SmartDelay™

Part One

Past, Present, and Future:
The Development and Evolution

SmartDelay™ within SmartCRT™

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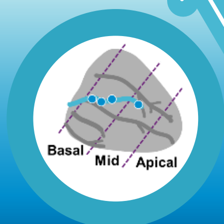
SmartCRT™ is Boston Scientific's approach to personalize CRT therapy by providing physicians with smart solutions to optimize **where**, **when**, and **how** to pace

SmartCRT™

Where
to pace

Site of latest activation



ACUITY™ X4 VectorGuide
17 vectors, RV-LV delay

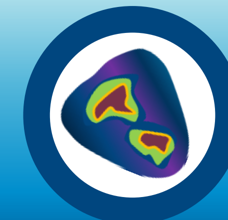
When
to pace

Maximize global contractility

SmartDelay™
Sensed and paced AV Delay
BiV or LV Only

How
to pace

Options to maximize response



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 LV-Only MSP, RA @ 2.0V, LVa @ 2.0V, LVb @ 2.0V, No LATITUDE™, No MV/Respiratory Sensor, No Heart Failure Sensor Suite.

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Back to the Basics

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Cardiac Output = Stroke Volume × Heart Rate

Stroke Volume is a function of:

Filling Pressure / Volume
Preload

Arterial Pressure
Afterload

Contractility

The standard for measuring **global contractility is dP/dt_{max}** because it's a direct, invasive, reliable measurement for evaluating cardiac performance

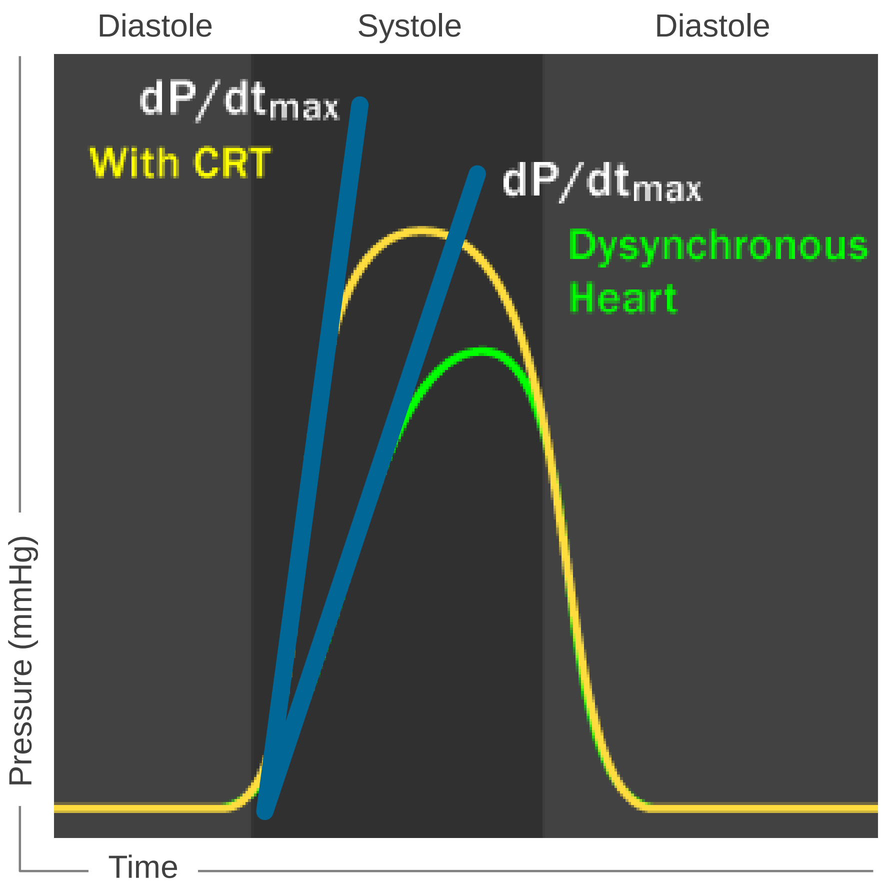
Berne RM and Levy MN Cardiovascular Physiology 7th ed. Mosby-Year Book, Inc. © 1997
Mohrman ED and Heller LJ Cardiovascular Physiology 5th ed. Lange Medical Books / McGraw-Hill © 2003

What Is LV dP/dt_{max}?

- **dP/dt_{max}** = maximal rise in LV pressure as the heart contracts and is typically measured invasively with a pressure catheter in the LV
- A strong, efficient heart will have a quicker and higher rise in LV pressure, and thus, a higher dP/dt_{max}

$$\frac{dP}{dt} = \frac{\text{delta P}}{\text{delta t}} = \frac{\text{Change in Pressure}}{\text{Change in Time}}$$

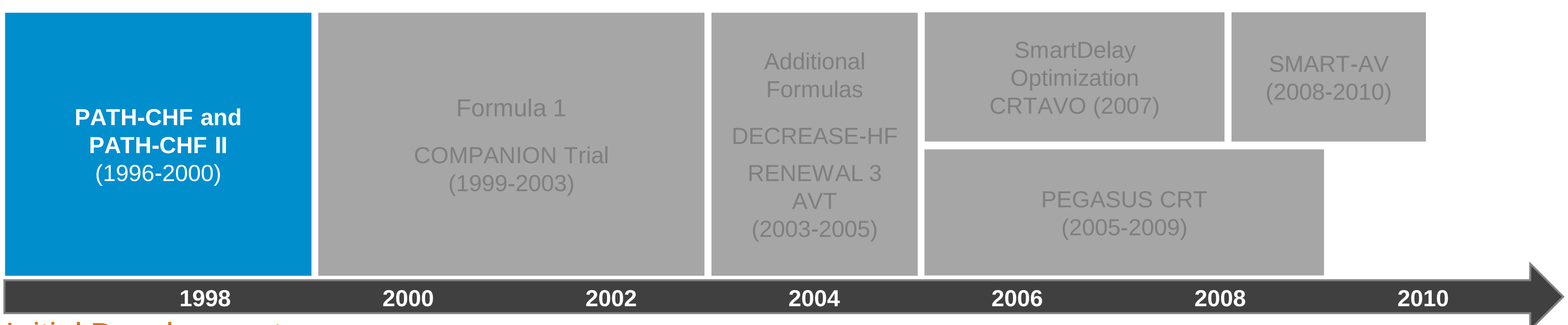
Steepest Slope = dP/dt_{max}



Development and Evolution

SmartDelay, a proprietary feature of Boston Scientific, is the result of many years of continuous research and development in CRT optimization

- In the PATH-CHF and PATH-CHF II trials[1],[2], patients were BiV/LV paced while an LV pressure catheter was inserted to determine peak dP/dt_{max} measurements over a range of AV Delays
- Also collected were the patients' intrinsic AVR (AS to RVS) intervals and QRS durations
- A mathematical analysis determined a relationship between AVR, QRS, and peak dP/dt_{max}

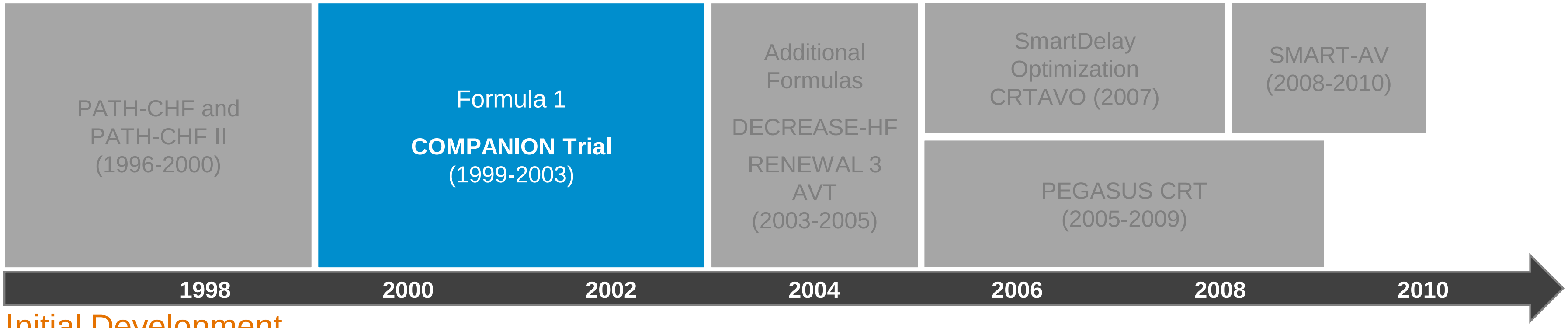


Initial Development

[1] Auricchio A, et al. The pacing therpapies for congestive heart failure study, rationale design, and endpoints of a prospective randomized multicenter study. *Am J Card*. 1999;83(5):130-135.
[2] Auricchio A, et al. Effectof pacing chamver and atrioventricular delay on acute systolic function of paced patients with congestive heart failure. *Circulation*. 1999;99:2993-3001.

Development and Evolution

An early form of the equations developed from the PATH trials was used in the COMPANION[3,4] Trial for programming AV Delay



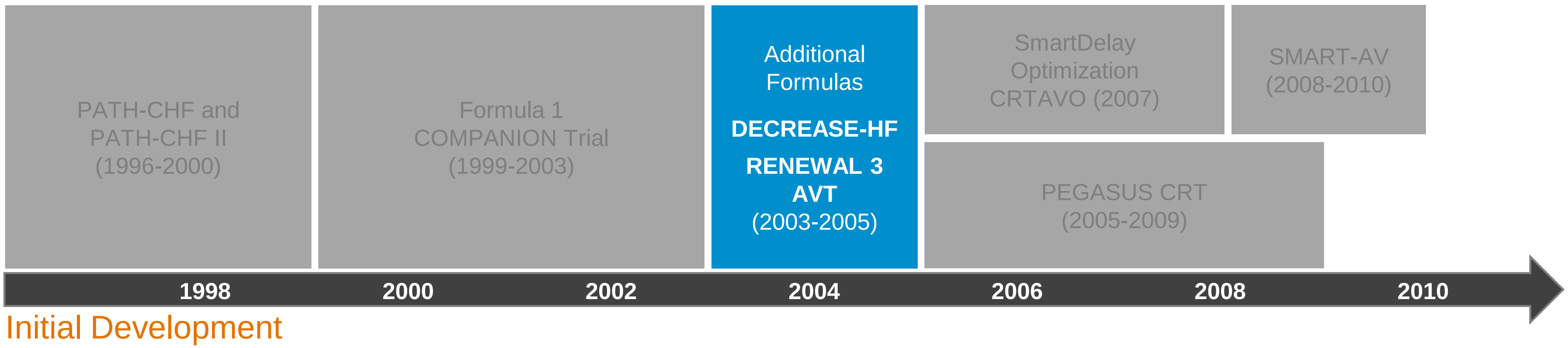
Initial Development

[3] Bristow MR et al. *J Card Fail* 6: 276-285., 2000.
[4] Bristow MR et al. *N Engl J Med* 350: 2140-2150, 2004

SmartDelay™

Development and Evolution

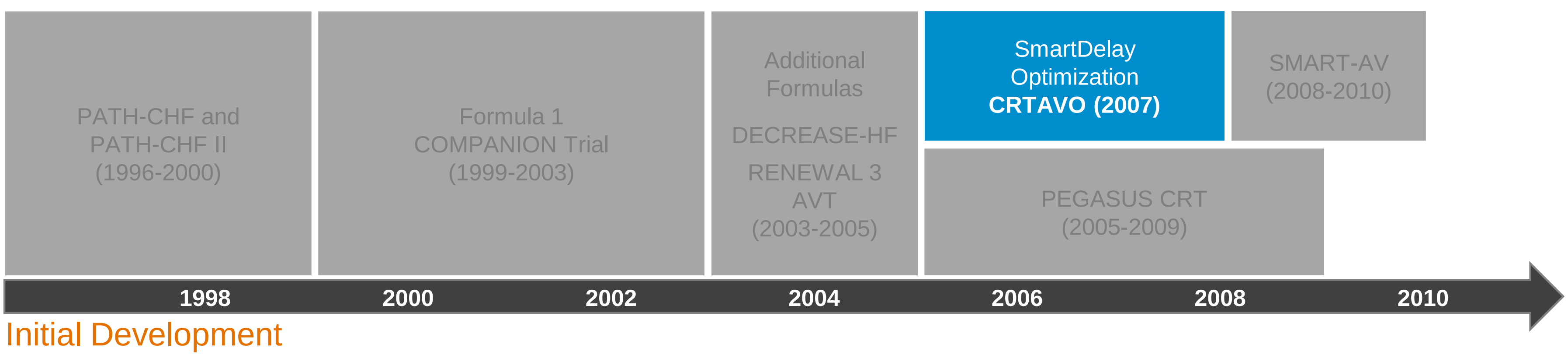
- As the algorithm evolved, several versions were used for recommending AV Delays in clinical trials such as DECREASE-HF[5,6] and RENEWAL 3 AVT[7]
- DECREASE-HF used a formula of 3 different QRS durations and 2 different sets of coefficients depending on LV lead location (Anterior or Free Wall)



[5] De Lurgio DB et al. *J Card Fail* 11: 233-239, 2005.
[6] Rao RK et al. *Circulation* 115: 2136-2144, 2007.
[7] Saxon LA et al. *J Cardiovasc Electrophysiol* 17: 520-525, 2006.

Development and Evolution

- The current SmartDelay algorithm was prospectively tested in the CRTAVO[8] study; the algorithm uses the QRS duration as a continuous variable in determining optimal AV Delays based on patients' native and paced conduction times, not using fixed offsets
- Using an invasive catheter to measure dP/dt_{max} the study compared several AV Delay optimization methods
- SmartDelay was FDA approved in 2008 using the CRTAVO study data which verified that the algorithm's recommendations strongly correlated with invasive dP/dt_{max} in maximizing LV contractile function

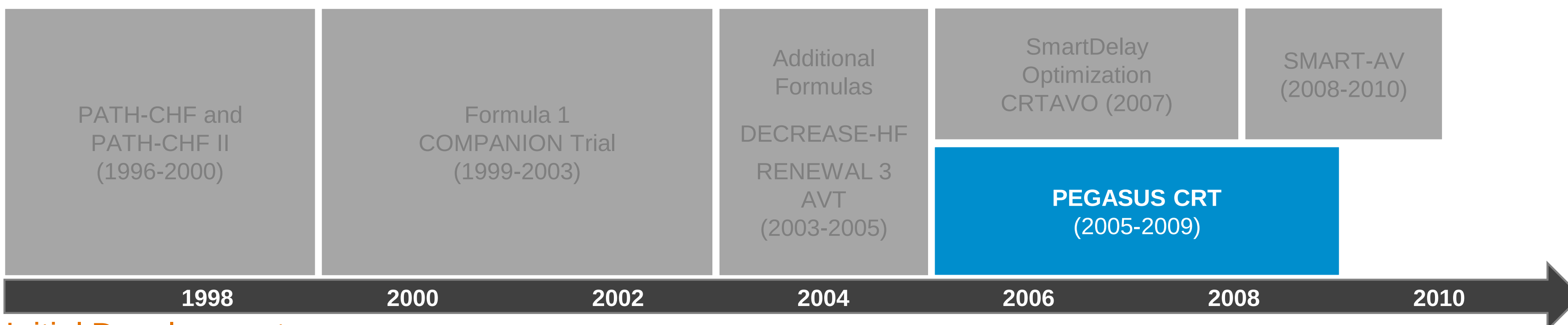


[8] Gold et al. *J Cardiovasc Electrophysiol* (2007) v18:490-496.

SmartDelay™

Development and Evolution

- SmartDelay was used in the PEGASUS CRT[9] study which was designed to evaluate the effects of atrial support pacing in approximately 1400 advanced HF patients
- Additional sub-analysis of 1342 patients enrolled in PEGASUS demonstrated that patients with longer RV-LV delay had an absolute reduction of 6.4% in HF hospitalization and death at 12 months as compared to shorter RV-LV delay[10]
- RV-LV delay can be easily measured at implant and follow-up in Boston Scientific devices and may provide a simple means of selecting optimal LV stimulation site

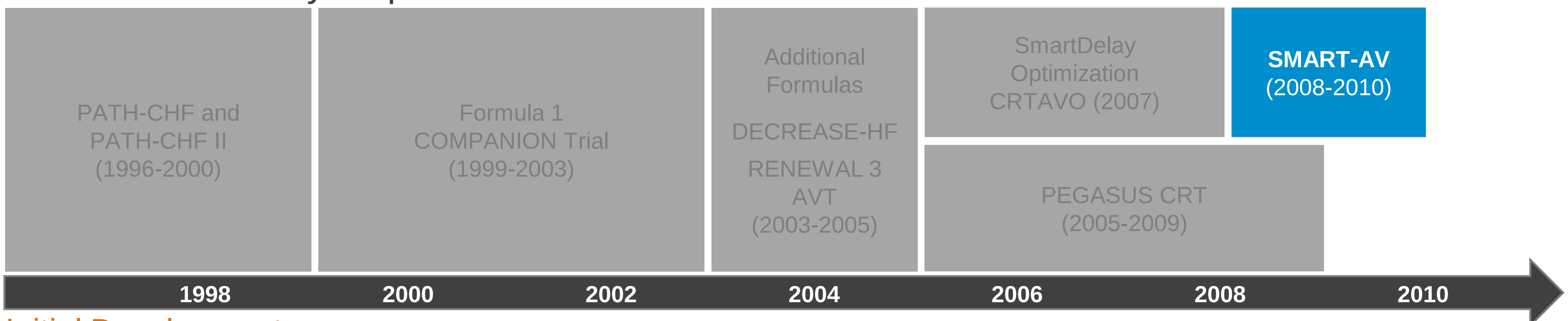


Initial Development

[9] Martin DO et al. *J Cardiovasc Electrophysiol* (23) 1317-1325, 2012
[10] Gold M, et al,, HRS Poster 2016

Development and Evolution

- Primary results in the SMART-AV trial in 2010 showed that neither SmartDelay nor echo was superior to a fixed AV Delay of 120ms[11]
- Furthermore, during 2013 sub-analysis, when QLV was measured from onset of QRS to peak of LV EGM, if QLV was >70ms SmartDelay had more than 2-fold increase in likelihood of a LVESV response, and at QLV >120ms, SmartDelay had more than a 6-fold increase[12]
- 2016 sub-analysis demonstrated that baseline electrical dyssynchrony, as measured by RV-LV duration, predicts reverse remodeling response, defined as a >15ml reduction in LVESV[13]; 82% of patients with RV-LV duration ≥ 105ms responded using SmartDelay, based on the absolute reduction in LVESV of > 15ml, whereas only 62% of patients with Fixed AV Delay responded[14]



Initial Development

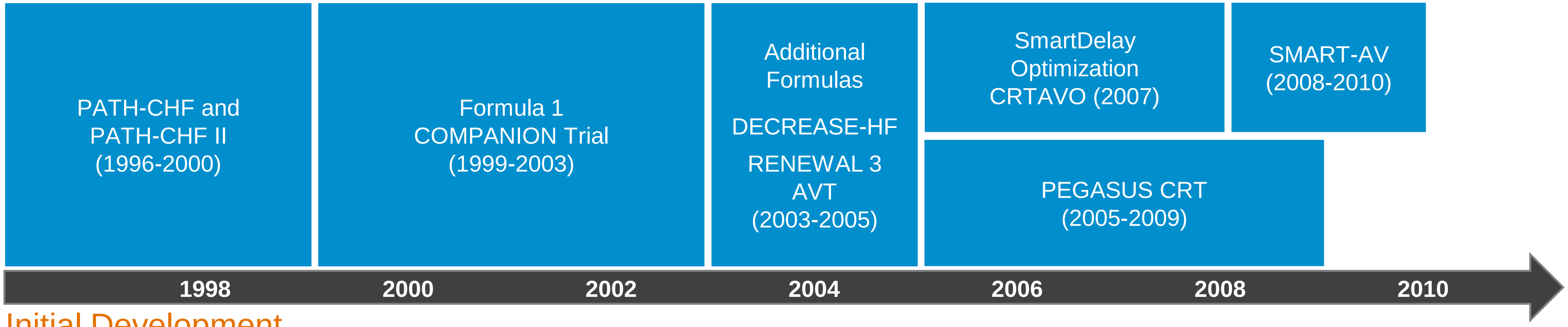
[11] Ellenbogen et al. *Circulation* 122:2660-2668, 2010
[12] Gold M., et al. *Heart Rhythm* 2013
[13] Gold M., et al. *JACC* EP 2016
[14] Gold M., et al. *AHA* Abstract 2016

SmartDelay™

Development and Evolution

Over 4000 patients in Boston Scientific trials have had an AV Delay recommended based on a formula that was used in the development of SmartDelay

- COMPANION (1999-2003) 1200+ patients
- RENEWAL 3 AVT Study (2003-2005) 130+ patients
- DECREASE-HF (2003-2005) 300+ patients
- PEGASUS CRT (2005-2009) 1700+ patients
- SMART-AV (2008-2010) 1000+ patients



Initial Development

2017 Clinical Study: **SMART CRT**

Boston Scientific plans to begin the SMART CRT clinical study in 2017

Study Objective	Estimated Enrollment	Estimated Study Start Date
To test the hypothesis that SmartDelay™ will produce a significantly greater reduction in left ventricular end systolic volume (LVESV) when compared to a fixed AV Delay in heart failure patients with an RV-LV ≥ 70ms	726	March 2017

SmartDelay™

Part Two

Technical Overview and Programming

smart solutions | PROVEN TO LAST

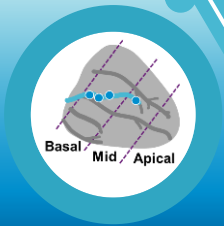
SmartDelay™ within SmartCRT™

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

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

Options to maximize response

MultiSite Pacing
Single Site or MultiSite pacing

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1. Assumes LV-Only MSP, RA @ 2.0V, LVa @ 2.0V, LVb @ 2.0V, No LATITUDE™, No MV/Respiratory Sensor, No Heart Failure Sensor Suite.

SmartDelay™

Patient Type:

Not intended for patients with complete AV Block, atrial or ventricular tachycardia, narrow QRS (<120 ms)

Recommendation of Nominal values likely to occur if:

- Intrinsic ventricular rate < 40bpm
- Atrial fibrillation in progress
- Frequent PACs / PVCs
- Ventricular rates > MTR
- Noise

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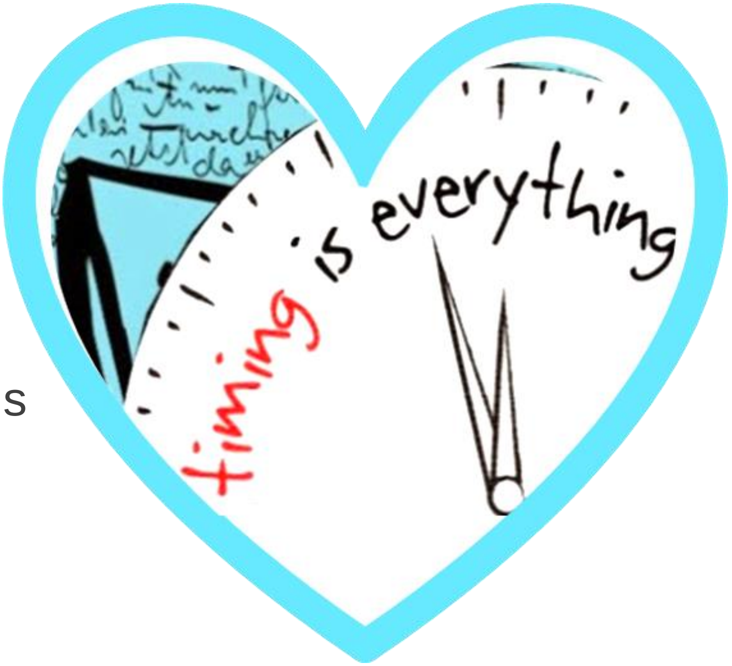
Empiric Programming

When an AV Delay is programmed …

Too Long	Too Short
Reduces atrial contribution to ventricular filling by shortening diastolic filling time	Can abruptly terminate late diastolic filling (“atrial kick”) due to onset of LV contraction
Reduces ventricular synchrony	Limits the contribution of atrial systole to ventricular filling period, i.e., loss of stroke volume (surrogate of pulse pressure)
Potential mitral regurgitation and loss of stroke volume (surrogate of pulse pressure)	Atrial contraction against closed mitral valve
	Eliminates fusion with global contraction of the intact portion of the conduction system
Results in reduction of LV dP/dt	Results in reduction of LV dP/dt

Principle of Fusion

- **SmartDelay** recommends AV Delays that maximize left ventricular contractility by promoting timed fusion of the intrinsic activation and the pacing stimuli
- Data shows that the critical event in CRT is timing of the left ventricular stimulation[1]



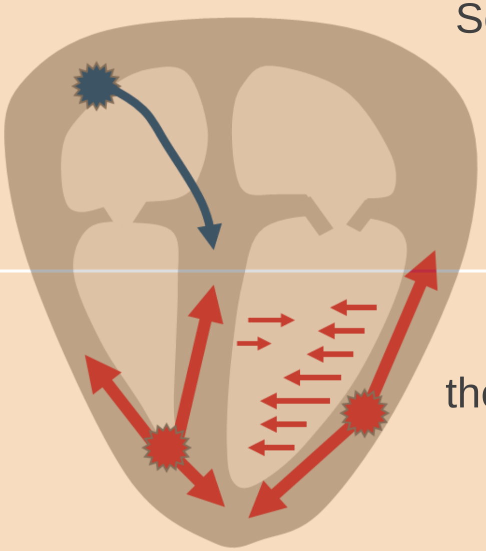
[1] Brabham W W, et. al. The role of AV and VV optimization for CRT. *Journal of Arrhythmia* 2013;29:153-161.

SmartDelay™

Fusion of Activation Waves

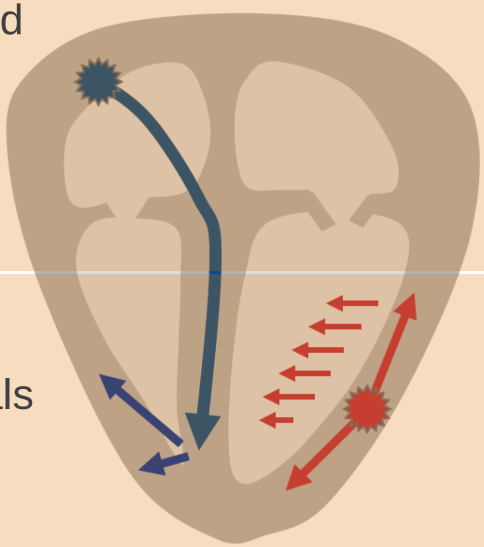
Fusion = the collision of activation wave fronts

For example: the electrical wave from intrinsic activation (blue) can collide with electrical waves from BIV pacing (red)



Sometimes longer than perhaps expected AV Delays are suggested by SmartDelay to allow for intrinsic right bundle activation to fuse with LV pacing

SmartDelay uses measurements from the A-RVs intervals and the A-LVs intervals to suggest paced and sensed AV Delays and chamber(s) to pace



Shorter AV Delay
results in more activation from BIV pacing stimuli

Longer AV Delay + LV-only pacing
fusion of wave fronts

Measurement and Calculation: **A to V Intervals**

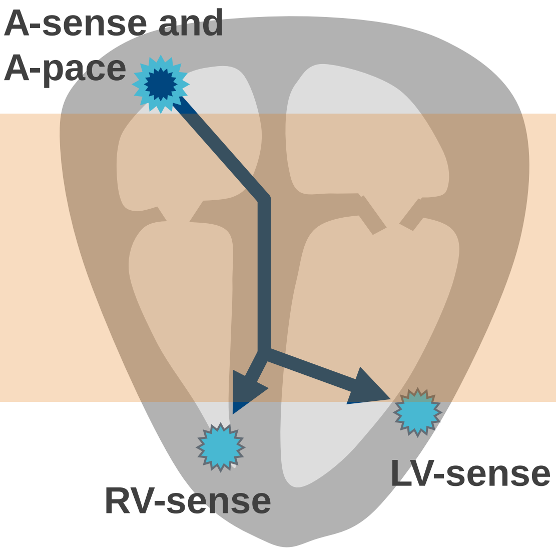
SmartDelay inputs:

1) Intrinsic and paced A to V intervals (ARV and ALV)

2) RVs-LVs derived from sensed ARV and sensed ALV
ΔL-R = ALV-ARV

Device determines:
- As to RVs
- As to LVs*
- Ap to RVs
- Ap to LVs*

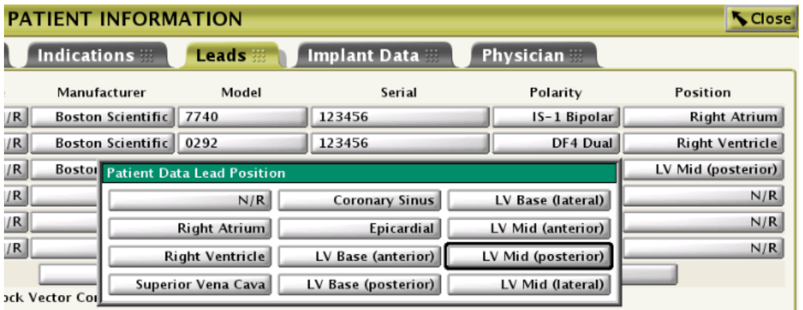
** Will always measure LV sensing from LV cathode to can*



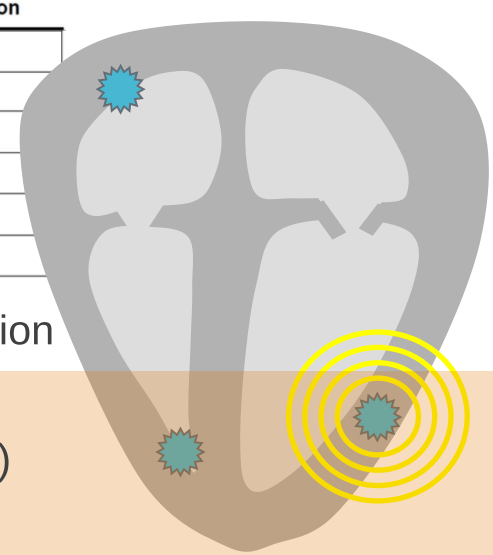
Measurement and Calculation: **Lead Location**

SmartDelay inputs:

3) LV Lead Location



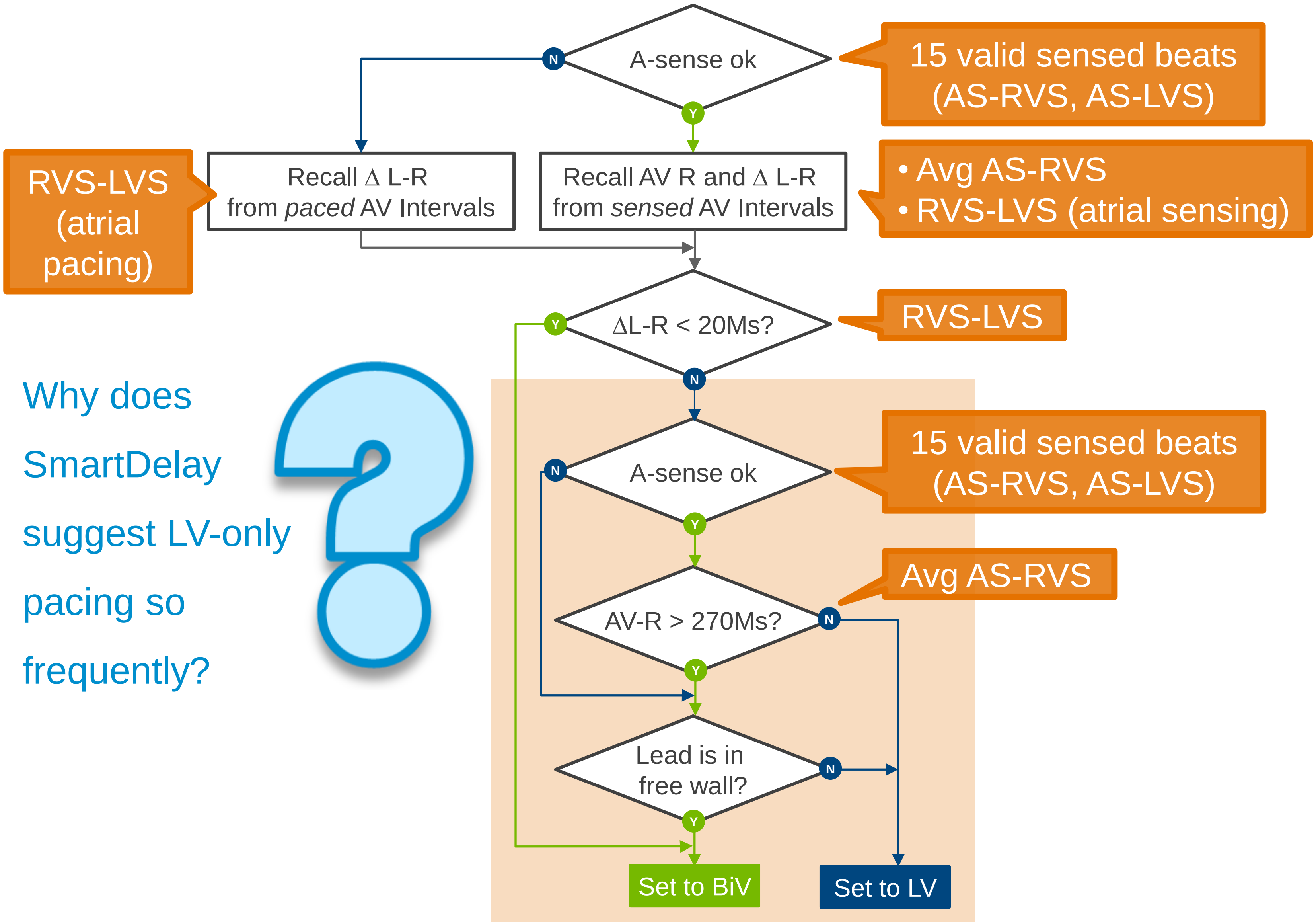
Lead Position Selections under Patient Info	SmartDelay LV Lead Location
LV Base (anterior)	Anterior
LV Base (posterior)	Free Wall
LV Base (lateral)	Free Wall
LV Mid (anterior)	Anterior
LV Mid (lateral)	Free Wall
LV Mid (posterior)	Free Wall



Device determines LV lead location from the stored Patient Information

- If LV lead location is not stored, SmartDelay will estimate the location using the averaged RV-LV interval (QRS surrogate)
- If time difference between averaged RV- LV is > 40ms: assumes “Free wall”, otherwise, assumes “Anterior”

Measurement and Calculation: **BiV or LV Only***



Why does SmartDelay suggest LV-only pacing so frequently?

LV-only Concerns

What if LV-only is suggested by SmartDelay and the physician prefers BiV?

Always consider the individual patient's conduction system status before enabling LV-only pacing

- 2013 ESC Guidelines address LV pacing alone in non-pacemaker dependent patients

Is the patient non-dependent but the concern of using LV-Only is around LV lead stability and loss of CRT?

- Consider BiV pacing post implant until LV lead position is considered chronic
- Consider the NAVIGATE X4 Study results[1]
  - »ACUITY™ Spiral: 99.1% stability
  - »ACUITY™ Straight: 98.7% stability
    (75% of Acuity X4 dislodgements occurred within 1 day)
  - »RV lead: 98.7% stability

Is loss of capture due to LV threshold variability the concern?

- LV PaceSafe™ and lead alerts from LATITUDE™ Patient Monitoring System

[1] Mittal S, et al. Performance of Anatomically Designed Quadripolar Left Ventricular Leads: Results from the NAVIGATE X4 Clinical Trial. J Cardiovasc Electrophysiol 2016; 27:1199-1205.

Circumstances in Which RV Pacing May Still Occur

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RV Pacing in LV-Only:[1]

Boston Scientific devices are based on RV timing whether in BiV or LV-only pacing mode

- ATR (mode switch)
- ATP therapy
- Electrocautery Protection Mode
- BiV Trigger
- RV safety pace if LV pace is inhibited due to LV sensing and no RV sensed event occurred before the scheduled pacing time

[1] Boston Scientific Primer for Cardiac Pulse Generators

Other Considerations for LV-only pacing

Avoid unnecessary RV pacing in patients with intact RBB conduction

- "Avoidance of Right Ventricular Pacing in Cardiac Resynchronization Therapy Improves Right Ventricular Hemodynamics in HF Patients"[1]
- "If It Is Not Broken, Don't Fix It"[2]

Hemodynamic impact of preserving RV with fusion pacing

- Allows a natural contraction sequence
- Role of RV in HF can be overlooked and underestimated
- It is recognized that in patients with advanced chronic HF, RV ejection fraction is a powerful and independent prognostic factor predicting functional capacity and survival [3,4,5,6]

"Acute invasive hemodynamic data has proven that in patients with normal intact AV conduction, LV pacing fused with intrinsic conduction is superior to any optimized BiV configuration in improving LV as well as RV systolic performance"[7,8]

[1]Lee LL et al. Avoidance of right ventricular pacing in cardiac resynchronization therapy improves right ventricular hemodynamics in heart failure patients. *J Cardiovasc Electrophysiol* 2007;18:497-204
[2]Birnie DH, Tang Anthony If it is not broken, don't fix it. *J Cardiovasc Electrophysiol*, Vol 18, pp 505-506, May 2007
[3] Di Salvo TG, Mathier M, Semigran MJ, Dec GW: Preserved right ven- tricular ejection fraction predicts exercise capacity and survival in advanced heart failure. *J Am Coll Cardiol* 1995;25:1143-1153.
[4] de Groote P, Millaire A, Foucher-Hossein C, Nugue O, Marchandise X, Ducloux G, Lablanche JM: Right ventricular ejection fraction is an independent predictor of survival in patients with moderate heart failure. *J Am Coll Cardiol* 1998;32:948-954
[5] Ghio S, Gavazzi A, Campana C, Inserra C, Klersy C, Sebastiani R, Arbustini E, Recusani F, Tavazzi L: Independent and additive prognostic value of right ventricular systolic function and pulmonary artery pressure in patients with chronic heart failure. *J Am Coll Cardiol* 2001;37:183-188.
[6] Ghio S, Tavazzi L: Right ventricular dysfunction in advanced heart failure. *Ital Heart J* 2005;6:852-855.
[7] Van Gelder, BM, et al. The hemodynamic effect of intrinsic conduction during left ventricular pacing as compared to biventricular pacing. *J Am Coll Cardiol* 2004;46:2305-10
[8] Kurzidim K, et al. Invasive optimization of cardiac resynchronization therapy: role of sequential biventricular and left ventricular pacing. *Pacing Clin Electrophysiol* 2005;83:89-92

BiV Pacing vs LV-only pacing

Recommendations	Class	Level
1) The goal should be to achieve biventricular pacing as close to 100% as possible since the survival benefit and reduction in hospitalization are strongly associated with an increasing percentage of biventricular pacing	IIa	B
2) Apical positon of the LV lead should be avoided when possible	IIa	B
3) LV lead placement may be targeted at the latest activated LV segment	IIb	B

Clinical perspectives

- The usual (standard) modality of CRT pacing consists of simultaneous biventricular pacing (RV and LV) with a fixed 100-120ms AV Delay with LV lead located in a posterolateral vein, if possible … Current evidence does not strongly support the performance of AV and VV optimization routinely in all patients receiving CRT.

- LV pacing alone … seems to be non-inferior to biventricular pacing for improving soft end-points (quality of life, exercise capacity and LV reverse remodeling) and might be considered to lower the costs and complexity of the procedure and to increase the longevity of the device. LV pacing alone seems particularly appealing in children and young adults.

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[1] Auricchio A, et al. 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy. European Heart Journal, 2013; 34:2281-2329.

BiV Pacing vs LV-only pacing

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"Several studies have demonstrated the non-inferiority of LV pacing alone"[1]

84 After 12 months follow-up, LV pacing induced similar improvement in clinical status, exercise capacity and LV dimensions and function, compared with BiV pacing; percentage of responders was comparable for both groups (75% LV, 70% BiV).

85 Clinical and echocardiographic performance of LV stimulation was non-inferior to that of BiV stimulation over a 6 month follow-up.

86 LV pacing induced similar improvements in 6-min walk distance, quality of life, NYHA functional class and peak oxygen consumption, compared with BiV pacing; BiV pacing tended to include larger improvements in LVEF and reductions in LV volumes compared with LV pacing.

87 LV pacing was similar to BiV pacing in terms of improvement in exercise capacity, LV function and volumes and H-terminal pro-B type natriuretic peptide circulating levels; additionally, a respective 21% and 17% of patients who did not respond clinically or echocardiographically to BiV pacing, responded to LV pacing modes.

88 In moderate to severe HF, BiV vs LV Only did not differ with regard to death/heart transplantation or need for hospitalization

84. Gasparini M, Bocchiardo M, Lunati M, Ravazzi PA, Santini M, Zardini M, Signorelli S, Passardi M, Klersy C. Comparison of 1-year effects of left ventricular and biventricular pacing in patients with heart failure who have ventricular arrhythmias and left bundle-branch block: the Bi vs. Left Ventricular Pacing: an International Pilot Evaluation on Heart Failure Patients with Ventricular Arrhythmias (BELIEVE) multicenter prospective randomized pilot study. *Am Heart J* 2006;**152**:155 e151–e157.
85. Boriani G, Kranig W, Donal E, Calo L, Casella M, Delarche N, Lozano IF, Ansalone G, Biffi M, Boulogne E, Leclercq C. A randomized double-blind comparison of biventricular versus left ventricular stimulation for cardiac resynchronization therapy: the Biventricular versus Left Univentricular Pacing with ICD Back-up in Heart Failure Patients (B-LEFT HF) trial. *Am Heart J* 2010;**159**:1052–1058 e1051.
86. Liang Y, Pan W, Su Y, Ge J. Meta-analysis of randomized controlled trials comparing isolated left ventricular and biventricular pacing in patients with chronic heart failure. *Am J Cardiol* 2011;**108**:1160–1165.
87. Thibault B, Ducharme A, Harel F, White M, O'Meara E, Guertin MC, Lavoie J, Frasure-Smith N, Dubuc M, Guerra P, Macle L, Rivard L, Roy D, Talajic M, Khairy P. Left ventricular versus simultaneous biventricular pacing in patients with heart failure and a QRS complex >/=120 milliseconds. *Circulation* 2011;**124**:2874–2881.
88. Boriani G, Gardini B, Diemberger I, Bacchi Reggiani ML, Biffi M, Martignani C, Ziacchi M, Valzania C, Gasparini M, Padeletti L, Branzi A. Meta-analysis of randomized controlled trials evaluating left ventricular vs. biventricular pacing in heart failure: effect on all-cause mortality and hospitalizations. *Eur J Heart Fail* 2012;**14**:652–660.

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"As long as the AV node is intact and the AV Delay is optimized, LV-only pacing can achieve similar dP/dt responses".[2]

1 12013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

2 Gold, MR, et al. A prospective, randomized comparison of the acute hemodynamic effects of biventricular and left ventricular pacing with cardiac resynchronization therapy. *Heart Rhythm* 2011; 8: 686-691.

Optimizing to Reduce % Non-Responders Source

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Optimizing CRT:

- Four major areas have been the subjects of research
- All areas may be achievable using VectorGuide™ and SmartDelay™ with ACUITY™ X4 leads that promote pacing at the latest site of LV activation
- LV pacing alone was identified as an option
- Restoring LV synchrony by either BiV pacing or LV-only pacing was patient dependent

3.2.2 Choice of pacing mode (and cardiac resynchronization therapy optimization)

The usual (standard) modality of CRT pacing consists of simultaneous (RV and LV) pacing with a sensed AV Delay programmed between 100-120ms with an LV lead possibly located in a lateral or posterolateral vein. This practice is largely empirically derived from pathophysiological reasoning and from the evidence provided by earlier clinical trials. Optimization of CRT has the objective of reducing the percentage of non-responders. In this respect, four major areas have been the subjects of research:

1. How to achieve biventricular pacing as close to 100% as possible;
2. How to select the best LV lead position;
3. How to program the AV interval in order to achieve the maximum contribution of LA contraction to LV filling (AV resynchronization); and
4. How to eliminate the residual LV dyssynchrony after simultaneous biventricular pacing by selecting the timing of RV and LV pacing by means of device interventricular (VV) interval optimization (including, at its extreme, LV pacing alone).

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From LV Only to BiV

Use the same AVD suggested for LV-Only for BiV programming

In this study, there were no significant differences between the optimal AVDs in LV-Only vs BiV[1]

A prospective, randomized comparison of the acute hemodynamic effects of biventricular and left ventricular pacing with cardiac resynchronization therapy

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[1] *Heart Rhythm* 2011; 8:685-691

SmartDelay

LV Offset Recommendation

Why doesn't SmartDelay suggest V-V timing (LV Offset)

There has been controversy as to whether there is a chronic benefit conferred due to routinely performing the optimization of VV delay as no clinical research study proved that VV timing would benefit the patient in their response to CRT

"It is evident that while VV optimization using the methods available may improve the acute hemodynamic response of CRT, long-term clinical improvement has not been definitely proven … it may be most useful in the population of CRT 'non-responders', although the benefit of this strategy requires further study"[1]

Studies have shown that "the majority of patients have optimal VV intervals that are within a range of ± 20ms"[2], which is often suggested by SmartOffset in MultiSite Pacing

With the addition of Boston Scientific's Multi-Site pacing capability, there are a number of combinations to individualize the timing of LV stimulation if desired by the Physician

[1] Brabham W.W., Gold M.R. The role of AV and VV optimization for CRT. *Journal of Arrhythmia* 29 (2013) 153-161
[2] Burri h. et al. Optimization of Device Programming for Cardiac Resynchronization Therapy. *PACE* 2006; 29:1416-1425.

Measurement and Calculation

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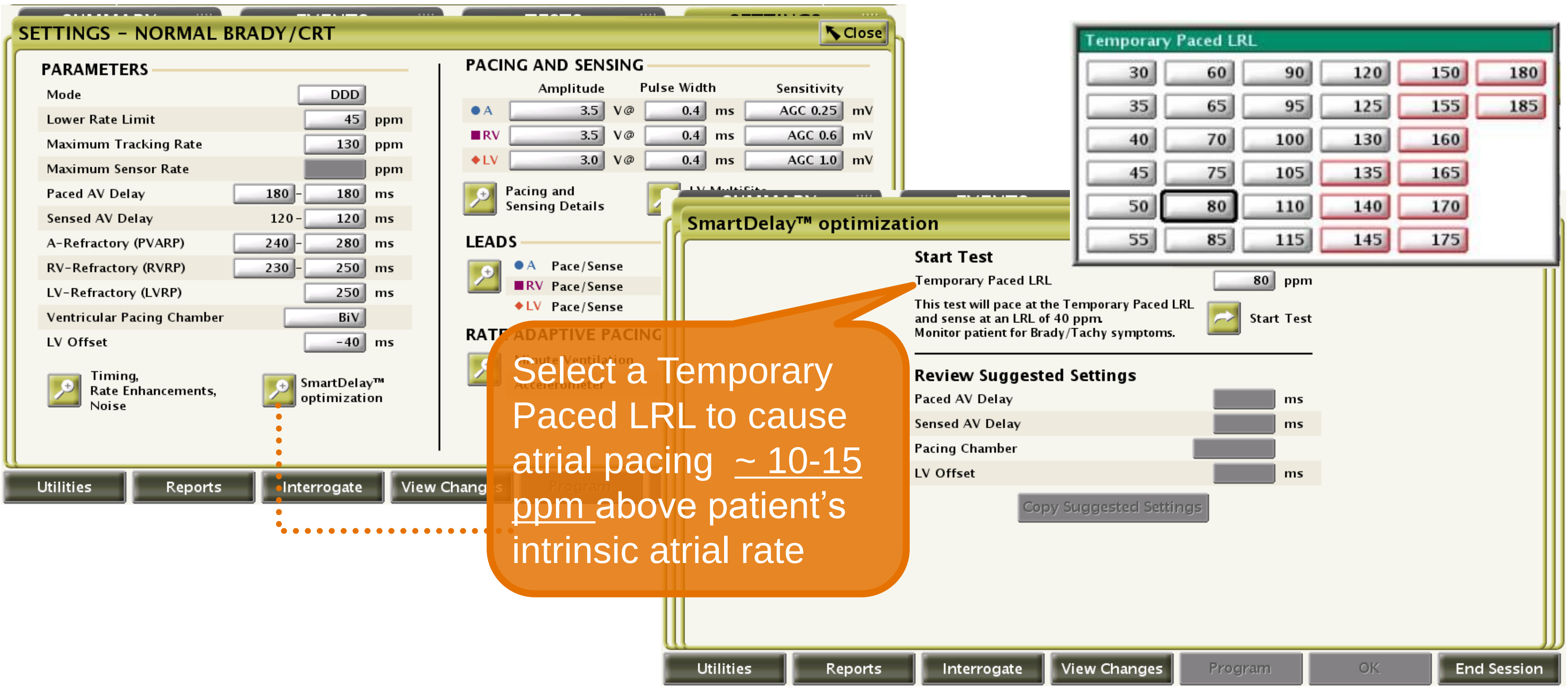
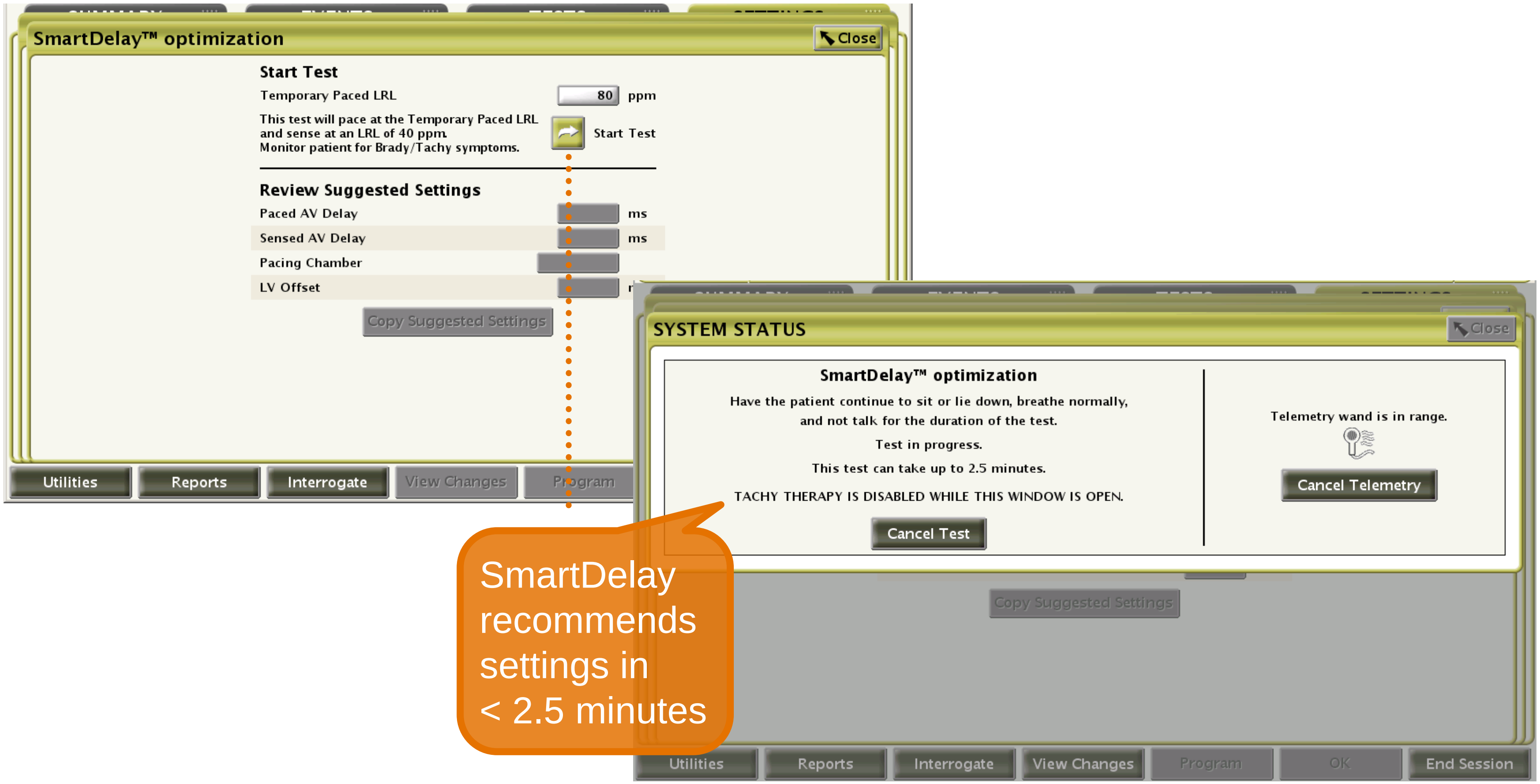
Always run VectorGuide™ to select the optimal LV pacing vector before starting test!



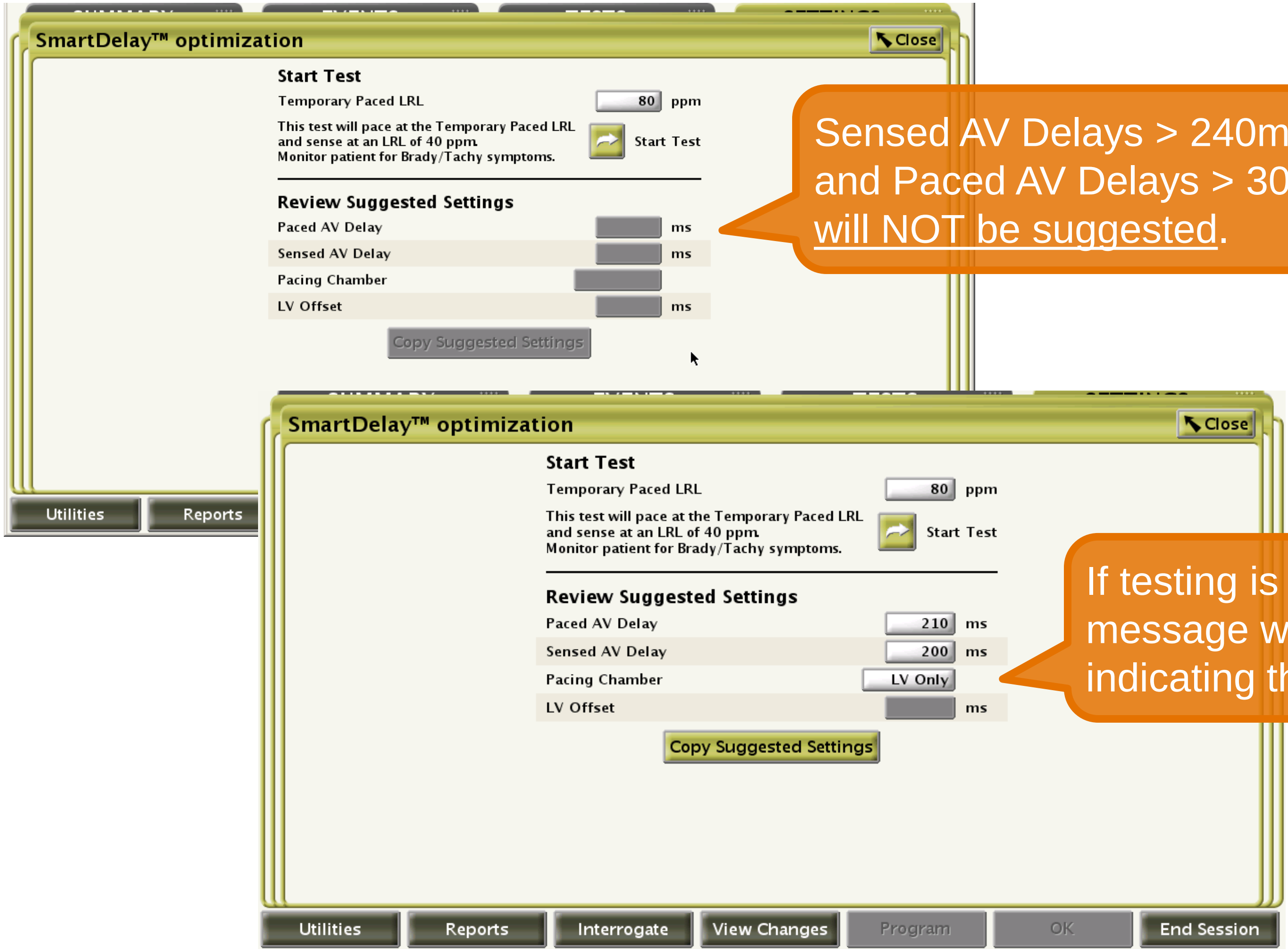
A-sense Test	DDD	LRL = 40 bpm	400 ms AV Delay
A-pace Test	DDD	LRL = Temporary Paced LRL (Default = 80 ppm)	450 ms AV Delay

Measurement and Calculation



SmartDelay recommends settings in < 2.5 minutes

Measurement and Calculation (simulated)



Sensed AV Delays > 240ms and Paced AV Delays > 300ms will NOT be suggested.

If testing is unsuccessful, a message will be displayed indicating the reason.

Measurement and Calculation

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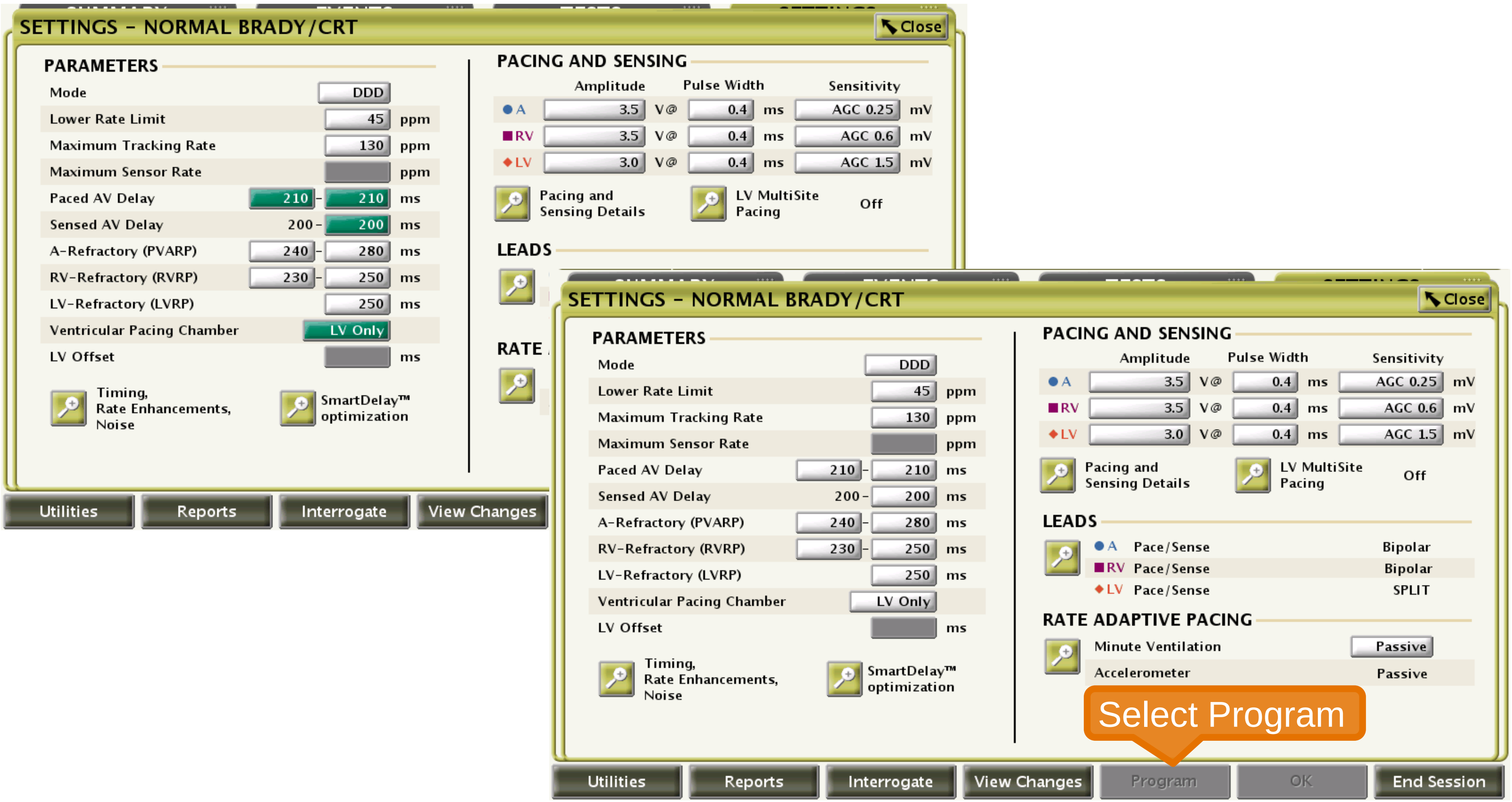
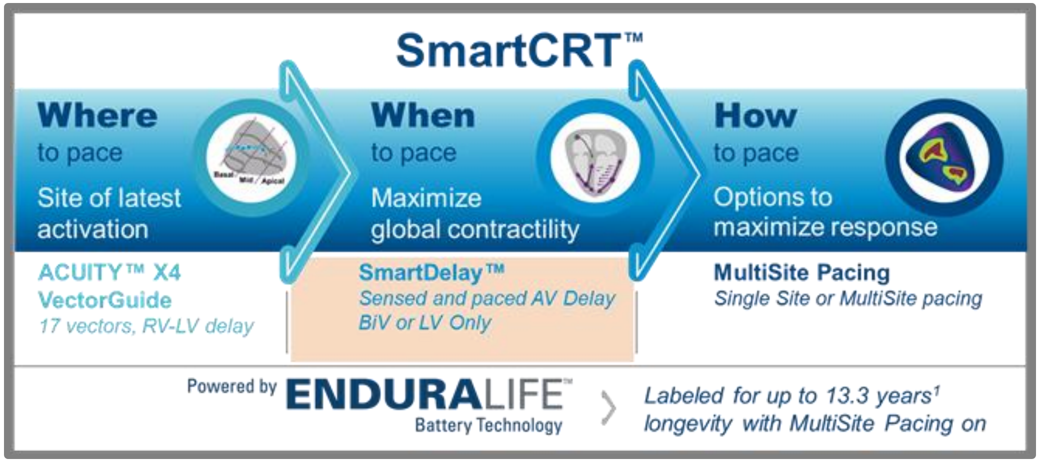


Key Takeaways

- **SmartDelay** recommends customized sensed and paced AV Delays to maximize global contractility
- The **AV Delay** suggested by SmartDelay is closely related to ARV, RV-LV (a surrogate of QRS), and is dependent on lead location



- Based on acute hemodynamic data, the **optimal AV Delay** is ~ 30-70% of the intrinsic activation
- A **shorter AV Delay** relative to the intrinsic AV conduction is applied with wider QRS measurements that results in a more pace dominated fusion, whereas a longer AV Delay relative to the intrinsic AV conduction is applied with more narrow QRS measurements, resulting in more intrinsic dominated fusion
- The goal of CRT is to resynchronize; BiV or LV-only modality is patient dependent and Physician determined; **SmartDelay recommends** the pacing chamber based on the patient's intrinsic AV conduction

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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