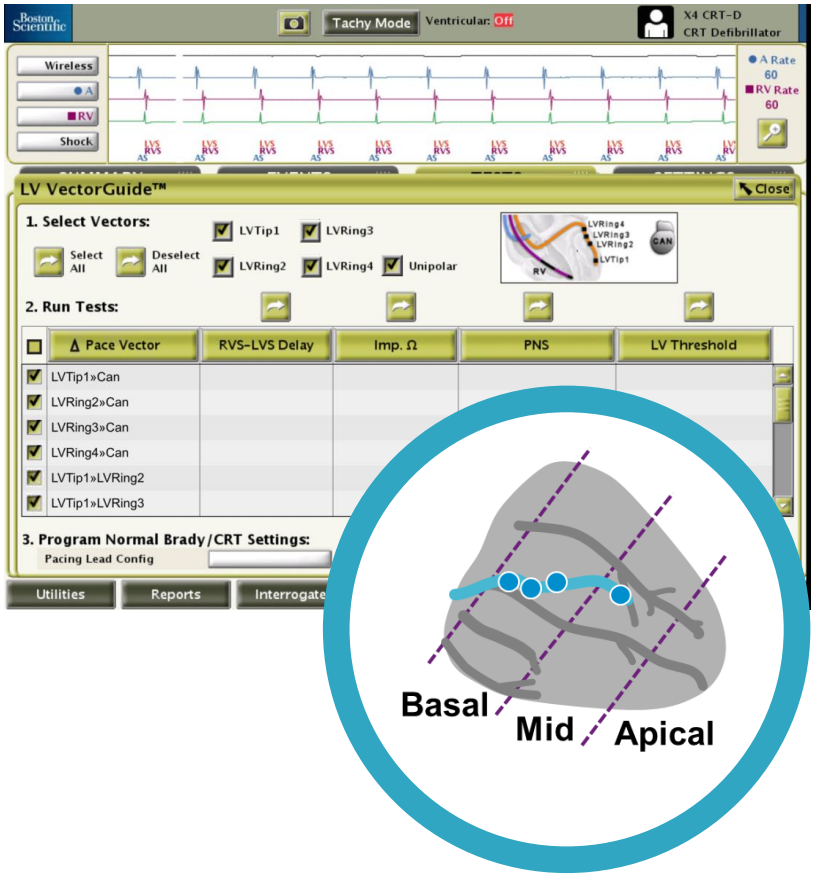
Powered by ENDURALIFE™ Battery Technology

Labeled for up to 13.3 years[1] 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.

LV VectorGuide™

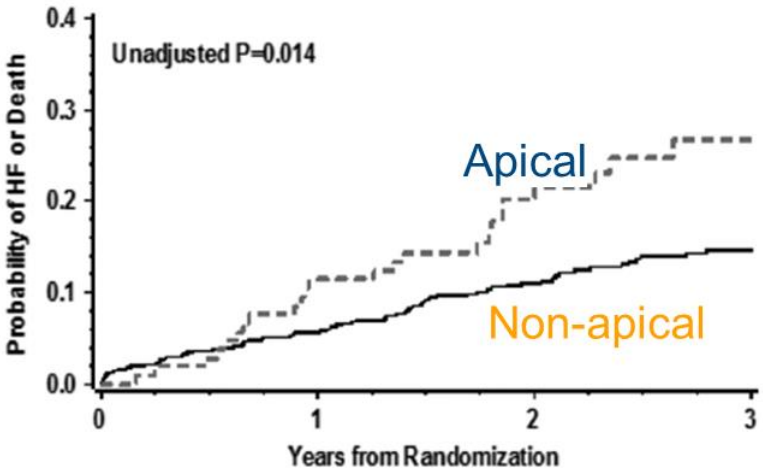
- Site of Latest Activation
- RV-LV Clinical Data
- How to use LV VectorGuide™
- When to use LV VectorGuide™



Where to Pace

In the MADID-CRT Sub-Study, at a **population level**, basal pacing resulted in better outcomes than apical pacing.

MADIT-CRT SUB-STUDY ON LV Lead Position[1]



Conclusion:

"LV leads positioned in the apical region were associated with an unfavorable outcome, suggesting that this lead location should be avoided in cardiac resynchronization therapy."[1]

This outcome could have been due to the fact that the site of latest activation is often located in the mid-lateral or base of the LV. ***But is it for every patient?***

[1] Singh JP, et al. Left Ventricular Lead Position and Clinical Outcome in the Multicenter Automatic Defibrillator Implantation Trial–Cardiac Resynchronization Therapy (MADIT-CRT) Trial. Circulation 2011; 123: 1159-1166

Where to Pace

For an **individual**, basal pacing may not always produce the best outcomes.

Electrical delay in apically positioned left ventricular leads and clinical outcomes after cardiac resynchronization therapy (N=31)

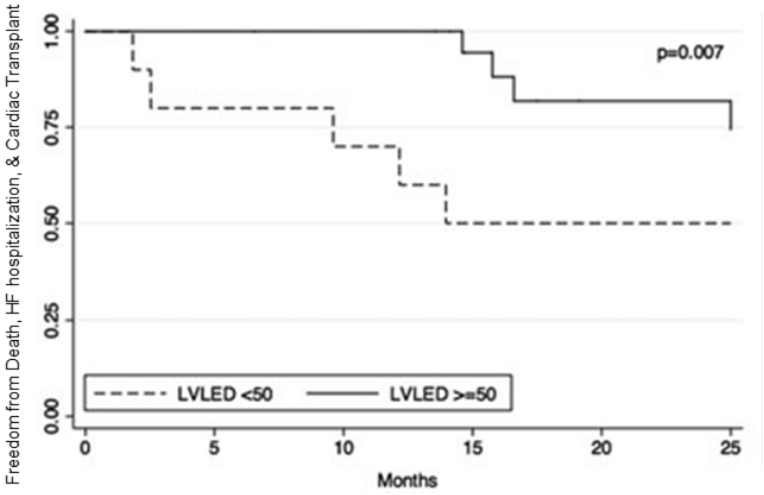


Figure 2:

Freedom from the primary composite endpoint of all-cause death, cardiac transplantation, or HF hospitalization at 2 years stratified by LVLED group.

LVLED = left ventricular lead electrical delay.

"It is possible that an apical position may work reasonably well for a subset of the patients where the apex is activated further into the depolarization wave front."[1]

[1] Kandala J, et al. Electrical Delay in Apically Positioned Left Ventricular Leads and Clinical Outcome After Cardiac Resynchronization Therapy. Journal of Cardiovascular Electrophysiology Vol. 24, No. 2, February 2013

Where to Pace

For **almost all patients** in this study, the site of latest activation had a high correlation with improved response.

Determination of the longest intrapatient Left Ventricular Electrical Delay may predict acute hemodynamic improvement in patients after Cardiac Resynchronization Therapy (N = 32)

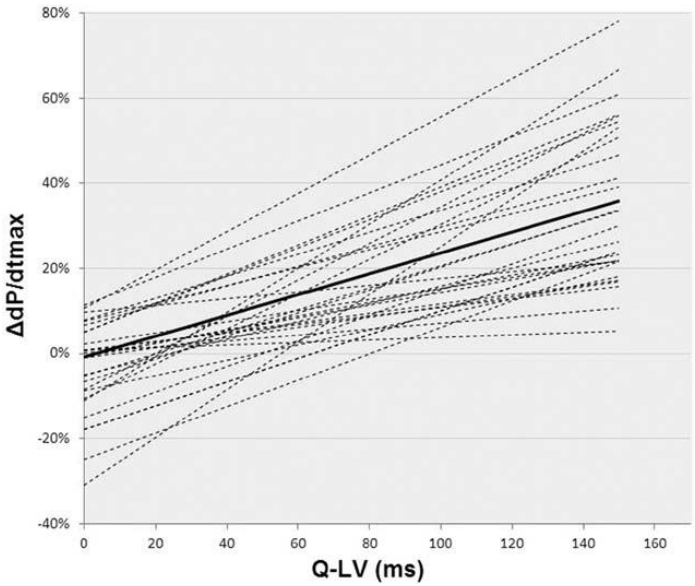


Figure 4:

Individual regression lines to depict variability. Dotted line indicates single regression; and dashed line, median regression for all patients.

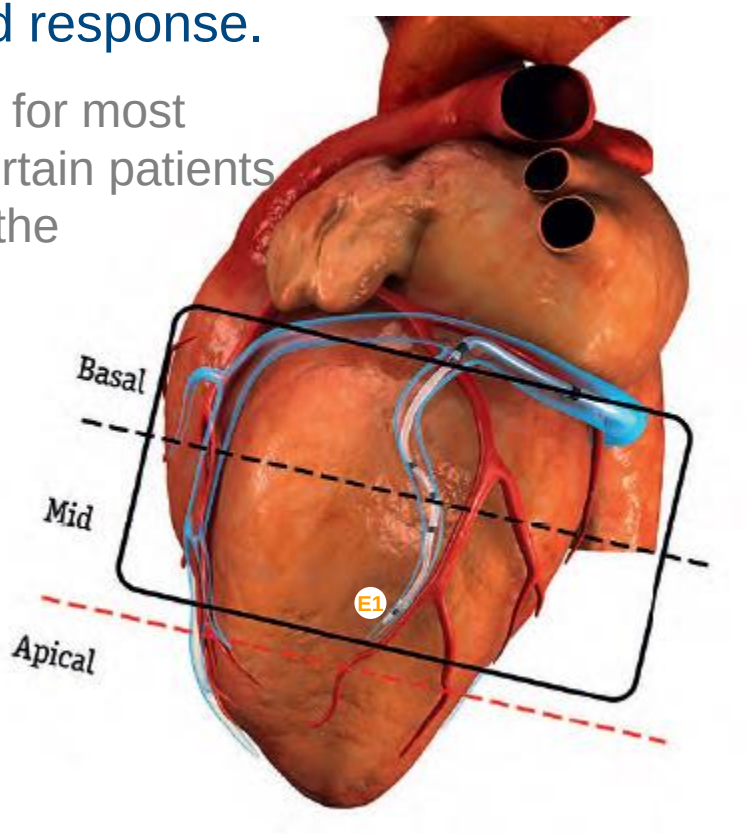
"Pacing the LV at the site of the latest activation yielded the greatest increase in cardiac contractility in 31 of 32 patients."[1]

[1] Zanon F, et al. Determination of the Longest Intrapatient Left Ventricular Electrical Delay May Predict Acute Hemodynamic Improvement in Patients After Cardiac Resynchronization Therapy. Circ Arrhythm Electrophysiol, 2014;7:377-383.

Where to Pace

For an **individual patient**, the site of latest activation is most important for attaining positive CRT outcomes and response.

- Although mid or basal pacing is best for most patients, studies have shown that certain patients benefit from apical pacing[1] and that the site of latest activation may predict improved CRT response.[2]
- E1 electrode is often located in the mid location, not apical.
- Every patient's electrical conduction pathway is unique.

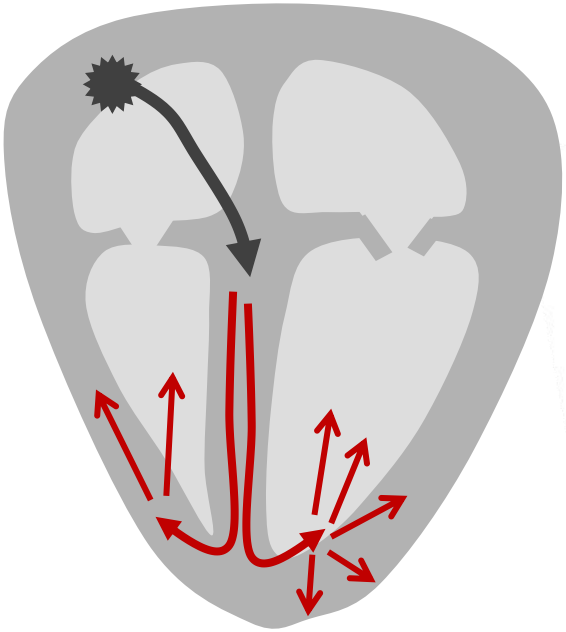


[1] Kandala J, et al. Electrical Delay in Apically Positioned Left Ventricular Leads and Clinical Outcome After Cardiac Resynchronization Therapy. Journal of Cardiovascular Electrophysiology Vol. 24, No. 2, February 2013

[2] Zanon F, et al. Determination of the Longest Intrapatient Left Ventricular Electrical Delay May Predict Acute Hemodynamic Improvement in Patients After Cardiac Resynchronization Therapy. Circ Arrhythm Electrophysiol, 2014;7:377-383.

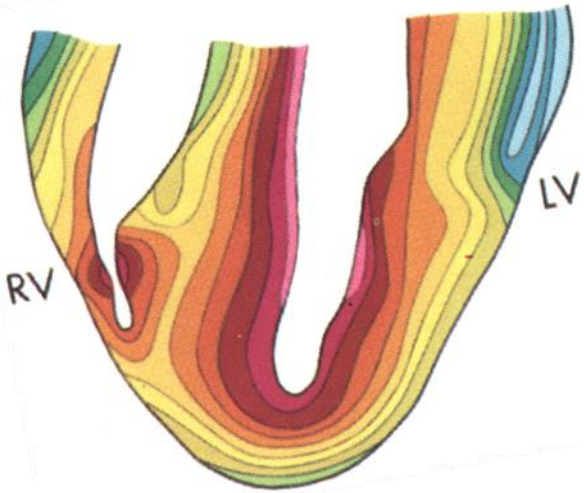
Where to Pace

Electrical Activation of the Heart

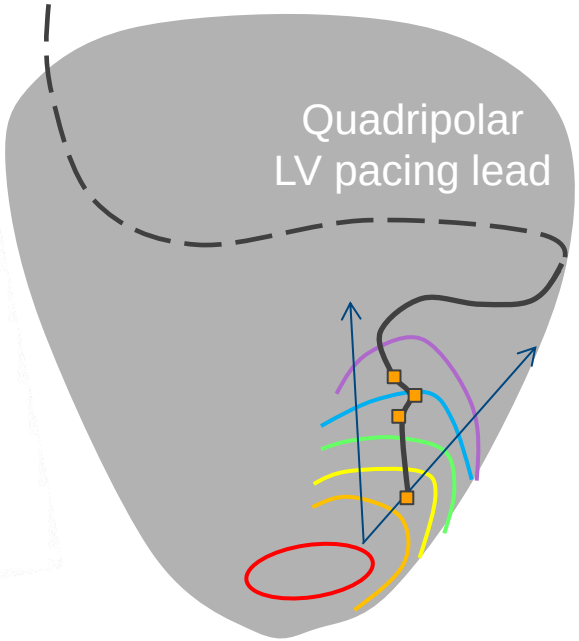


Color Map:

Spread of the electrical activation inside the heart



Normal Heart



Heart Failure Heart

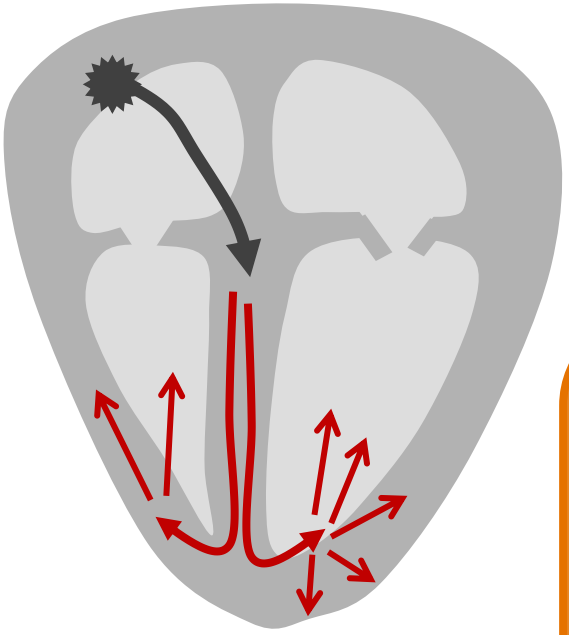
1 Inside The Heart

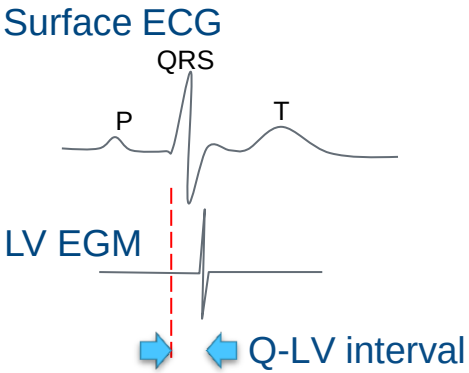
Red lines show the spread of electrical activation inside the heart

2 Outer Surface Of Heart

The LV lead has multiple electrodes which will detect electrical activation at different time points as the electrical wave spreads out

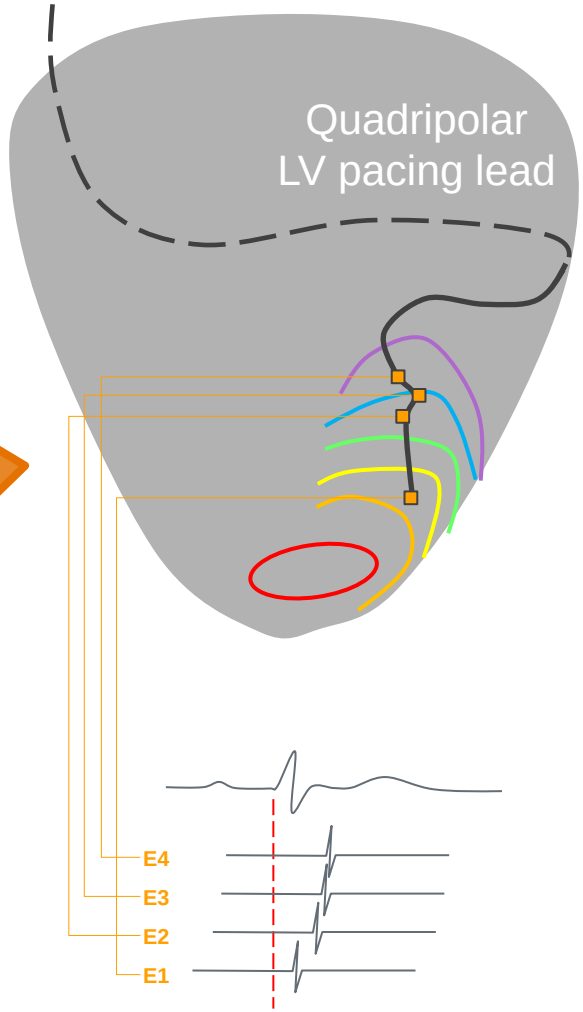
Measuring Electrical Delay: QLV



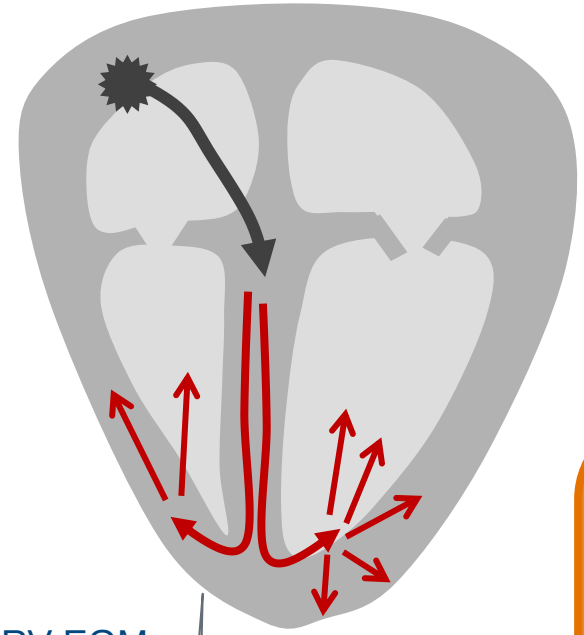


By measuring the electrical delay from the beginning of ventricular activation (Q point) to each LV lead electrode we can determine the QLV interval.

For a quadripolar lead, this would result in four QLV values.



Measuring Electrical Delay: RV-LV



RV EGM

(instead of surface ECG)

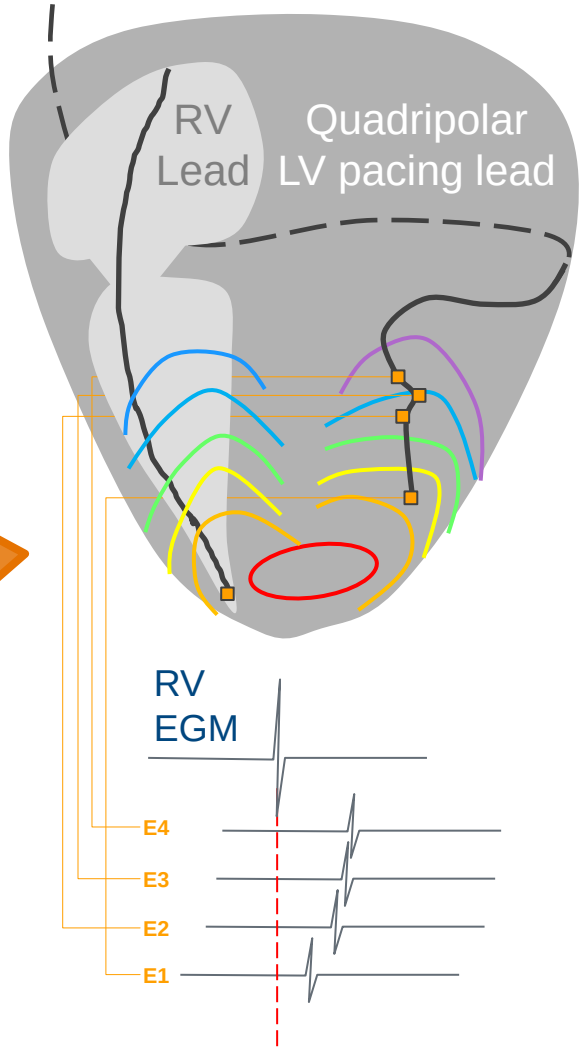
LV EGM

RV-LV interval

RV-LV is another measure of electrical delay, but is determined in a slightly different fashion than QLV.

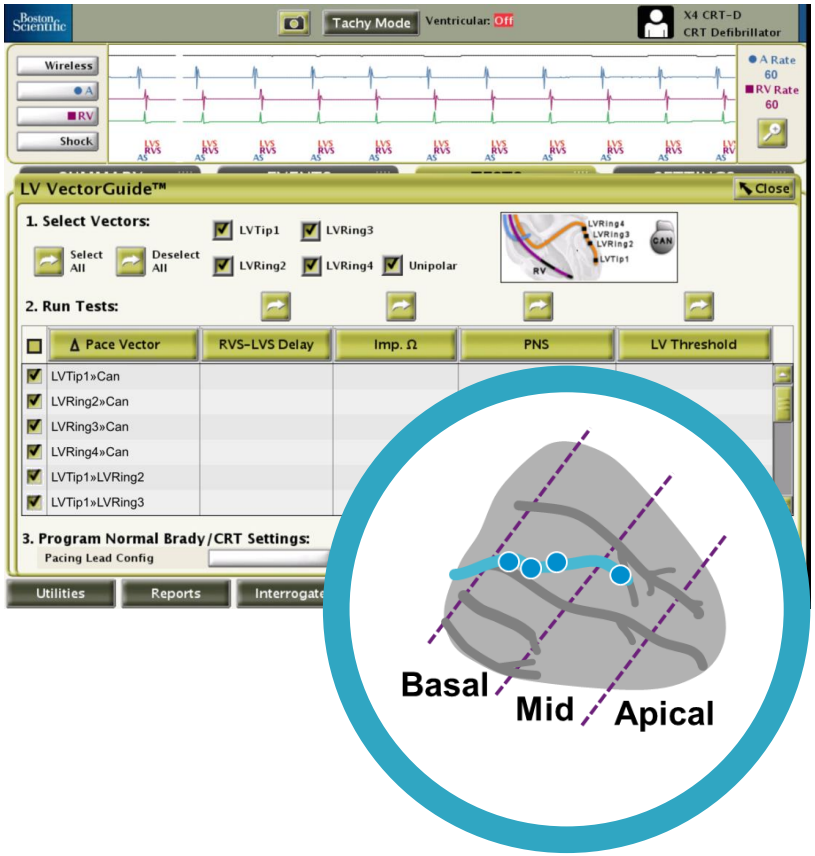
By measuring the difference in activation between the RV and LV, we can determine the RV-LV interval.

For a quadripolar lead, this would also result in four RV-LV values.



LV VectorGuide™

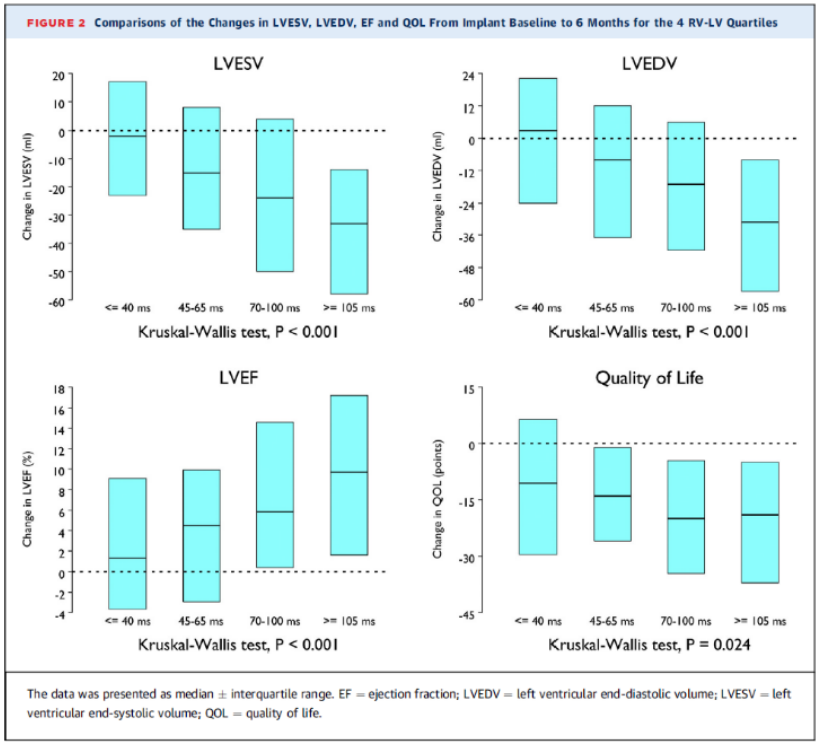
- Site of Latest Activation
- RV-LV Clinical Data
- How to use LV VectorGuide™
- When to use LV VectorGuide™



RV-LV Clinical Data

For an **individual**, basal pacing may not always produce the best outcomes.

Interventricular Electrical Delay is predictive of response to Cardiac Resynchronization Therapy (N=419)



Study Conclusions

"The RV-LV interval is a strong and independent predictor of remodeling with CRT.

This parameter predicted reverse remodeling even in subgroups traditionally associated with low response rates.

Based on these results, measuring RV-LV time at implantation may help to identify optimal pacing sites."[1]

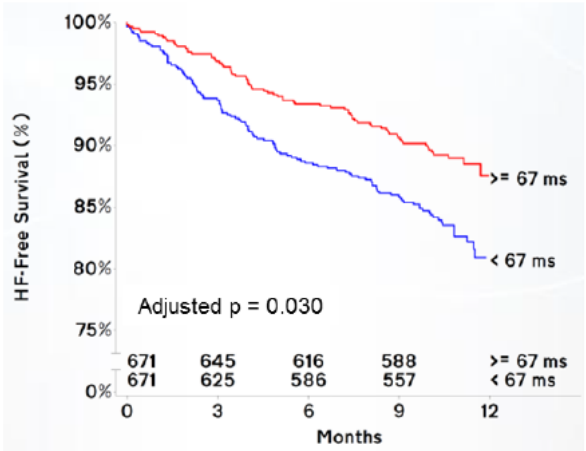
Key takeaway: the RV-LV interval is an important measure to be considered at the time of LV lead implant.

[1] Gold M, et al. Interventricular Electrical Delay Is Predictive of Response to Cardiac Resynchronization Therapy. JACC Clin Electrophysiol Vol. 2, No. 4, August 2016

RV-LV Clinical Data

Clinical data show longer RV-LV was associated with improved CRT **outcomes** and **response**

30% reduction of risk of HF hospitalization or death associated with longer RVS-VS delay[1]



Kaplan-Meier curves of HF-Free Survival for the short and long RV-LV groups

82% response rate achieved when RV-LV ≥105 ms[2]

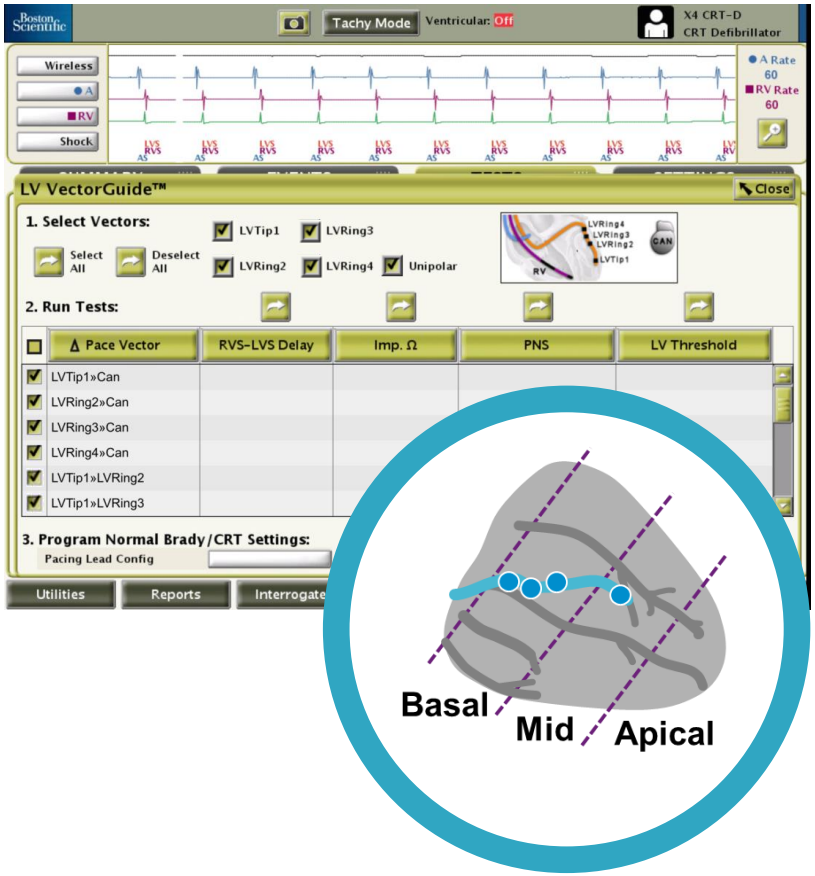
RV-LV	% Responders
≤ 40 ms	33%
45-65 ms	58%
70-100 ms	63%
≥ 105 ms	82%

[1] Gold M, et al. ESC 2014 (N=1342)

[2] Gold M, et al. AHA 2016 (N=419)

LV VectorGuide™

- Site of Latest Activation
- RV-LV Clinical Data
- How to use LV VectorGuide™
- When to use LV VectorGuide™

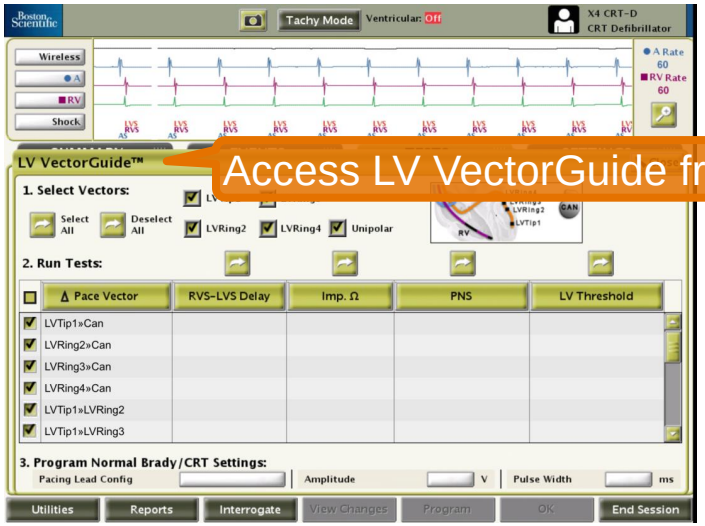


Overview

Select the vectors you want to test

Options:

a) Select all
b) Select by Cathode
c) Select all Unipolar
d) Select individually from the table



Access LV VectorGuide from the Tests tab

Run tests

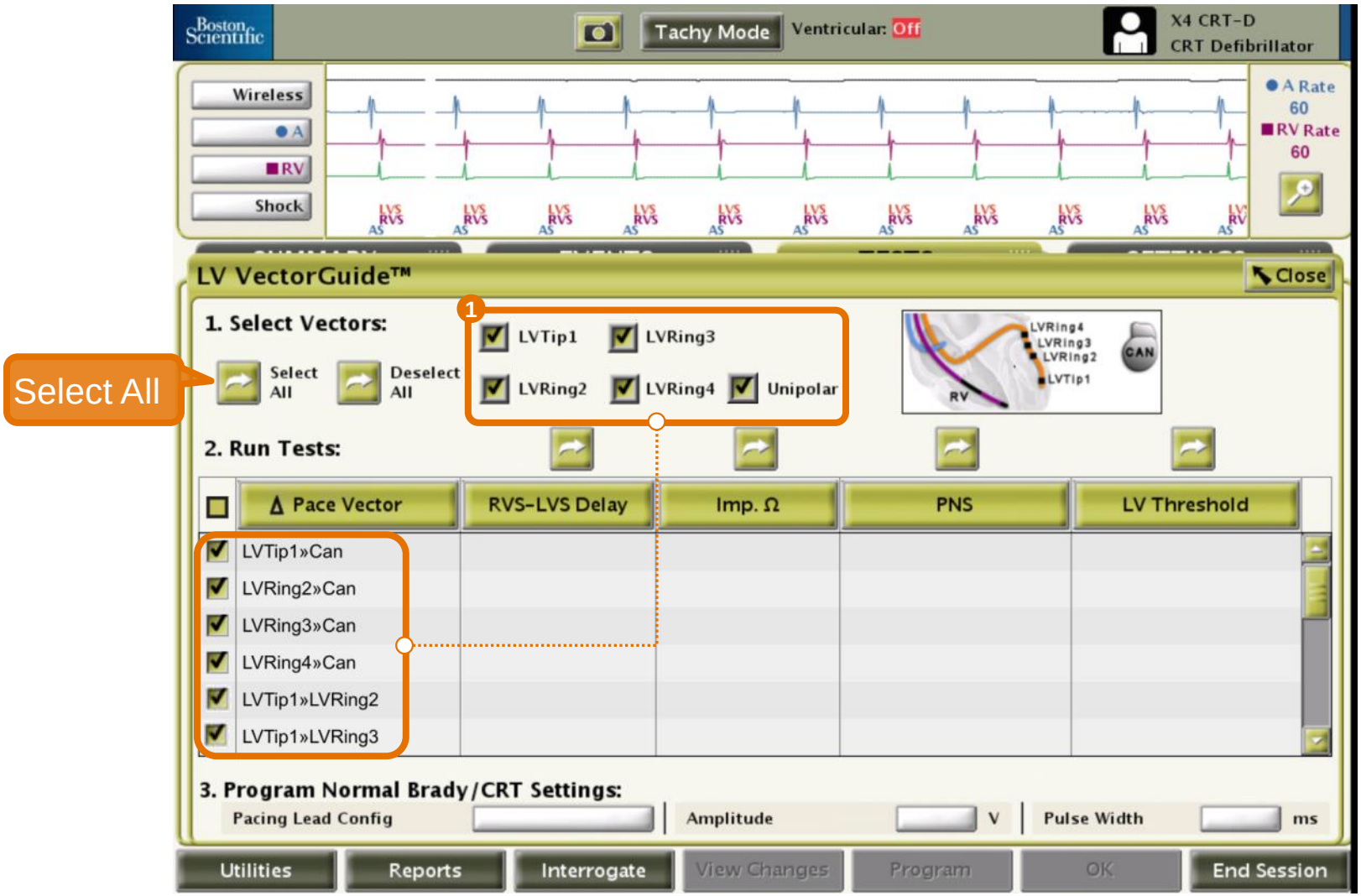
a) Recommended order is left to right, but can be run in any order
b) RVS-LVS and Impedance test are fully automated
c) Use the scroll bar on the right to view all 17 vectors (only 6 are visible at a time)
d) Tap column headers to sort values in that column; Tap again to sort in other direction.
e) Deselect individual vectors throughout the testing process to narrow down selection

Program pacing lead configuration

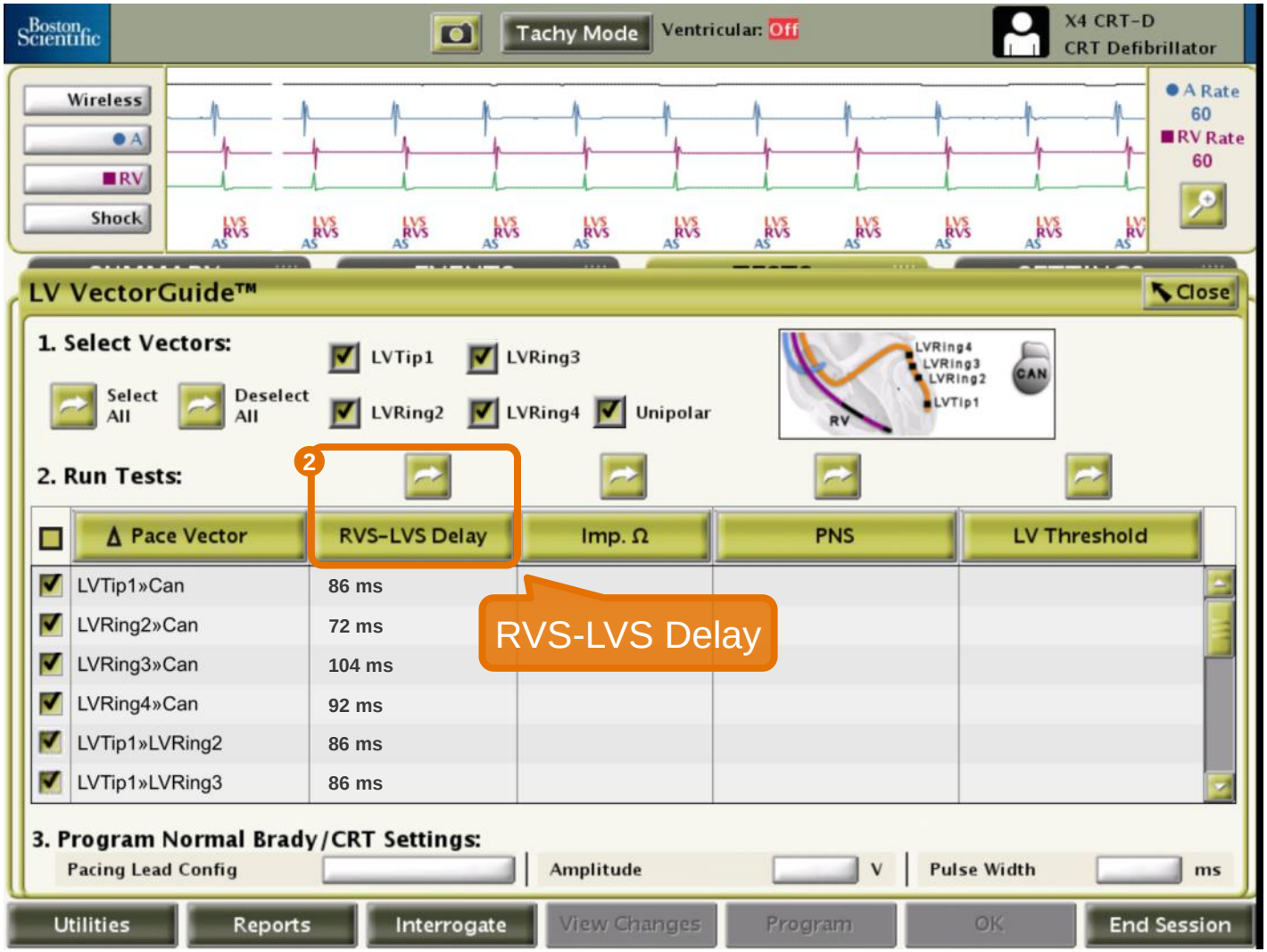
a) Choose desired vector
b) Select Amplitude & Pulse Width

Print LV VectorGuide Report to document testing

Select Vectors



RVS-LVS Delay Test



Rules of thumb:

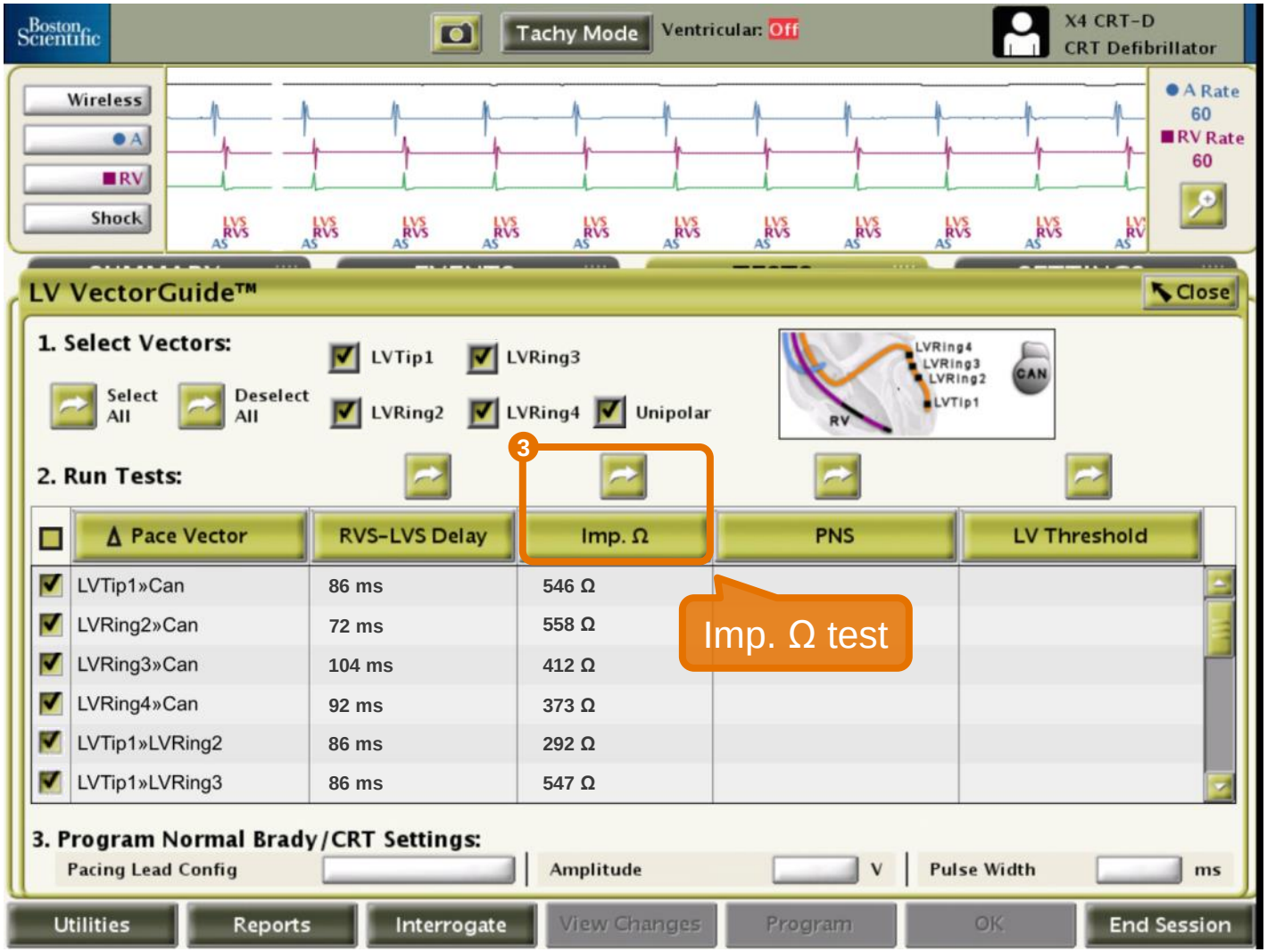
- Fully automatic test; takes 10-15 sec per cathode
- Consider eliminating cathodes with short RV-LV delays at this point

SmartAV Substudy

AHA - Nov. 2016
419 patients

RV-LV	% Responders
≤ 40 ms	33%
45-65 ms	58%
70-100 ms	63%
≥ 105 ms	82%

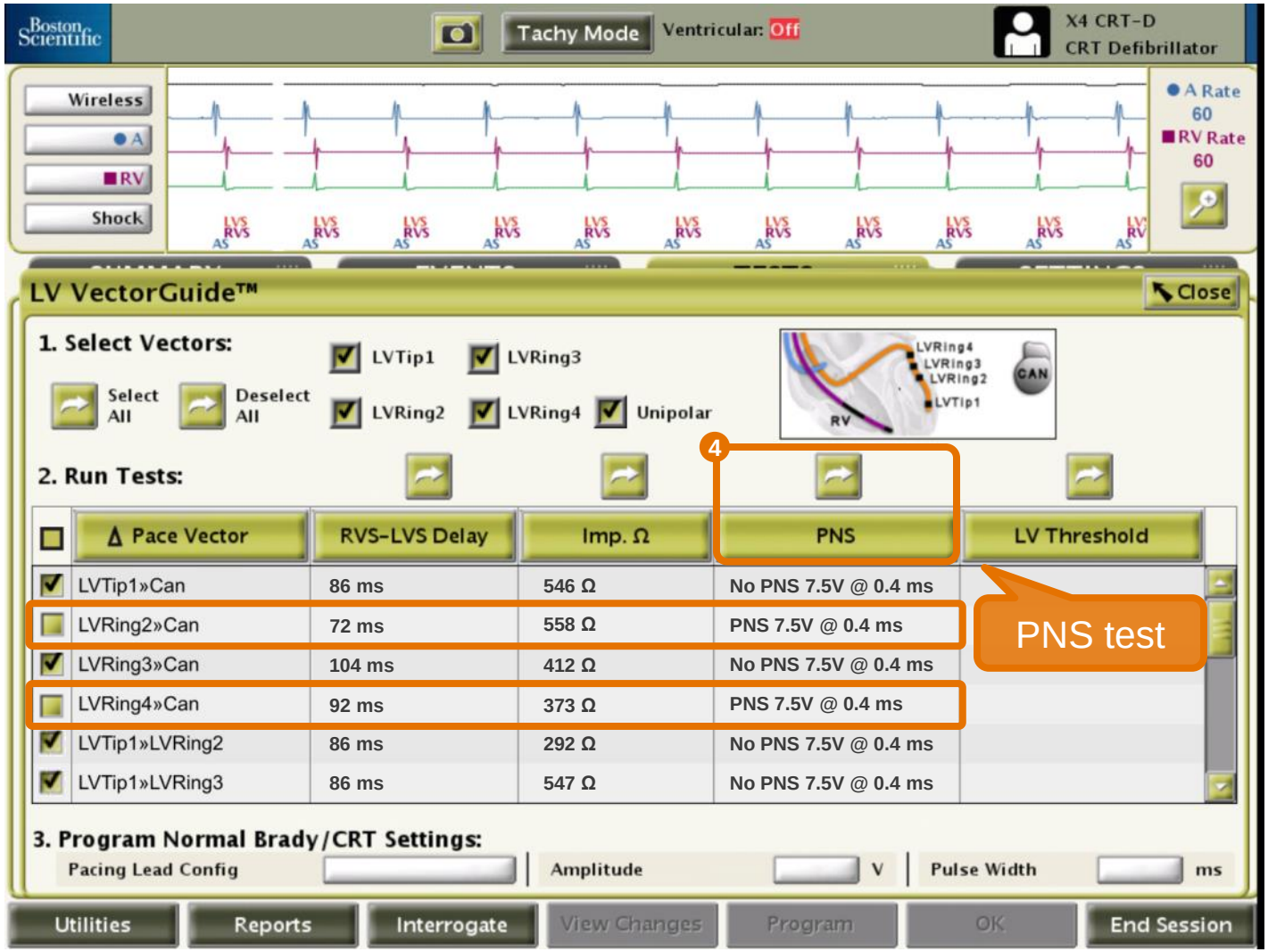
Impedance Test



Rules of thumb:

- Fully automatic test; takes about 1 second per vector
- Don't eliminate vectors based on impedance unless values are out of range
- Lowest labeled projected longevity is 7.4 years

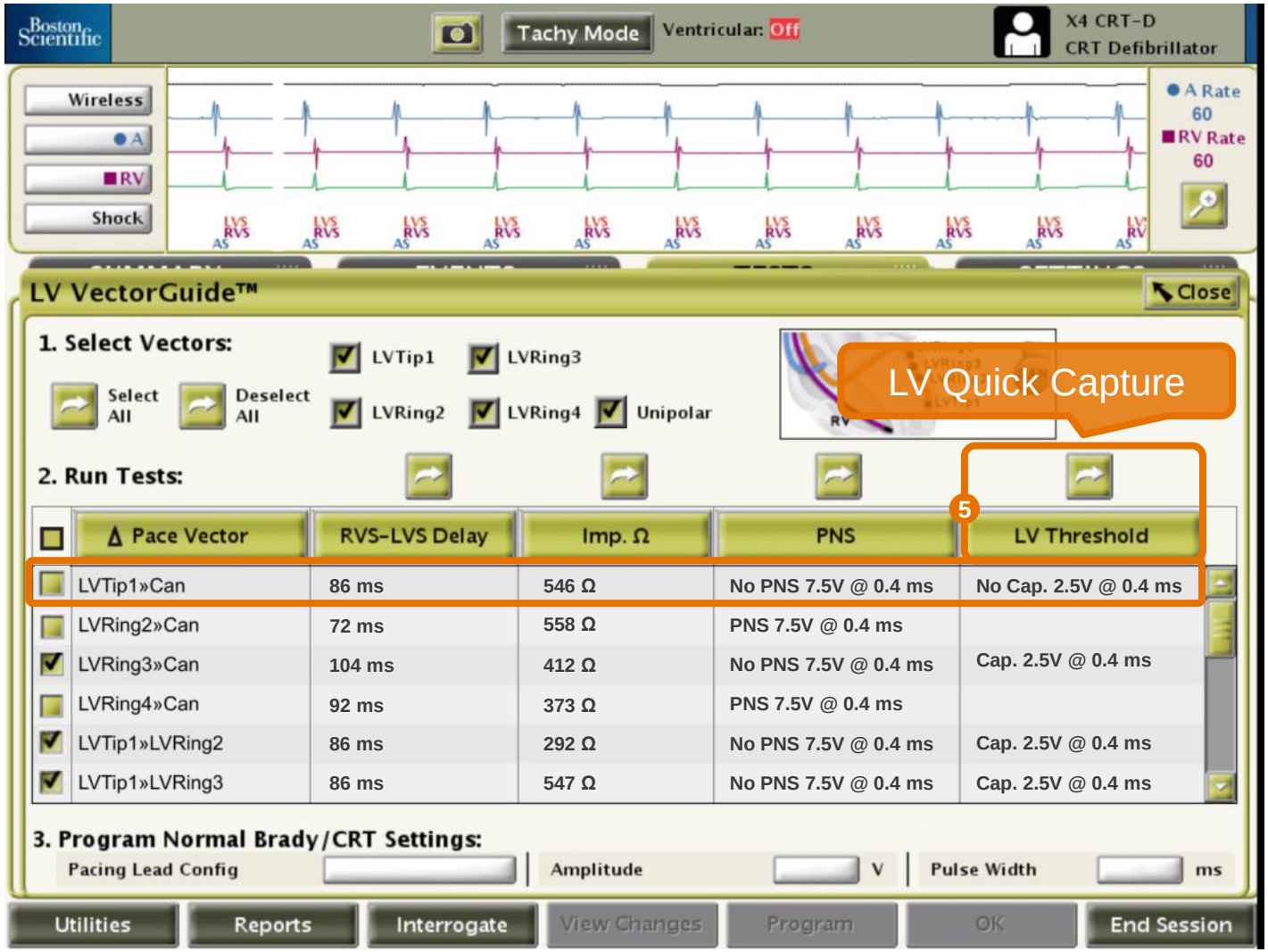
PNS Test



Rules of thumb:

- Nominal output is 7.5V at 0.4 ms
- Eliminate all vectors with PNS

LV Quick Capture Test

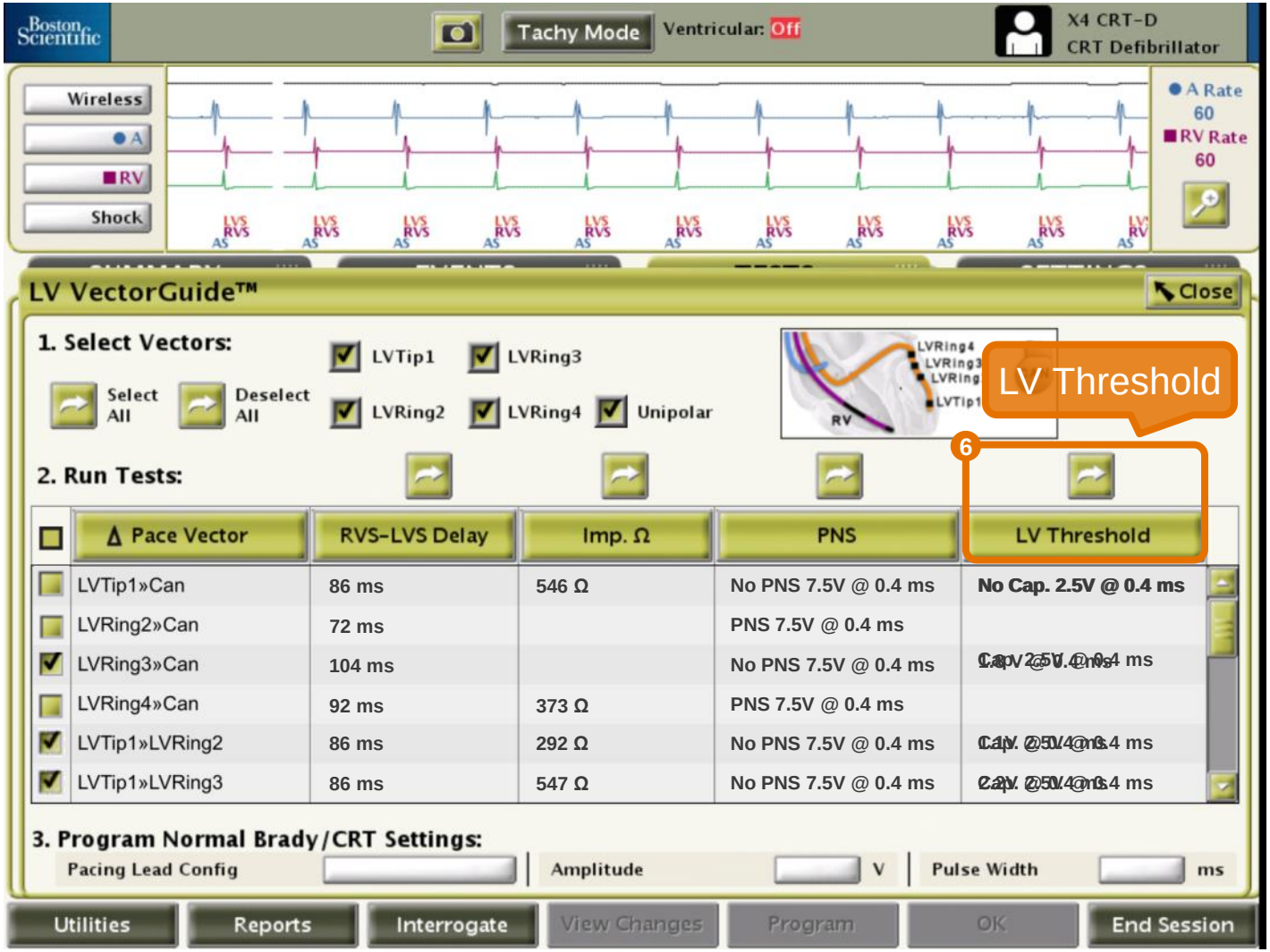


Rules of thumb:

- Quick capture nominal setting is 2.5V at 0.4 ms
- A targeted threshold ≤2.5V was achieved in 644 (94%) patients in the NAVIGATE X4 Study*

* MITTAL, S., NAIR, D., PADANILAM, B. J., et al. (2016), Performance of Anatomically Designed Quadripolar Left Ventricular Leads: Results from the NAVIGATE X4 Clinical Trial. J Cardiovasc Electrophysiol. doi:10.1111/jce.13044

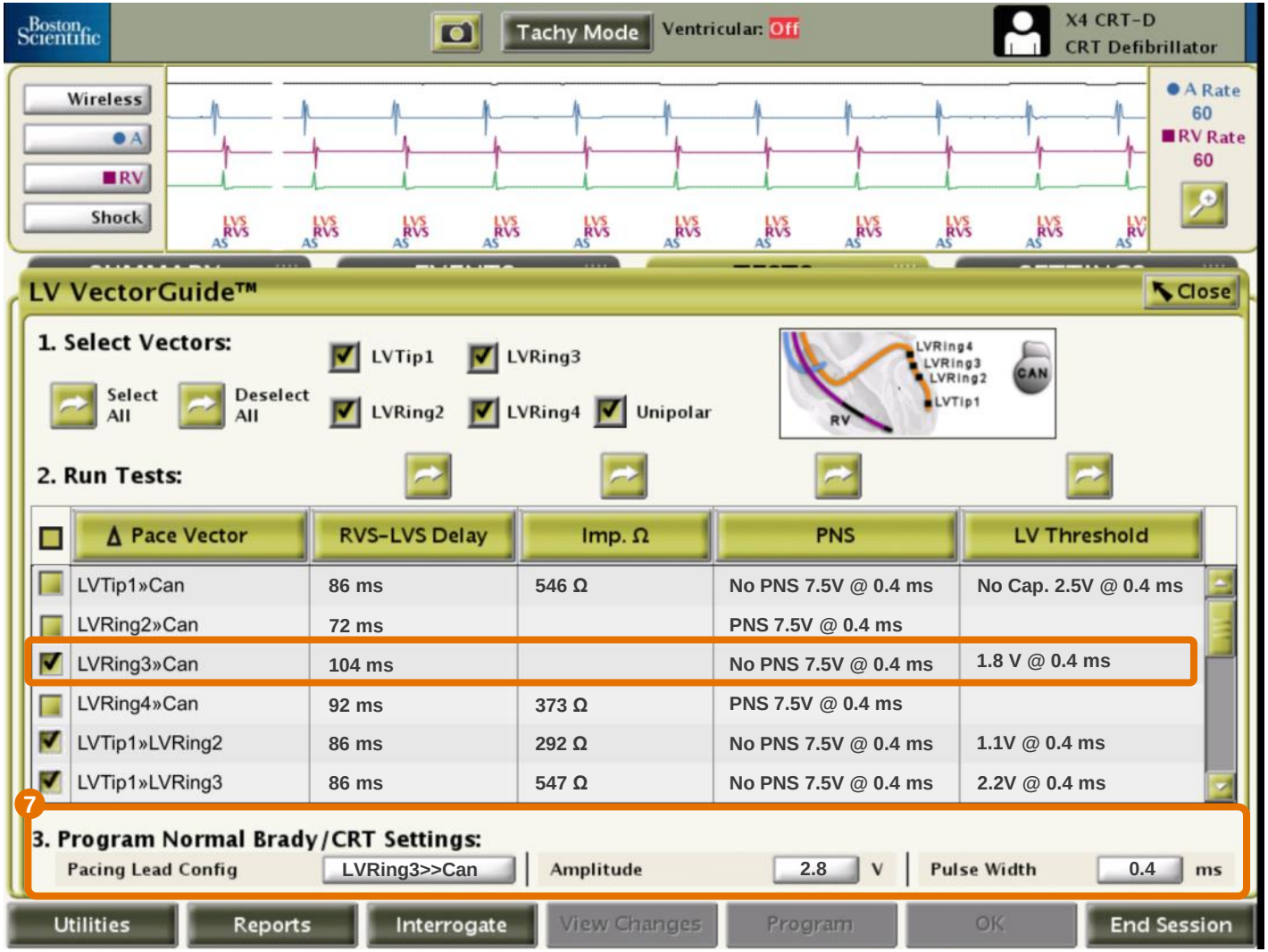
LV Threshold Test



Rules of thumb:

- If the Threshold test is not completed, PaceSafe will determine the pacing amplitude automatically if PaceSafe is set to “Auto”
- Lowest labeled longevity is 7.4 years

Programming



Rules of thumb:

Consider selecting pacing lead configuration based on longest RV-LV delay with no PNS instead of only considering low thresholds

RESONATE™, VIGILANT™ & MOMENTUM™ CRT-D Longevity Projections

Even with higher thresholds and MultiSite Pacing ON, the lowest labeled longevity is projected at 7.4 years, further reinforcing that RV-LV timing should be given priority.

Table 8. Pulse generator life expectancy estimation (implant to explant) with ENDURALIFE™ battery

All Models[a]						
Pacing				Longevity (years)		
Ventricular Chambers	RA/RV	LV	LVb[d]	500Ω with LATITUDE[b]	700Ω with LATITUDE[b]	700Ω with No LATITUDE, RS, or HFSS[c]
BiV	2.0V	2.0V	Off	11.3	11.9	13.0
BiV	2.0V	3.0V	Off	10.2	10.9	11.9
BiV	2.0V	3.5V	Off	9.5	10.4	11.2
BiV	2.5V	3.0V	Off	9.7	10.5	11.3
BiV	2.5V	3.5V	Off	9.1	10.0	10.8
BiV	3.5V	3.5V	Off	8.1	9.0	9.7
BiV MSP	2.0V	2.0V	2.0V	10.3	10.9	11.9
BiV MSP	2.5V	3.0V	3.0V	8.2	9.1	9.7
BiV MSP	2.5V	3.5V	3.5V	7.4	8.3	8.9
LV-Only	2.0V / Off	2.0V	Off	12.9	13.2	14.7
LV-Only	2.5V / Off	3.0V	Off	11.3	12.0	13.2
LV-Only	2.5V / Off	3.5V	Off	10.6	11.3	12.4
LV-Only MSP	2.0V / Off	2.0V	2.0V	11.5	12.1	13.3
LV-Only MSP	2.5V / Off	3.0V	3.0V	9.3	10.2	11.0
LV-Only MSP	2.5V / Off	3.5V	3.5V	8.3	9.3	10.0

a. Assumes ZIP telemetry use for 2 hours at implant and for 40 minutes annually for in-clinic follow-up checks.
b. Assumes standard use of the LATITUDE Communicator as follows: Daily Device Check on, quarterly scheduled remote follow ups, and other typical interrogations.
c. Assumes LATITUDE Communicator is not used, Respiratory Sensor is Off, and Heart Failure Sensor Suite is Off.
d. Applies to models with MultiSite Pacing (MSP).

* Physician's Technical Manual 360198-001 EN US 2016-10

Report

The LV VectorGuide™ Report documents any testing accomplished with LV VectorGuide software in that programming session.

- The report can be saved to a USB drive and either printed or saved to a patient's EMR.
- Once the programmer session is closed, the data is not retained for future sessions due to storage limitations.

Boston Scientific

ZOOM ® View™

LV VectorGuide™ Report

Report Created 10 Feb 2016

Date of Birth N/R N/R N/R
Device X4 CRT-D G179/ 268019AC7812624EFFFFFFF1
Tachy Mode Monitor + Therapy

Last Office Interrogation
10 Feb 2016
Implant Date
N/R

LV Pace Vector	RVS-LVS Delay	Impedance (200-2000 Ω)	PNS	LV Threshold
LVRing3>>LVRing2	84 ms	546 Ω	No PNS 7.5 V @ 0.4 ms	0.8 V @ 0.4 ms
LVRing3>>Can	84 ms	430 Ω	No PNS 7.5 V @ 0.4 ms	1.1 V @ 0.4 ms
LVRing3>>LVRing4	84 ms	546 Ω	No PNS 7.5 V @ 0.4 ms	Cap. 2.5 V @ 0.4 ms
LVRing3>>RV	84 ms	541 Ω	No PNS 7.5 V @ 0.4 ms	Cap. 2.5 V @ 0.4 ms
LVRing2>>Can	88 ms	430 Ω	No PNS 7.5 V @ 0.4 ms	No Cap. 2.5 V @ 0.4 ms
LVRing2>>LVRing3	88 ms	546 Ω	No PNS 7.5 V @ 0.4 ms	No Cap. 2.5 V @ 0.4 ms
LVRing2>>LVRing4	88 ms	547 Ω	PNS 7.5 V @ 0.4 ms	
LVRing2>>RV	88 ms	544 Ω	PNS 7.5 V @ 0.4 ms	
LVRing4>>Can	62 ms	430 Ω		
LVRing4>>LVRing2	62 ms	547 Ω		
LVRing4>>LVRing3	62 ms	546 Ω		
LVRing4>>RV	62 ms	541 Ω		
LVTip1>>Can	60 ms	430 Ω		
LVTip1>>LVRing2	60 ms	547 Ω		
LVTip1>>LVRing3	60 ms	546 Ω		
LVTip1>>LVRing4	60 ms	547 Ω		
LVTip1>>RV	60 ms	541 Ω		

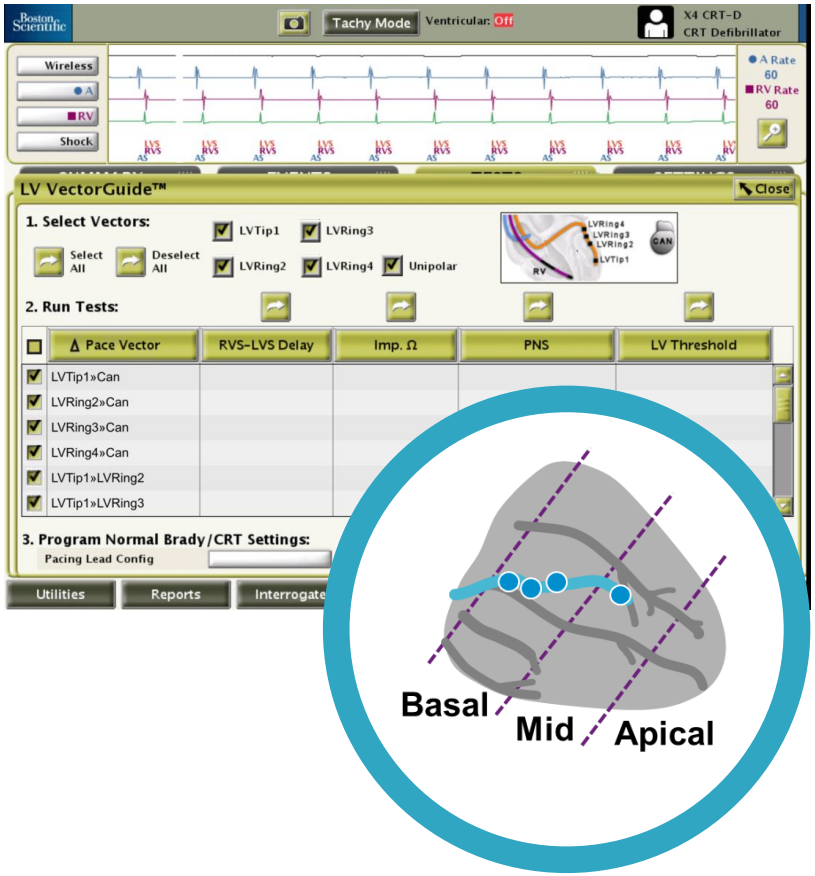
2868 Software Version: 3.05.33
G179 Firmware Version: E_v1.02.00(1.21)

Page 1 of 1

Clinician Signature:

LV VectorGuide™

- Site of Latest Activation
- RV-LV Clinical Data
- How to use LV VectorGuide™
- When to use LV VectorGuide™



When to Use LV VectorGuide™

Implant

- First opportunity to identify site of latest activation to maximize response

Pre-discharge

- Second opportunity to identify site of latest activation
- Confirm that implant settings are still valid

First in-hospital follow-up after implant

- Lead position stabilized
- Re-check RV-LV timing and if necessary adjust accordingly

Subsequent follow-ups

- Probably less frequent
- Responders likely require less reprogramming
- For sub-optimal responders, ensure optimal vector is chosen based on RV-LV timing

Remember that Boston Scientific CRT-Ds are powered by EnduraLIFE Battery Technology: **RV-LV timing should be the programming priority** – not thresholds

Powered by ENDURALIFE™ Battery Technology

Limitations

LV VectorGuide cannot be used to determine RVs-LVs intervals in **pacing dependent** patients:

- Intrinsic conduction is required
- LV VectorGuide can still be used to determine the best possible pacing vector:
  - »Impedance
  - »PNS
  - »Pacing threshold

According to one study of over 6400 patients, only 4% of CRT patients were pacing dependent

Comparative Effectiveness of Cardiac Resynchronization Therapy Among Patients With Heart Failure and Atrial Fibrillation

Findings From the National Cardiovascular Data Registry's Implantable Cardioverter-Defibrillator Registry

Prateeti Khazanie, MD, MPH; Melissa A. Greiner, MS; Sana M. Al-Khatib, MD, MHS; Jonathan P. Piccini, MD, MHS; Mintu P. Turakhia, MD, MAS; Paul D. Varosy, MD; Frederick A. Masoudi, MD, MSPH; Lesley H. Curtis, PhD; Adrian F. Hernandez, MD, MHS; for the National Cardiovascular Data Registry

Background—Atrial fibrillation is common in patients with heart failure, but outcomes of patients with both conditions who receive cardiac resynchronization therapy with defibrillator (CRT-D) compared with an implantable cardioverter-defibrillator (ICD) alone are unclear.

Methods and Results—Using the National Cardiovascular Data Registry's ICD Registry linked with Medicare claims, we identified 8951 patients with atrial fibrillation who were eligible for CRT-D and underwent first-time device implantation for primary prevention between April 2006 and December 2009. We used Cox proportional hazards models and inverse probability-weighted estimates to compare outcomes with CRT-D versus ICD alone. Cumulative incidence of mortality (744 [33%] for ICD; 1893 [32%] for CRT-D) and readmission (1788 [76%] for ICD; 4611 [76%] for CRT-D) within 3 years and complications within 90 days were similar between groups. After inverse weighting for the probability of receiving CRT-D, risks of mortality (hazard ratio, 0.83; 95% confidence interval, 0.75–0.92), all-cause readmission (hazard ratio, 0.86; 95% confidence interval, 0.80–0.92), and heart failure readmission (hazard ratio, 0.68; 95% confidence interval, 0.62–0.76) were lower with CRT-D compared with ICD alone. There was no significant difference in the 90-day complication rate (hazard ratio, 0.88; 95% confidence interval, 0.60–1.29). We observed hospital-level variation in the use of CRT-D among patients with atrial fibrillation.

Conclusions—Among eligible patients with heart failure and atrial fibrillation, CRT-D was associated with lower risks of mortality, all-cause readmission, and heart failure readmission, as well as with a similar risk of complications compared with ICD alone. (***Circ Heart Fail.* 2016;9:e002324. DOI: 10.1161/CIRCHEARTFAILURE.115.002324.**)

Key Words: atrial fibrillation ■ cardiac resynchronization therapy ■ heart failure ■ hospitalization ■ prevalence

Cardiac resynchronization therapy with defibrillator (CRT-D) improves survival and prevents hospitalizations in patients with symptomatic heart failure, reduced left ventricular ejection fraction, and prolonged QRS duration.[1-6] The prevalence of atrial fibrillation in this population is 25% to 50%, and many patients with concurrent heart failure and atrial fibrillation have reduced left ventricular ejection fraction with dyssynchrony. However, clinical practice guidelines designate CRT-D as a class IIa indication in patients with heart failure and atrial fibrillation who otherwise meet clinical criteria for CRT-D.[7,8]

See Clinical Perspective

It is unclear whether CRT-D is beneficial compared with an implantable cardioverter-defibrillator (ICD) alone.[9] Patients with atrial fibrillation are poorly represented in clinical trials of CRT-D, despite its common co-occurrence with heart failure. Randomized trials of CRT-D in heart failure have evaluated devices in only 272 patients with atrial fibrillation (3.6% of all patients).[10] Data from observational studies are also limited[11] but suggest that CRT-D is less beneficial in patients with atrial fibrillation.[9,12]

Received May 7, 2015; accepted April 28, 2016.

From the Duke Clinical Research Institute (P.K., M.A.G., S.M.A.-K., J.P.P., L.H.C., A.F.H.) and Department of Medicine (P.K., S.M.A.-K., J.P.P., L.H.C., A.F.H.), Duke University School of Medicine, Durham, NC; Veterans Affairs Eastern Colorado Healthcare System, Denver, CO (P.D.V.); University of Colorado Anschutz Medical Campus, Aurora, CO (F.A.M.); and Veterans Affairs Palo Alto Health Care System, Palo Alto, CA and Stanford University School of Medicine, CA (M.P.T.).

The Data Supplement is available at http://circheartfailure.ahajournals.org/lookup/suppl/doi:10.1161/CIRCHEARTFAILURE.115.002324/-/DC1.

Correspondence to Adrian F. Hernandez, MD, MHS, Duke Clinical Research Institute, PO Box 17969, Durham, NC 27715. E-mail adrian.hernandez@duke.edu

Circ Heart Fail **is available at http://circheartfailure.ahajournals.org** **DOI: 10.1161/CIRCHEARTFAILURE.115.002324**

*DOI: 10.1161/CIRCHEARTFAILURE.115.002324

Conclusion

- Pacing from the site of latest activation is important to attaining CRT Response
- RV-LV timing is a simple way to find the site of latest activation on ACUITY™ X4 Quadripolar LV leads
- LV VectorGuide™ offers a fully automatic test for quickly measuring RV-LV timing on all 17 vectors
- LV VectorGuide™ can be used at implant, pre-discharge, and at follow-up as a way to optimize patient programming
- EnduraLIFE™ Battery Technology enables clinicians to prioritize a pacing site based on site of latest activation without worrying about finding the lowest threshold

Powered by ENDURALIFE™ Battery Technology

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.

CRM-449301-AA JAN2017

smart solutions | **PROVEN TO LAST**