The challenges of CRT Optimization

Boston Scientific

Reducing the risk of replacement

>60% of CRT-D patient survival at 5 years[1],
but not all ***battery technologies*** have the same performance over time

Maximizing CRT response

Non-Apical pacing is associated with ***better CRT outcome[2]***
versus Apical pacing, but is harder to achieve without ***dedicated lead design***

Longer RVS-LVS interval has shown ***improved CRT response[3]***,
but a ***measurement*** is needed for each patient due to conduction variability

1 Saxon, Leslie A.; Hayes, David, L; Gilliam, F. Roosevelt, et al . Long-Term Outcome after ICD and CRT Implant and the Influence of Remote Device Follow-up: The ALTITUDE Survival Study. Circulation, December 2010. Accessed from http://circ.ahajournals.org/ on December 1, 2010. 2. 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. *Adjusted significant p-value 3. Gold M. et al. The Role RV-LV Delay to Predict Time to First Heart Failure Hospitalization and Mortality with Cardiac Resynchronization Therapy. ESC 2014.

2

A Tailored Approach to CRT Optimization

Reducing the risk of replacement

Unmatched device longevity shown in independent real-world studies[1]

Maximizing CRT response

Acuity X4 family of leads for more non-apical pacing options

VectorGuide™ one-click test to help you identify the longest RVS-LVS interval

1 Saxon, Leslie A.; Hayes, David, L; Gilliam, F. Roosevelt, et al . Long-Term Outcome after ICD and CRT Implant and the Influence of Remote Device Follow-up: The ALTITUDE Survival Study. Circulation, December 2010. Accessed from http://circ.ahajournals.org/ on December 1, 2010

What is the need for long-lasting CRT-D devices?

- **What are the risks associated with device replacements?**
- **What would be the clinical benefit of a CRT-D that lasts 8-10 years instead of a CRT-D that lasted 4-5 years?**

- ✓ Compared to a first implant, the cumulative incidence of surgical re-intervention following device replacement is 2.5 times higher – and goes up to 7-9% (Borleffs 2010)[1]
- ✓ 30% of device related infections could be avoided if device batteries lasted at least 9 years (Ramachandra 2010)[4]

1 Borleffs Recurrent Implantable Cardioverter-Defibrillator Replacement Is Associated with an Increasing Risk of Pocket-Related Complications.
2 Lekkerkerker, J.C. et al. Risk Factors And Time Delay Associated With Cardiac Device Infections. HEART 2009; 95:715-720 .
3 Tarakji, Khaldoun G. et al. Cardiac Implantable Electronic Device Infections: Presentation, Management and Patient Outcomes. Heart Rhythm Aug 2010; 7:1043-1047
4 Ramachandra I. PACE 33: 314-310, March 2010. Impact of ICD Battery Longevity on Need for Device Replacements—Insights from a Veterans Affairs Database.

ENDURALIFE™ Battery Technology[1]

Capacity
High battery capacity is nearly double the standard capacity of other ICDs and CRT-Ds.[2]

Chemistry
Li/MnO2 chemistry maintains stable Operating voltage and internal resistance for more effective battery utilization.[3]

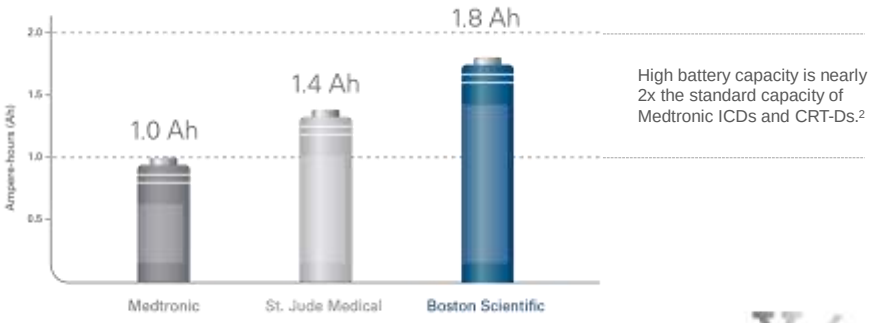
Efficiency
Advanced manufacturing capabilities enable a device that is up to 11% smaller and 24% thinner with nearly twice the capacity than other manufacturers.[4]

Powered by ENDURALIFE Battery Technology

1. EnduraLife™ Battery Technology is featured in X4 CRT-Ds and EL ICDs, as well as Cognis, Teligen, Punctua, Energen, Incepta ICDs and CRT-Ds.
2. Boston Scientific ICDs and CRT-Ds with contemporary battery technology have 1.8 Ah. Medtronic ICDs and CRT-Ds have 1.0 Ah. 3. Data on file at Boston Scientific Corporation.
4. Boston Scientific Physician's Technical Manual for X4 CRT-D and CRT-D 359059-019 EN Europe 2013-04and for EL ICDs and MINI ICDs 359060-001 EN Europe 2013-04 page 28. PROTECTA™ XT VR D314VRM 2013 page 330. EVERA™ XT VR DVBB1D4 2013 page 24. AnalyST™, AnalyST Accel™, Current™, Current Accel™, Fortify™, Fortify™ ST, Promote™, Promote Accel™, Promote™ Q, Unify™ Devices User's Manual 2013 page 29. St. Jude Medical™ High-Voltage Devices User's Manual 2013 page 16.

Capacity

ENDURALIFE Battery Technology has the largest battery capacity in the industry.[2]



High battery capacity is nearly 2x the standard capacity of Medtronic ICDs and CRT-Ds.[2]

OVERVIEW | CAPACITY | CHEMISTRY | EFFICIENCY

ENDURALIFE Battery Technology

REFERENCES

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A Unique two-step approach for maximizing CRT response (1/2)

Boston Scientific

1

More effective pacing options in a non-apical location

- **MADIT CRT and other studies have shown that most patients benefit from non-apical pacing[1]**

Acuity X4 Family of leads offers three options to **select the most suitable LV lead**

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.

1

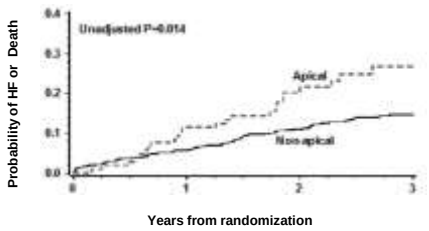
"Apical pacing should be avoided in CRT"

Circulation
JOURNAL OF THE AMERICAN HEART ASSOCIATION

Left Ventricular Lead Position and Clinical Outcome in MADIT-CRT Trial.
Singh J. et al., Circulation, 2011[1]

↑72%
Increased risk for HF/death with apical pacing[1]

Probability of survival free of heart failure or death



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. *Adjusted significant p-value

1

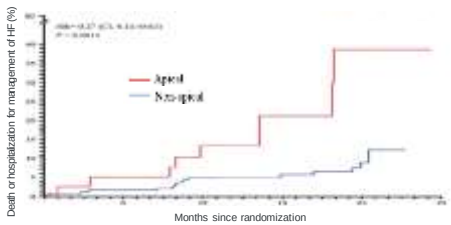
"Position of the RV lead tip was indifferent"

EUROPEAN SOCIETY OF CARDIOLOGY®

Sites of LV and RV lead implantation and response to CRT observations from REVERSE trial.
Thebault C et al., European Heart Journal, 2012[1]

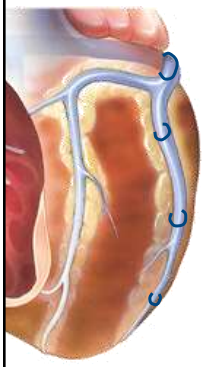
↑73%
Increased risk for HF/death with apical pacing[1]

Probability of survival free of heart failure or death



1. Thebault C et al. Sites of left and right ventricular lead implantation and response to cardiac resynchronization therapy observations from the REVERSE trial. Eur Heart J 2012;33:2662–2671. *Defined as proportion of patients whose LVESVi had decreased by ≥15% at 12 months

1 The challenges of Non-Apical pacing



	Challenges			
	Threshold[1]	Stability	PNS[2]	Patient Outcome[3]
Non-Apical	Worse capture (poor electrode-myocardial contact)	Higher risk of dislodgement	Better	Better
Apical	Better capture (close electrode-myocardial contact)	Lower risk of dislodgement	Worse	Worse

Non-Apical pacing locations, which shown to have **better clinical outcomes**, may be harder to achieve in the implant setting.

1. Dan Blendea, MD, PhD, Variability of coronary venous anatomy in patients undergoing cardiac resynchronization therapy: a high-speed rotational venography study, Heart Rhythm, Vol 4, No 9, September 2007.
2. Occurrence of phrenic nerve stimulation in cardiac resynchronization therapy patients: the role of left ventricular lead type and placement site.
3. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy - European Heart Journal doi:10.1093/eurheartj/eht150

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1 More effective pacing options in a non-apical location

Long veins

ACUITY™ X4 Spiral L

Short veins

ACUITY™ X4 Spiral S

Narrow or tortuous veins

ACUITY™ X4 Straight

The Acuity™ X4 family of LV leads offers different electrode spacing to **accommodate individual anatomy** and to help you **pace at your target location**

Photos taken by Boston Scientific

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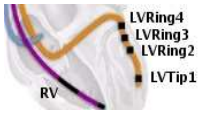
A Unique two-step approach for maximizing CRT response (2/2)

Boston Scientific

2

A one-click test to identify the longest RVS-LVS electrical delay

- **Patients ventricular activation patterns may vary considerably**
- **Longer electrical delay at pacing site has shown to reduce HF hospitalization and increase the number of responders[1]**



VectorGuide™ tool offers a one-click test to **target the most appropriate electrode**

One additional click for a potential lifetime benefit

1. Khan FZ et al. Targeted left ventricular lead placement to guide cardiac resynchronization therapy: the TARGET study: a randomized, controlled trial. J Am Coll Cardiol 2012;59:1509–1518
2. Boston Scientific Reference Guide for X4 CRT-D and CRT-D 359209-001 EN Europe 2013-04. AUTOGEN X4 reference guide supplement (part# 359386-001)

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2

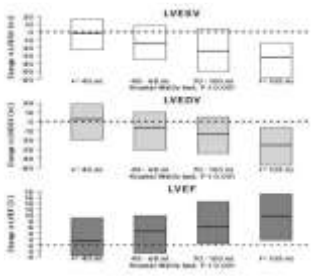
Longer RVS-LVS interval at pacing site: independent predictor of CRT response?

Boston Scientific

Gold M. et al. ESC 2014 *(n=419)*[1]

Longer RVS-LVS was an independent predictor of structural responses to CRT

Response rates varies from 30% to 75% (quartiles 1 and 4 respectively)

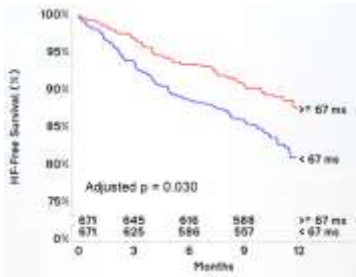


The changes in LVESV, LVEDV and LVEF responses from implant to 6 months for RV-LV quartiles.

Gold M. et al., ESC 2014 (*n=1342*)[2]

30%

Reduction of risk of HF hospitalization or death associated with longer RVS-LVS delay



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

1. Gold M. et al. The Relationship Between RV-LV Delay and Left Ventricular Reverse Remodeling With Cardiac Resynchronization Therapy. ESC 2014. Patients were grouped by RV-LV quartiles with cutoffs of 40, 65 and 100 ms. Response rates by quartile were 30%, 49%, 59% and 75% respectively.
2. Gold M. et al. The Role RV-LV Delay to Predict Time to First Heart Failure Hospitalization and Mortality with Cardiac Resynchronization Therapy. ESC 2014.

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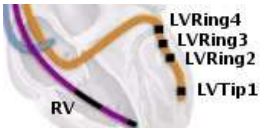
2 One click test to identify the longest RVS-LVS electrical interval

Boston Scientific

2. Run Tests:

Pace Vector	RVS-LVS Delay
LVTip1»Can	60 ms
LVRing2»Can	88 ms
LVRing3»Can	84 ms
LVRing4»Can	62 ms



VectorGuide™ is designed to **quickly identify** the best of 17 vectors options based on **clinically relevant tests including RVS-LVS delay**

* Example of RVS-LVS delay test results from a Rally X4 Study patient. Data on file

Boston Scientific Reference Guide for X4 CRT-D and CRT-D 359209-001 EN Europe 2013-04. AUTOGEN X4 reference guide supplement (part# 359386-001)

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X4
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Now with VectorGuide™
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