Unify™ CRT-D and Fortify™ ICD

Sales Reference Guide

Product Overview
Competitive Comparisons
FAQs

Portfolio Foundation

All of the products in the St. Jude Medical high voltage portfolio rest on a foundation of robust leads and advanced lead delivery tools designed to support a level of confidence in procedural outcomes not found with competitive systems. The latest additions to this portfolio foundation are profiled in this guide.

Durata® ICD Lead
Designed for Durability Even in the Most Challenging Cases

Feature	Benefit
Optim® insulation	■ Flexibility and long-term durability ■ Stands up to the risks of abrasion ■ Maneuverability and handling characteristics including lubricity
Curved distal coil and soft silicone tip	■ Reduced tip pressure
Redundant construction	■ Added safety in the unlikely event of a conductor failure
Small 7 F diameter	■ Improved venous passage ■ Reduced risk of venous thrombosis or clavicular crush ■ Enhanced ability to accommodate multiple leads in a single vessel
SJ4 connector option	■ Simplified implant ■ Defibrillation connections consolidated into a single terminal pin

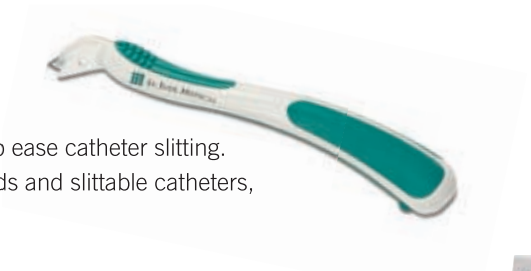
Next-Generation CRT Lead Delivery Tools

- CPS Direct® SL II slittable outer guide catheter
- CPS Aim® SL slittable inner catheter cannulator
- CPS Aim® SL slittable inner catheter subselector
- CPS® Universal slitter

The newest Performance360™ LV lead delivery tools are designed to decrease implant times and increase predictability. The tools share a common feature set with differences as noted in the following tables.

Feature	CPS Direct SL II	CPS Aim SL Cannulator	CPS Aim SL Subselector
Integrated hemostasis valve	✔	✔	✔
Increased curve retention	✔		
Enhanced braid pattern	✔	✔	✔
Soft tip	✔	✔	✔
New shape (Amplatz)		✔	
Radiopaque material construction			✔
Platinum ring at the distal tip			✔

CPS Universal Slitter



The first ergonomic slitter from St. Jude Medical provides stability to ease catheter slitting. The universal slitter is fully compatible with all St. Jude Medical leads and slittable catheters, eliminating the need for multiple tools.

Implant and Patient Management Instruments

The Merlin® Pacing System Analyzer (PSA) and Merlin.net® Patient Care Network (PCN) provide physicians with critical implant support and ongoing access to crucial patient and device information, thereby improving procedural efficiency and patient care.

Merlin PSA
Delivering an Integrated Solution Designed to Optimize Speed, Safety and Confidence at Implant.

The Merlin PSA is an integrated, easy-to-use technology that can provide physicians with greater confidence and more control at implant by quickly delivering accurate measurements for optimal lead positioning and streamlined implant.

Feature	Benefit
Fast application speeds Measurements of P/R waves and impedances on a beat-by-beat basis	▪ Speed: Quick delivery of accurate measurements facilitates rapid lead placement and results in a more streamlined implant process
Measurements on a beat-by-beat basis Dedicated current of injury display that can be viewed on an external monitor Emergency battery backup	▪ Confidence: Performance and safety features for accurate lead placement
Ease of use Integrated into Merlin® Patient Care System (PCS) programmer Three-channel monitoring (atrial, RV and LV)	▪ Integrated solution: Enables more extensive lead analysis

Merlin.net PCN
Simplified Data Integration for Enhanced Patient Care

Merlin.net PCN allows integration of essential device data with electronic health records for timely, convenient access to key information that can help optimize clinic resources and streamline patient care.

Feature	Benefit
Remote device interrogation	▪ For enhanced patient safety and therapy assurance
Data integration	▪ For convenient, single-point access for accurate patient information ▪ For direct interface with patient's electronic health record
Wireless USB Adapter	▪ For simple connection to any Merlin@home® transmitter and data transmission on the cellular network
DirectCall® message	▪ An integrated and automated patient communication system designed to reduce routine calls usually performed by medical office staff
DirectTrend® viewer	▪ Viewer provides dynamic views of device and clinical trends

High Voltage Benefits
Selling Benefits

Portfolio Sales Call Execution

Clinical Need Selling Tools

The sell sheets designed to support the high voltage portfolio have all been organized around a clinical need. The following table contains a brief description of the item and its intended use.

Sales Tool	Description	Intended Use
Spec Sheets		
Fortify™ DR ICD Fortify™ VR ICD Unify™ CRT-D	2-sided, with key feature overview and product technical specifications	Primarily for contract purposes
Product Overview		
Downsize Without Compromise	Bifold introduction to Unify CRT-Ds and Fortify ICDs, and the benefits of Smaller, Smarter, Stronger	Introduce customers to exciting new products and lay groundwork for in depth follow-up conversations
Benefit Sell Sheets & Feature Focus	Bifold with copy supporting in-depth conversations on a particular focused topic	
Enhanced Battery Technology	Describes the QHR® battery design, clinical benefits and longevity	Overcome objections and concerns about QHR battery technology
Greater Therapy Assurance	Discusses St. Jude Medical leadership in high energy shocks and DeFT Response® technology	To highlight St. Jude Medical innovation specific to managing high defibrillation thresholds
Safety and Reliability	Highlights SJM leadership in safety and reliability in lead and device design	To show not all companies are the same when it comes to product reliability and performance
Appropriate ICD Therapy	Overview of SJM solutions for ensuring appropriate therapy delivery	To highlight SJM solutions for reducing inappropriate therapies.
Streamlined Patient Management	Overview of St. Jude Medical advantages in streamlining the patient follow-up process	To highlight the advantages of choosing St. Jude Medical regarding follow-up of implanted CRM devices
PowerPoint Presentations		
Unify CRT-D and Fortify ICD Rep to Physician PPT	PPT presentation covering each of the “sell sheet” topics	Intended to facilitate discussion of sell sheet topics with a larger group of customers. Hide PPT sections other than the “sell sheet” topics targeted for the audience.
Demos		
Unify CRT-D (SJ4) Fortify VR ICD (SJ4)	Plastic replica of the Unify CRT-D and Fortify ICD	Train physicians and clinics on product

Customer Targeting:

Clinical Need	Customer Belief	St. Jude Medical Feature Focus	St. Jude Medical Product(s)	"Clinical Need" Sell Sheet
Identify clinical needs of highest importance to each customer	Identify customers based on their clinical beliefs.	List SJM features that meet that specific clinical need	Newly released St. Jude Medical products that offer those features	Targeted sales tool to differentiate St. Jude Medical based on real clinical needs
Safe and reliable device therapy	I believe all companies are equivalent when it comes to robust product design and reliability.	Redundant hardware and software, lead design advantages, QHR® battery, Merlin.net® PCN, Merlin@home® transmitter	Entire Portfolio	Safety and Reliability Sell Sheet
Reduce defibrillation therapy	I am concerned about painful and unnecessary defib shocks; I believe competitors are ahead of St. Jude Medical in reducing hv therapies.	Low frequency attenuation filter & ATP prior to or while charging	Fortify™ ICD Unify™ CRT-D	Appropriate ICD Therapy Sell Sheet
Ensure patients receive therapy based on their unique needs and clinical status	I believe device companies offer about the same amount of delivered energy in their devices. I would like to minimize or eliminate DFT testing.	40 J (delivered) safety shock and DeFT Response® technology	Fortify ICD, Unify CRT-D	Greater Therapy Assurance Sell Sheet
Automatic and timely data for more streamlined patient follow-up	My practice is getting busier and I am needing to hire more staff to handle all of the device checks.	Total Capture Confirmation, Merlin@home transmitter with wireless adapter, Merlin.net PCN	Fortify ICD, Unify CRT-D	Streamlined Patient Management Sell Sheet
Reliable battery that is predictable and meets therapy needs (consistent charge times and longevity)	I am concerned about battery reliability and longevity. How can I be assured the QHR battery is safe and delivers therapy over an acceptable time frame?	QHR battery	Fortify ICD, Unify CRT-D	Enhanced Battery Technology Sell Sheet

Uncovering Customer Needs

By creating a belief in your customer's mind, then identifying their problem, you set up your solution to be positively received.

High Defibrillation Thresholds		
Belief/Need: All high voltage devices offer about the same amount of delivered energy. I need to be assured that my patient receives therapy during an arrhythmic event.	**Problem:** Invasive methods for lowering DFTs add risk and time to procedures, and some patients are too sick to undergo the procedures. **Discovery Questions:** Have you had difficulties in getting an adequate DFT safety margin in some patients? Have you seen a significant change in the DFTs following a medication change? Do you perform DFT checks on all of your patients at implant? Would you like to minimize the risk of unsuccessful therapy due to changes in a patient's DFT? Would you prefer to have a larger defibrillation safety margin if there were no compromise on size or longevity?	**Solution:** Latest devices from St. Jude Medical provide a 40 J safety shock, the highest delivered energy available. DeFT Response® technology offers the most noninvasive options for managing high DFTs.
Reducing Inappropriate or Unnecessary Therapy		
Belief/Need: I am concerned about inappropriate defibrillation shocks.	**Problems:** SVT and sensing abnormalities such as noise or T-wave oversensing can cause inappropriate shocks. Shocks have been shown to correlate with worse patient outcomes. **Discovery Questions:** Do you use rhythm discriminators in your device programming for most patients? Have you had patients with inappropriate therapy due to T-wave oversensing?	Introduce customers to exciting new products and lay groundwork for in depth follow-up conversations

Competitive Comparisons

Selling Against the Competition

Clinical Need Selling Tools

The focus of this section is to present an overview of competitive messages and late-breaking information at the time of printing.

The St. Jude Medical response to these claims and key St. Jude Medical advantages over each competitor are presented. These St. Jude Medical responses can be helpful as you develop talking points for follow-up discussions with customers.

The competitive information is organized by company and therapy.

Feature ordering: Atrial/Brady, Tachy, HF

	St. Jude Medical	Medtronic	Boston Scientific	Biotronik	Sorin
Safety Features	Multiple hardware and software system safeguards Vibratory patient notifier clinically proven superior to auditory notifiers; Daily, multivector subthreshold HVLI check	Audible patient alerts (CareAlert®) signals Painless HVLI & daily/ automatic alert	Safety Core™ feature feature provides basic pacing and VF shocks if nonrecoverable or repeated fault conditions occur that cause the central processing unit (CPU) to be unavailable. Safety Core feature is isolated from the device CPU, so fault conditions that affect the CPU would not affect Safety Core feature operation. The Safety Core feature would keep the basic life-saving therapy of the device running, even under fault conditions, as long as there is battery energy and sense amplifiers are available; Audible patient alert (limited programming options); Painless HVLI & daily automatic alert	Shocks in backup mode - with a VF zone limit of 150 bpm or 400 ms which may deviate from the originally programmed zone limit	Unable to confirm
Atrial Therapy	AF Suppression™ algorithm	Atrial Preference Pacing, Atrial ATP, Atrial Cardioversion with patient activation	Atrial Preference Pacing, ProAct	None	None
AT/AF Alerts	**Alerts:** ■ AT/AF burden (per day or per week) ■ AT/AF continuous episode duration exceeds threshold ■ High V Rate time during AT/AF **Notification:** ■ Patient notification ■ Programmer alert ■ Merlin.net® Patient Care Network (PCN) alert **Programmability:** ■ AT/AF Burden (Total time in AT/AF and Evaluation period) ■ AT/AF (Continuous time in AT/AF) ■ V Rate during AT/AF (High V Rate threshold and Total time in High V Rate)	**Alerts:** ■ AT/AF onset ■ Average V rate during AT/AF ■ Detection **Notification:** ■ Patient notification ■ Programmer alert ■ CareLink® alert **Programmability:** ■ AT/AF burden and rate settings	**Alerts:** ■ Atrial arrhythmia burden in 24-hr period **Notification:** ■ LATITUDE.com alert ■ Programmer alert **Programmability:** ■ AT/AF burden threshold	**Alerts:** ■ AT/AF duration Activity report that includes patient susceptibility to Atrial Arrhythmias including Atrial Burden (length of episodes), number of episodes & duration **Notification:** ■ Programmer ■ CardioMessenger® II **Programmability:** ■ Evaluation period	AF burden diagnostic trending only - no alerts
BiV Therapy Assurance	BiV Trigger Mode - triggers pacing in response to ventricular sensed events and ensures BiV pacing during atrial arrhythmias % BiV Pacing Alert - notifies clinics when % BiV pacing is less than programmed threshold	Ventricular Sense Response (VSR) in DDD mode; Conducted AF Response; Atrial Tracking Recovery; LV Capture Management	BiV Trigger - a BiV pace is triggered within 8-10 ms after an RV-sensed event between the LRL and MPR; functions the same during post-shock pacing as in normal pacing and can be used in conjunction with VRR. BiV Trigger in conjunction with VRR is designed to provide additional CRT support during atrial arrhythmias % BiV Pacing Alert - the CRT % pacing alert is designed to notify you that the cardiac resynchronization pacing percentage has dropped below a selected threshold.	■ AMS base rate ■ RV Sense Trigger (BiV trigger) - designed to ensure CRT when rapid atrial intrinsic rate interferes with pacing. It triggers LV pacing after intrinsic sensing in the RV. Triggered pacing can be programmed to react to only normal RV-sensed events or to RV extra systoles as well as normal RV-sensed events. MTR is normally limited to the programmed UTR but can also be programmed to function up to a separate higher max trigger rate.	FMS + AMS base rate Pacing mode to manage all types of AV blocks; BTO® Brady Tachy Overlap offers overlap of max pacing rate and tachy zone

Feature ordering: Atrial/Brady, Tachy, HF

	St. Jude Medical	Medtronic	Boston Scientific	Biotronik	Sorin
Capture Confirmation	Beat-by-Beat™ AutoCapture™ Pacing System ensures ventricular capture ACap® Confirm algorithm and BiVCap® Confirm capture confirmation automatically, periodically and independently measures and trends the capture thresholds of all chambers and provides reliable and automatic pacing adjustment.	Complete Capture Management® - RVCM, ACM, LVCM	Capture verification is not available	RV and LV Automatic Threshold Management (ATM); Atrial capture confirmation not available	Not available
Intrinsic Conduction	Ventricular Intrinsic Preference (VIP ®) algorithm helps reduce unnecessary RV pacing by automatically extending the AV delay up to 450 ms with no dropped beats	MVP® Algorithm; allows intrinsic conduction longer than 450 ms; allows dropped beats; can be proarrhythmic	AV Hysteresis – up to 400 ms; no dropped beats; BSX supported Intrinsic RV Trial. Reverse mode switch. Nominally Off, Programmable to AAI with VVI backup.	IRS (Intrinsic Rhythm Support) - AV Hysteresis -Extends AV delay to 400 ms Dynamic AV Delay - Can program low, medium or high delay; can also program a fixed AV delay applicable to all pacing rates or individualize the AV delay for certain rates; extends AV delay for up to 350 ms	SafeR™ feature promotes intrinsic conduction
Sensing	**Sense*Ability*® Technology** ■ Threshold start ■ Decay delay ■ Low frequency attenuation filter increases the R to T wave amplitude ratio by a factor of 2 to 3, which enhances sensing performance and makes it possible to reduce the possibility of oversensing T-waves; Filter is ON by default ■ In challenging case, provides programming flexibility without sacrificing safety	Programmable RV sensing vector; Must decrease sensitivity to avoid T-wave oversensing	■ Must decrease sensitivity to avoid T-wave oversensing. ■ SmartSensing® Technology includes dynamic noise reduction algorithm 1- Dynamic noise reduction algorithm 2- Cross Chamber Blanking 3- Automatic Gain Control	Automatic sensitivity control with Enhanced T-wave suppression and Enhanced VF sensitivity; Far-field protection	Unable to confirm
VT/VF Therapy	DeFT Response® Technology: ■ 40 J delivered energy ■ Programmable pulse width; shocking vectors and tilt options ■ SVC ON/OFF ■ RV Anode Nominally (shown to be optimal polarity) ■ Programmable pulse width clinically proven to reduce DFTs ■ ATP prior to and while charging ■ DC Fibber™ Induction	■ 35 J delivered energy ■ Fixed tilt (not programmable) ■ Programmable SVC ■ Reverse polarity for last shock ■ ATP before and during charging	■ 35 J delivered energy ■ Fixed tilt (not programmable) ■ SVC ON/OFF ■ Reverse last shock ■ Quick Convert® feature (ATP before charge)	SMART Detection™ - differentiates VT from SVT; 35 J delivered energy; ATP Optimization and ATP One Shot (quick burst before charge); 2 programmable waveforms	PARAD® + tachyarrhythmia discrimination; ATP for VTs ranging from 100-255 bpm; stability analysis for fast VT

Feature ordering: Atrial/Brady, Tachy, HF

	St. Jude Medical	Medtronic	Boston Scientific	Biotronik	Sorin
Heart Failure Diagnostics	**Data:** Heart-In-Focus® report featuring exercise trend; AF burden; HR histogram, HR in AMS **Alerts:** AF burden	**Data:** Cardiac Compass™ Report plots long-term trends in heart rhythm and device status for up to 14 months; includes the OptiVol® fluid status monitoring. HR histogram report, flashback memory diagnostic stores interval data for several minutes prior to recent detected arrhythmia episodes, and prior to interrogation **Alerts:** AT/AF Burden/ rate settings, OptiVol Fluid Settings	**Data:** Insight Heart Failure reporting includes HR, activity level, atrial burden, Resp Rate, SDANN, HRV footprint, ABM (Autonomic Balance Monitor); also includes weight and BP if optional equipment is purchased	PE clinical research underway evaluating lung water index. Patient Activity; Mean Heart rate (active & resting); Heart Rate Variability; Holter memory; Episode List	Physiological Diagnostic (PhD), a new sensor-based diagnostic feature that detects device indicated heart failure events; can be used to quantify hemodynamic variability. Uses activity and ventilation monitoring to assess HF status. Other new features: PEA - measures contractility using a sensor placed at the tip of the electrode
Noninvasive LV Lead Repositioning	VectSelect® programmable LV pulse configurations - Three programmable LV pacing configurations	Three programmable LV pacing configurations ■ Bipolar (tip to ring) ■ Tip to RV coil, ■ Ring to RV coil	Electronic Repositioning™ - Six pacing and five sensing programmable LV pacing configurations: ■ Bipolar (tip to ring) ■ Tip to RV coil ■ Ring to tip (reverse bipolar) - pace only ■ LV ring to can ■ LV tip to can	Four programmable LV pacing configurations ■ LV tip-LV ring ■ LV tip-RV ring ■ LV ring-LV tip (reverse bipolar) ■ LV ring-RV ring	Two programmable LV pacing configurations ■ Bipolar ■ Tip to RV coil
Timing Cycle Optimization	QuickOpt® Timing Cycle Optimization ■ Simple and accurate solution to optimize both AV and VV timing at each follow-up ■ Novel algorithm uses intracardiac electrograms ■ Requires touching only one button and takes about a minute ■ Clinically proven to correlate with more complicated echo-based optimization techniques ■ Multiple publications supporting the feature	■ Recommending echo to optimize AV delay ■ M-mode echo can then be used to optimize V-V timing *New AV-VV Optimization Study underway (Adaptive CRT)	SmartDelay® AV optimization - automatically optimizes AV delays and recommends positive or negative LV offsets in less than 2.5 minutes. The BSX LV offset recommendations are based on retrospective data and are not tailored based on an individual patient's timing cycle needs.	Dynamic AV Delay; can manually program V to V	CLEAR (optimization) Study results expected Q2 2010; randomized study, 320 pts, PEA vs. standard practice, composite score @ 12 months - VV delays and AV Delays optimization, correlation with heart noises; will be integrated and sold in future CRT-D, Q2 2010
Remote Monitoring	Merlin.net® Patient Care Network (PCN) is the only system that lets clinicians merge in-clinic and remote data to give "the total picture," and the only one that allows data to be sent in directly to the clinic's electronic health records system Transmitter is easily paired to any patient or clinic without returning to manufacturer Merlin@home® transmitter allows for seamless remote monitoring Automatically transmits follow-up data using wireless telemetry	Medtronic CareLink® network, etc. First Internet-based system Must go through Paceart™ system to transfer data to electronic health records system Transmitter tied to both patient and clinic	LATITUDE® Programmer ■ Offers the option of adding a blood pressure cuff and weight scale (at additional cost) ■ All communicators tied to device ■ Uses 869 MHz bandwidth for RF(off-the-shelf bandwidth used for common household appliances) ■ CustomSelect™ architecture, a feature of LATITUDE programmer, allows both device-following and health-following physicians to independently select follow-up and monitoring schedules that best meet the needs of their practice and their patients.	Biotronik Home Monitoring® device; CardioMessenger feature Does not offer full reports	Sorin is working with Orange Business Services (OBS) to develop and service a remote monitoring solution. OBS will manage data transmission from device to clinician

Medtronic – Selling Against Medtronic ICD Therapy

What Medtronic is saying about their products

Medtronic Vision 3D™ Portfolio Unparalleled Clinical Options

Secura® ICD with Complete Capture Management – The Right Therapy at the Right Time

In addition to Virtuoso® ICD:

- AT/AF Management – Offers unprecedented diagnostics and therapies including Cardiac Compass trends, ATP, Conducted AF Response and dual-channel EGM
- Automaticity with Complete Capture Management – ensures pacing capture in all chambers and automatically provides a complete device check daily

Virtuoso ICD with Conexus® Wireless Telemetry – The First Complete System to Assist in Managing Heart Disease

In addition to Maximo® II ICD:

- OptiVol fluid status monitoring – Provides unprecedented insight into patients' clinical status

Maximo II ICD – Wireless Efficiency Integrating Medtronic's Best Pacing and ICD Exclusives

- Safer, more efficient implants
- Easy remote follow-up
- Medtronic PainFREE® Solutions – Proven strategies to reduce shocks (ATP During Charging, PainFREE programming)
- Better disease management – Successful options only from Medtronic (MVP algorithm, Cardiac Compass Trends, Four real-time EGM channels)

Sprint Quattro Secure® ICD Leads – The Standard for Exceptional Performance

- Reliability
- Easy introduction, navigation and handling
- Energy efficiency

St. Jude Medical Response

Feature	SJM Response
Automaticity	▪ SJM offers two ICDs with fully automatic thresholds ▪ RV AutoCapture® pacing system uses beat-by-beat monitoring for an additional safety margin not provided with the Medtronic Capture Management threshold checks
Reducing unnecessary pacing	▪ MVP could allow dropped beats, while VIP operates in DDD mode
Medtronic PainFREE solutions	▪ SJM devices support ATP prior to or while charging in the VF zone for rates up to 300 bpm ▪ Medtronic PainFREE programming recommendations can be implemented in SJM devices if desired as well
Lead reliability	▪ SJM Durata® lead offers a proven structural design and proprietary insulation material with excellent long-term durability
Lead size	▪ The 7 F Durata lead better accommodates multiple leads in a single vessel and eases passage through difficult anatomies reducing the risk of implant complications

Key SJM features over Medtronic ICDs

40 J safety shock, smallest footprint available, streamlined SJ4 connector, DeFT Response® technology, 7 F lead, Optim® insulation

Late-breaking Notes

Medtronic will launch a new ICD device called Protecta™ ICD in 2010. They will tell customers that this device is designed to deliver fewer inappropriate shocks. However, the Protecta ICD will only be catching up to the Fortify™ ICD in several key areas, including automatic sensitivity control and advanced T wave filtering.

	Medtronic		Medtronic		Medtronic	
	Secura®		**Virtuoso®**		**Maximo® II**	
	VR	DR	VR	DR	VR	DR
Model number - VR	D224VRC	D224DRG	D164VWC	D164AWG	D284VRC	D284DRG
Volume (cc)	37		37		37	
Weight (g)	68		68		68	
H x W x D (mm)	64 x 51 x 15		64 x 51 x 15		65 x 51 x 15	
Max Delivered Energy (J)	35		35		35	
Charge Time to Max Delivered Energy (sec)	7.7		8.2		7.7	
Longevity (year) - VR	**7.6** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks/yr	**6.7** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 15% A&V pacing, 4 max shocks/yr	**7.2** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks/yr	**6.4** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 15% A&V pacing, 4 max shocks/yr	**8.8** @ 15% VVI at 2.5V, 0.4 ms, 60 ppm, 600 ohms; pre-arrhythmia EGM storage off, 2 shocks/yr	**7.6** @ 2.5V, 0.4 ms, 60 ppm, 600 ohms, 50% atrial and 5% ventricular pacing in MVP mode
HV Therapy - ATP	Yes - RV Only		Yes - RV Only		Yes - RV Only	
ATP During Charge	Yes		Yes		Yes	
HV Therapy - Reverse Last Therapy	Yes		Yes		Yes	
HV Therapy - Shock Vector Programmability	Yes - Can On/Off and SVC On/Off		Yes - Can On/Off		Yes - Can On/Off and SVC On/Off	
HV Therapy - Waveform Programmability	No	Polarity	No	Polarity	Polarity	
Induction - DC Fibber	No		No		No	
Pacing Options - Reduced V-pacing	N/A	Yes - MVP	N/A	Yes - MVP	N/A	Yes - MVP
Pacing Options - AV Optimization	N/A	No	N/A	No	N/A	No
AF Management - Prevention	N/A	Yes - Atrial Preference Pacing, PMOP, Atrial Rate Stabilization	N/A	Yes - Atrial Preference Pacing, PMOP, Atrial Rate Stabilization	N/A	Yes - Atrial Preference Pacing, PMOP, Atrial Rate Stabilization
Capture Confirmation - RV	Yes		No		No	
Capture Confirmation - Atrial	N/A	Yes	N/A	No	N/A	No
Sensing - T-wave Oversensing Reduction Filter	No		No		No	
Discrimination - Morphology Discrimination	Wavelet™ algorithm - in the RV only		Wavelet algorithm - in the RV only		Wavelet algorithm - in the RV only	
HF Diagnostics - Thoracic Impedance	Yes - OptiVol® fluid status monitoring		Yes - OptiVol fluid status monitoring		Yes - OptiVol fluid status monitoring	
Rhythm Diagnostic - AT/AF Burden Trend	N/A	Yes	N/A	Yes	N/A	Yes
Rhythm Diagnostic - AT/AF Alert	N/A	Yes	N/A	Yes	N/A	Yes
IEGM Storage - Capacity (min)	23.5 - 1 ch, 14 - 2 ch		23.5 - 1 ch, 14 - 2 ch		23.5 - 1 ch, 14 - 2 ch	
System Diagnostics - HV Lead Impedance	Yes		Yes		Yes	
Remote Management - Remote Monitoring	Yes - CareLink® RF		Yes - CareLink RF		Yes - CareLink RF	
Battery	SVO		SVO		SVO	
Wireless Telemetry	Yes - Conexus™ MICS band RF		Yes - Conexus MICS band RF		Yes - Conexus MICS band RF	
Patient Alert	Yes - audible		Yes - audible		Yes - audible	
Safety Platform	Yes	No	Yes	No	No	
Full Page 8-1/2" x 11"Printouts	No		No		No	

Boston Scientific – Selling Against Boston Scientific ICD Therapy

What Boston Scientific is saying about their products

Discover Innovation

Teligen® ICD – The smallest, thinnest high-energy ICD in the world, featuring innovative new technologies with exceptional longevity. This full-featured device was designed, built and tested with patient safety and reliability in mind.

In addition to Confient® ICD:
- Reverse mode switch to promote intrinsic ventricular conduction without dropped beats
- Quick Convert delivers a burst of ATP in the VF zone to avoid painful shocks
- Choice of rhythm discriminators between onset/stability or Rhythm ID to tailor therapy
- Remote monitoring and follow-up with the LATITUDE Patient Management System
- 9.9 mm thin and 31.5 cc volume

Confient ICD – ZIP™ wandless telemetry for wireless communication, allowing safe implant and efficient follow-up

In addition to Vitality® and Vitality® 2 ICDs:
- RF telemetry
- New hybrid battery technology for stable charge times throughout the life of the device and improved longevity
- Extended AV delay for more appropriate therapy delivery (up to 400 ms AV search)

Vitality & Vitality 2 ICDs Designed to be life-saving devices with individual solutions for individual needs of patients and physicians

- Rhythm ID correctly identifies VT/VF episodes 100% of the time and correctly identifies SVT episodes 94% of the time
- At 30 cc and 11 mm thickness, the Vitality 2 ICD provides benefit to any patient who would appreciate the small, thin shape of the device
- 41 J high-energy shock for HE models
- Industry leading 7-year limited warranty for EL models
- AV search hysteresis to reduce unnecessary RV pacing

Endotak Reliance® G Defibrillation Leads

- Easy extraction – GORE™ ePTFE
  – Only defibrillation lead designed for easier lead extraction through the prevention of tissue in-growth between and around individual shocking coil filars
- Enhanced performance with lubricious coating
- Demonstrated reliability with redundant Insulation and limited lifetime warranty

St. Jude Medical Response

Feature	SJM Response
Device size	▪ Although the Teligen ICD is the thinnest device available, the large footprint requires a larger incision ▪ Teligen ICD may be suboptimal for some patients' body type
Shock energy	▪ The SJM Fortify ICD has 40 J delivered and 45 J stored energy safety shock ▪ The Teligen ICD has 41 J stored energy and 35 J delivered energy
Shock reduction	▪ The Teligen ICD Quick Convert provides ATP before but not during charge in the VF zone ▪ The nominal setting in SJM devices is ATP during charge, which does not add any additional delay to delivering HV therapy.
Reliable design	▪ The failure rates of the Teligen ICD shown thus far appear to be consistent with products developed under the Guidant quality system ▪ Three advisories have been issued on Teligen ICD during 1.5 years after market release
Lead size	▪ The SJM Durata® ICD lead requires only a 7 F lead introducer and better accommodates multiple leads in a single vessel and eases passage through difficult anatomies ▪ The Endotak Reliance G ICD lead requires a 9 F introducer without a guidewire
Lead extraction	▪ The SJM Durata lead uses flat wire defibrillation coils completely back-filled with silicone to prevent tissue in-growth ▪ There is no clinical data to suggest that GORE ePTFE coating makes lead extractions easier ▪ The GORE coating does not extend to the very end of the coils, so there is still a section of unprotected shocking coil. Case reports have shown this section is susceptible to tissue in-growth causing difficulty in extraction
Inappropriate postshock sensing	▪ No dedicated bipolar option for the Endotak Reliance G lead which may increase the risk of inappropriate sensing following shock therapy
Lead durability	▪ Endotak Reliance G lead is a silicone-based lead with a lubricious coating ▪ Silicone has been shown to be more susceptible to insulation abrasion over time than the Optim insulation used on Durata leads

Key SJM features over Boston Scientific ICDs

40 J safety shock, DeFT Response® technology, ATP while charging, Total Capture Confirmation, smaller footprint, 7 F lead, Optim® insulation.

* GORE is a trademark of W.L. Gore & Associates, Inc

	Boston Scientific		Boston Scientific		Boston Scientific	
	Teligen®		**Confient®**		**Vitality® 2**	
	VR	DR	VR	DR	VR	DR
Model number - VR	F102	F110	F010	E030		
Volume (cc)	31.5			44	30	
Weight (g)	72		87.5		82	
H x W x D (mm)	74.5 x 61.7 x 9.9		82.5 x 67.0 x 14.5		65 x 59 x 11	
Max Delivered Energy (J)	35		35		27	
Charge Time to Max Delivered Energy (sec)	8.4		7.7		7	
Longevity (year) - VR	**8.4** @ 2.5V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 6 max shocks/yr	**7.8** @ 2.5V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 6 max shocks/yr	**6.9** @ 2.6V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks/yr	**6.8** @ 2.6V, 0.4 ms, 60 ppm, 500 ohms, 15% A&V pacing, 4 max shocks/yr	**6.4** @ 500 ohms, 15% RV pacing	**5.6** @ 500 ohms, 15% A&V pacing
HV Therapy - ATP	Yes - RV Only		Yes - RV Only		Yes - RV Only	
ATP During Charge	No		No		No	
HV Therapy - Reverse Last Therapy	Yes		Yes		Yes	
HV Therapy - Shock Vector Programmability	Yes - SVC On/Off		Yes		No	
HV Therapy - Waveform Programmability	Yes - Polarity		Yes - Polarity		Yes - Polarity	
Induction - DC Fibber	No		No		No	
Pacing Options - Reduced V-pacing -VR	N/A	Yes - AV Hysteresis, Reverse Mode Switch	N/A	Yes - AV Hysteresis	N/A	Yes - AV Hysteresis
Pacing Options - AV Optimization	N/A	Yes - SmartDelay	N/A	No	N/A	No
AF Management - Prevention	N/A	Yes - APP, ProAct	N/A	Yes - APP, ProAct	N/A	Yes - APP, ProAct
Capture Confirmation - RV	No		No		No	
Capture Confirmation - Atrial	N/A	No	N/A	No	N/A	No
Sensing - T-wave Oversensing Programmability	No		No		No	
Discrimination - Morphology Discrimination	Yes - Rhythm ID		No		Yes - Rhythm ID	
HF Diagnostics - Thoracic Impedance	No		No		No	
Rhythm Diagnostic - AT/AF Burden Trend	N/A	Yes	N/A	No	N/A	No
Rhythm Diagnostic - AT/AF Alert	N/A	Yes	N/A	No	N/A	No
IEGM Storage - Capacity (min)	19		19		19	
System Diagnostics - HV Lead Impedance	Yes		Yes		Yes	
Remote Management - Remote Monitoring	Yes - LATITUDE		No		No	
Battery	MnO2		QHR		SVO	
Wireless Telemetry	Yes - ZIP Telemetry		Yes - ZIP Telemetry		No	
Patient Alert	Yes - audible		Yes - audible		Yes - audible	
Safety Platform	Yes - Safety Core feature		No		No	
Full Page 8-1/2" x 11"Printouts	No		No		No	

Biotronik – Selling Against Biotronik ICD Therapy

What Biotronik is saying about their products

Advanced Patient Management

Lumax™ 540 ICD Series – Your Patient. Our Priority. The Lumax 540 Series comprises the latest technology in a full complement of patient-focused CRM products engineered for physicians who demand superior quality and reliability.

Compared to Lumos® ICD:
- More programming solutions for success in treating your patients' dynamic needs (shock pathway and pulse width options, I-Opt RV pacing reduction)
- Enhanced painless therapy spares your patients the stress and anxiety of unnecessary shocks (ATP One Shot)
- Extended lifetime increases the time between device replacements, so your patients benefit from reduced procedure risk

Lumos ICD – Lumos is the first ICD featuring IEGM Online™, offering superior protection for patients

Compared to Lexos® ICD:
- IEGM Online enables you to easily monitor therapy effectiveness
- Intrinsic Rhythm Support Plus
- Heart Failure Monitor
- Early detection of AF

Lexos ICD – A New Dimension in Intelligent Diagnostics

- Biotronik Home Monitoring Services enables you to analyze therapies whenever and wherever you like
- Superior SVT discrimination with SMART Detection (93% Specificity, 100% Sensitivity)

Linox® ICD Leads – The Standard for Exceptional Performance

- Reliable fixation
- Long-term stability

St. Jude Medical Response

Feature	SJM Response
Painless therapy	▪ The Biotronik ATP One Shot feature is similar to the Boston Scientific Quick Convert feature in that it offers ATP before but not during charge in the VF zone
Remote monitoring	▪ Merlin.net PCN is the only CRM remote monitoring system to win an award for Medical Design Excellence and has the ability to link directly to electronic health record systems ▪ Biotronik has a unique wireless transmitter, and the company emphasizes it in corporate messages about its Biotronik Home Monitoring System; however, ask physicians how many patients are willing to carry their monitor with them at all times
Longevity	▪ All products in the SJM ICD portfolio have longevity expectations that meet or exceed those of the Biotronik Lumax 540 ICD

Key SJM features over Biotronik ICDs
40 J safety shock, DeFT Response® technology, ATP while charging, Total Capture Confirmation, 7 F lead, Optim® insulation

	Biotronik		Biotronik		Biotronik	
	Lumax™ 540		Lumos®		Lexos®	
	VR	DR	VR	DR	VR-T	DR-T
Model number - VR	360348	360346	353219	353220	346999	347001
Volume (cc)	37.2		31		31	
Weight (g)	92		78		78	
H x W x D (mm)	66 x 55 x 13		67 x 55 x 12		67 x 55 x 12	
Max Delivered Energy (J)	35		30		30	
Charge Time to Max Delivered Energy (sec)	10				8.6	
Longevity (year) - VR	**9.7** @ 2.5V, 0.4 ms, 60 ppm, 700 ohms, 15% RV pacing, 4 max shocks/yr	**9.1** @ 2.5V, 0.4 ms, 60 ppm, 700 ohms, 50% RA and 15% RV pacing	**6.8** @ 2.8V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks per year	**6.4** @ 2.8V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks per year	**6.8** @ 2.8V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks per year	**6.3** @ 2.8V, 0.4 ms, 60 ppm, 500 ohms, 15% RV pacing, 4 max shocks per year
HV Therapy - ATP	Yes - RV only		Yes - RV only		Yes - RV only	
ATP During Charge	No		No		No	
HV Therapy - Reverse Last Therapy	Yes		No			
HV Therapy - Shock Vector Programmability	Yes		No		No	
HV Therapy - Waveform Programmability	Yes - Polarity		Yes - Polarity		Yes - Polarity	
Induction - DC Fibber	No		No		No	
Pacing Options ¬Reduced V-pacing - VR	N/A	Yes - Intrinsic Rhythm Support	N/A	Yes - AV Hysteresis	N/A	Yes - Intrinsic Rhythm Support
Pacing Options - AV Optimization	N/A	Yes - Dynamic AV Delay	N/A	Yes - Dynamic AV Delay	N/A	Yes - Dynamic AV Delay
AF Management - Prevention	N/A	No	N/A	No	N/A	No
Capture Confirmation - RV	Yes		No		No	
Capture Confirmation - Atrial	N/A	No	No	No	No	No
Sensing - T-wave Oversensing Programmability	Yes - Enhanced T-wave Suppression		Yes - Enhanced T-wave Suppression		Yes - Enhanced T-wave Suppression	
Discrimination - Morphology Discrimination	Smart Detection		Smart Detection		Smart Detection	
HF Diagnostics -Thoracic Impedance	No		No		No	
Diagnostics - Ischemia Trending	No	Yes	No	Yes	No	Yes
Rhythm Diagnostic -AT/AF Burden Trend	N/A	Yes	No	Yes	No	Yes
Rhythm Diagnostic -AT/AF Alert	N/A		No		No	
IEGM Storage -Capacity (min)	32 - 3 ch		30 - 2 Ch		30 - 2 Ch	
System Diagnostics -HV Lead Impedance	Yes				Yes	
Remote Management -Remote Monitoring	Yes - CardioMessenger feature		Yes - CardioMessenger feature		Yes - CardioMessenger feature	
Battery	LiMnO2 or QHR		LiMnO2		LiMnO2	
Wireless Telemetry	Yes		No		No	
Patient Alert	No		No		No	
Safety Platform	No		No		No	

Sorin – Selling Against Sorin ICD Therapy

What Sorin is saying about their products

PARADYM™ ICD with Complete Capture Management – By allowing spontaneous conduction, delivering accurate therapies, and providing augmented energy, PARADYM DR ICD is changing the rules.

In addition to Ovatio® ICD:
- Increased longevity
- Highest shock energy (42 J stored / 37 J delivered)
- Larger size (33 cc) compared with Ovatio ICD

Ovatio ICD

In addition to Maximo® II ICD:
- The comfort of painless therapy (ATP up to 255 bpm), significantly improving quality of life
- SafeR 99.9% intrinsic conduction with management of all AV blocks
- PARAD+ Superior tachyarrhythmia discrimination to minimize inappropriate shocks
- Smallest dual-chamber ICD available (29 cc)
- Essential for patients who need more energy to treat life-threatening arrhythmias, Ovatio ICD offers 34 J (stored) of maximum output

Isoline™ ICD Lead – The First in a Long Line of Leaders

- Optimal positioning before helix extension for easy mapping
- Position and extend the helix with a single stylet for quick handling
- Helix extension with x-ray markers for easy confirmation
- Polyurethane overlay for abrasion resistance

St. Jude Medical Response

Feature	SJM Response
Reduced RV pacing	▪ The SJM VIP® algorithm minimizes RV pacing while maintaining AV synchrony without dropping any beats when DDD pacing is needed ▪ Sorin SafeR feature works similarly to the Medtronic algorithm with the same type of challenges with short-long-short rhythms in patients who have transient AV block
Appropriate therapy	▪ The capabilities of Sorin to ensure appropriate therapy are limited ▪ PARAD rhythm discrimination is based on timing cycle data only, not morphology – Compromised in single-chamber devices without the benefit of atrial timing cycle information
Shock energy	▪ The SJM Fortify ICD delivers a 40 J safety shock and has 45 J stored energy ▪ The Sorin PARADYM ICD delivers 37 J, which is 3 J lower than the SJM Fortify ICD family and only one J higher than the SJM Current® ICD family ▪ PARADYM ICD does not offer DeFT Response technology to optimize the shocking waveform and maximize the defibrillation safety margin
Lead size	▪ The 7 F Durata lead better accommodates multiple leads in a single vessel and eases passage through difficult anatomies reducing the risk of implant complications ▪ The Isoline defibrillation lead requires a larger 8 F introducer without a guidewire
Lead durability	▪ Polyurethane has been shown to be more susceptible to environmental stress cracking over time than the Optim insulation used on Durata® leads

Key SJM features over Sorin ICDs

40 J safety shock, DeFT Response® technology, 7 F lead, Optim insulation, Total Capture Confirmation, ATP while charging.

ELA / Sorin			ELA / Sorin	
	PARADYM™		Ovatio®	
	VR	DR	VR	DR
Model number - VR	8250	8550	6250	6550
Volume (cc)	33		29	
Weight (g)	94		85	
Thickness (mm)	11		10.9	
Max Delivered Energy (J)	37		29.3	
Charge Time to Max Delivered Energy (sec)				
Longevity (year) - VR	**6.5** @ 2.5V, 0.35 ms, 60 ppm, 500 ohms, 15% DDD pacing, 4 shocks/yr		**6.9** @ 2.5V, 0.35 ms, 60 ppm, 500 ohms, 15% VVI pacing	**6.5** @ 2.5V, 0.35 ms, 60 ppm, 500 ohms, 15% DDD pacing, 4 shocks/yr
HV Therapy - ATP	Yes - RV, LV, RV+LV		Yes	
ATP During Charge	No		No	
HV Therapy - Reverse Last Therapy	Yes		Yes	
HV Therapy - Shock Vector Programmability	Yes		Yes	
HV Therapy - Waveform Programmability	Yes - Polarity	No	Yes - Polarity	No
Induction - DC Fibber	No		No	
Pacing Options - Reduced V-pacing - VR	N/A	Yes - SafeR	N/A	Yes - SafeR
Pacing Options - AV Optimization	N/A	No	N/A	No
AF Management - Prevention	N/A	No	N/A	No
Capture Confirmation - RV	No		No	
Capture Confirmation - Atrial	N/A	No	N/A	No
Sensor -Automatic	No		No	
Sensing -T-wave Oversensing Programmability	No		No	
Discrimination - Morphology Discrimination	PARAD+ technology		PARAD+ technology	
HF Diagnostics -Thoracic Impedance	No	Yes	No	Yes
Rhythm Diagnostic - AT/AF Burden Trend	N/A	Yes	N/A	No
Rhythm Diagnostic - AT/AF Alert	N/A		N/A	
IEGM Storage - Capacity (min)	19		19	
System Diagnostics - HV Lead Impedance	Yes		No	
Remote Management -Remote Monitoring	No		No	
Battery	QHR®		SVO	
Wireless Telemetry	No		No	
Patient Alert	No	No	No	No
Full Page 8-1/2" x 11"Printouts	No		No	

QHR is a registered trademark of Greatbatch LTD

	St. Jude Medical		St. Jude Medical		St. Jude Medical	
	Fortify™ ICD(SJ4 Header)		Current Accel® (SJ4 Header)		Current® Plus (SJ4 Header)	
	VR	DR	VR	DR	VR	DR
Model number - VR	CD1231-40(Q)	CD2231-40(Q)	CD1215-36(Q)	CD2215-36(Q)	CD1211-36(Q)	CD2211-36(Q)
Volume (cc)	35		41		41	42(41)
Weight (g)	76(75)		79		79	80
H x W x D (mm)	73(71) x 40 x 14	74(71) x 40 x 14	76(74) x 50 x 14		76(74) x 50 x 14	77(74) x 50 x 14
Max Delivered Energy (J)	40		36		36	
Charge Time to Max Delivered Energy (sec)	10		9.2		9.2	
Longevity (year) - VR	**10.1** @ VVI, 2.5V, 0.5 ms, 60 ppm, 500 ohms, 25% pacing, 3 shocks/yr	**8.9** @ DDD 2.5V, 0.5 ms, 500 ohms, 60 ppm, 25% pacing, 3 shocks/yr, 18 month shelf-life	**8.0** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 25% pacing, quarterly shocks	**7.5** @ DDD 2.5V, 0.5ms, 500ohms, 60ppm, 25% pacing, 4 shocks/yr, 18 month shelf-life	**8.0** @ 2.5V, 0.5 ms, 60 ppm, 500 ohms, 25% pacing, quarterly shocks	**7.5** @ DDD 2.5V, 0.5 ms, 500 ohms, 60 ppm, 25% pacing, 4 shocks/yr, 12 month shelf-life
HV Therapy - ATP	Yes - RV only		Yes - RV only		Yes - RV only	
ATP During Charge	Yes		No		No	
HV Therapy - Reverse Last Therapy	No - RV anode nominal		No - RV anode nominal		No - RV anode nominal	
HV Therapy - Shock Vector Programmability	Yes - SVC On/Off		Yes - SVC On/Off		Yes - SVC On/Off	
HV Therapy - Waveform Programmability	Pulse width, polarity, tilt		Pulse width, polarity, tilt		Pulse width, polarity, tilt	
Induction - DC Fibber	Yes		Yes		Yes	
Pacing Options -Reduced V-pacing - VR	N/A	Yes - VIP® feature	N/A	Yes - VIP feature	N/A	Yes - VIP feature
Pacing Options - AV Optimization	N/A	Yes - QuickOpt® Timing Cycle Optimization	N/A	Yes - QuickOpt Timing Cycle Optimization	N/A	Yes - QuickOpt Timing Cycle Optimization
AF Management	N/A	Yes - AF Suppression® Algorithm	N/A	Yes - AF Suppression Algorithm	N/A	Yes - AF Suppression Algorithm
Capture Confirmation - RV	Yes		Yes		No	
Capture Confirmation - Atrial	N/A	Yes	N/A	Yes	N/A	No
Sensing - T-wave Oversensing Programmability	Yes - Sense*Ability*® algortithm; Threshold Start, Decay Delay, Low Frequency Attenuation		Yes - Sense*Ability* algortithm; Threshold Start, Decay Delay		Yes - Sense*Ability* algortithm; Threshold Start, Decay Delay	
Discrimination - Morphology Discrimination	Yes		Yes		Yes	
HF Diagnostics -Thoracic Impedance	No		No		No	
Rhythm Diagnostic -AT/AF Burden Trend	N/A	Yes	N/A	Yes	N/A	Yes
Rhythm Diagnostic -AT/AF Alert	N/A	Yes	N/A	Yes	N/A	Yes
IEGM Storage - Capacity (min)	45 - 1 ch; 22 - 2 ch; 15 - 3 ch		45 - 1 ch; 22 - 2 ch; 15 - 3 ch		45 - 1 ch; 22 - 2 ch; 15 - 3 ch	
System Diagnostics -HV Lead Impedance	Yes - multivector, automatic, daily		Yes - multivector, automatic, daily		Yes - multivector, automatic, daily	
Remote Management -Remote Monitoring	Yes - Merlin@home® transmitter		Yes - Merlin@home transmitter		Yes - Merlin@home transmitter	
Battery	QHR		SVO		SVO	
Wireless Telemetry	Yes - InvisiLink wireless telemetry		Yes - InvisiLink wireless telemetry		Yes - InvisiLink wireless telemetry	
Patient Alert	Yes - vibratory		Yes - vibratory		Yes - vibratory	
Safety Platform	Multiple System Safeguards		Multiple System Safeguards		Multiple System Safeguards	
Full Page 8-1/2" x 11"Printouts	Yes		Yes		Yes	

Medtronic – Selling Against Medtronic CRT-D Therapy

What Medtronic is saying about their products

Medtronic Vision 3D™ Portfolio Unparalleled Clinical Options

Consulta® ICD CRT-D with Complete Capture Management – The Right Therapy at the Right Time

In addition to Concerto® CRT-D:
- AT/AF Management - Offers unprecedented diagnostics and therapies including Cardiac Compass trends, ATP, Conducted AF Response, and dual channel EGM
- Automaticity with Complete Capture Management – ensures pacing capture in all chambers and automatically provides a complete device check daily

Concerto CRT-D with Conexus® Wireless Telemetry – The First Complete System to Assist in Managing Heart Disease

In addition to Maximo® II CRT-D:
- OptiVol fluid status monitoring – Provides unprecedented insight into patients' clinical status
- LV Capture Management to ensure cardiac resynchronization therapy

Maximo II CRT-D – Wireless Efficiency Integrating Medtronic's Best Pacing and ICD Exclusives

- Safer, more efficient implants
- Easy remote follow-up
- Medtronic PainFREE Solutions – Proven strategies to reduce shocks (ATP During Charging, PainFREE programming)
- Better disease management – Successful options only from Medtronic (MVP algorithm, Cardiac Compass Trends, Four real-time EGM channels)

Attain® CRT Leads – The Standard for Exceptional Performance

- The Attain bipolar over-the-wire – 6 F lead designed for medium to large veins with moderate tortuosity
- Attain StarFix®– First active fixation left-heart lead with a 0% chronic dislodgement rate*
- Exclusive deployable lobes, allowing for customized lead placement in a wide range of vein sizes and locations
- Attain Ability® bipolar** left-heart lead – First 4 F bipolar left-heart lead featuring a flexible, tapered distal end that is deliverable through inner catheter for direct delivery

*Chronic is defined as two days or greater post-implant

** Dual electrode

St. Jude Medical Response

Feature	SJM Response
Automaticity	▪ SJM offers two CRT-Ds with fully automatic thresholds
Medtronic PainFREE solutions	▪ SJM devices support ATP prior to or while charging in the VF zone for rates up to 300 bpm ▪ Medtronic PainFREE programming recommendations can be implemented in SJM devices if desired as well
Lead size	▪ QuickFlex® µ LV lead is the smallest left ventricular lead on the market enabling access to small target veins that may have been unreachable in the past. It offers Direct-To-Target™ delivery when used with the CPS Aim® SL inner catheter subselector*
LV lead fixation	▪ Medtronic does not have long-term data on the risk of extracting active fixation left-sided leads when compared with passive fixation leads

Key SJM features over Medtronic CRT-Ds

40 J safety shock, DeFT Response technology, QuickOpt timing cycle optimization

*Pending FDA approval

	Medtronic	Medtronic	Medtronic
	Consulta®	**Concerto®**	**Maximo® II**
Model number	D234TRK	C15DWK	D284TRK
Volume (cc)	38	38	38
Weight (g)	68	68	68
H x W x D (mm)	69 x 51 x 15	69 x 51 x 15	69 x 51 x 15
Max Delivered Energy (J)	35	35	35
Charge Time to Max Delivered Energy (sec)	7.7	8.2	7.7
Longevity (year)	**5.2** @ 100% BiV pacing, RV 2.5V, LV 3.0 V, A 2.5 V, 0.5 ms, 60 ppm, 500 ohms, Q shocks, Pre-EGM storage On	**4.8** @ 100% BiV pacing w/atrial tracking, 2.0 V (RA/RV) 3.0 V&0.4 ms (RA, RV, LV), 60 ppm, 500 ohms, Q shocks, EGM storage On	**5.2** @ 100% BiV pacing, RV 2.5V, LV 3.0 V, A 2.5 V, 0.5 ms, 60 ppm, 500 ohms, Q shocks, Pre-EGM storage On
HV Therapy - ATP	RV/LV/BiV	RV/LV/BiV	RV/LV/BiV
ATP During Charge	Yes	Yes	Yes
Max Rate for ATP Zone	300 bpm	300 bpm	300 bpm
HV Therapy - Reverse Last Therapy	Yes	Yes	Yes
HV Therapy - Shock Vector Programmability	Yes - Can On/Off	Yes - Can On/Off	Yes - Can On/Off
HV Therapy - Waveform Programmability	Polarity	Polarity	Polarity
Induction - DC Fibber	No	No	No
Pacing Options - Reduced V-pacing	No	No	No
Pacing Options - AV Optimization	No	No	No
AF Management - Prevention	No	No	No
Resynch Therapy - V-V Optimization	No	No	No
Resynch Therapy - V-V Interval (range)	0-80 ms	0-80 ms	0-80 ms
Resynch Therapy - V-V Interval (step)	5 ms	5 ms	5 ms
Resynch Therapy - Algorithm for Max CRT in AT	Yes - atrial tracking recovery	Yes - atrial tracking recovery	Yes - atrial tracking recovery
Resynch Therapy - Algorithm for Max CRT in AF	Yes - conducted AF response, ventricular sense response	Yes - conducted AF response, ventricular sense response	Yes - conducted AF response, ventricular sense response
Resynch Therapy - Rate Smoothing	Yes	Yes	Yes
Resynch Therapy - LV Pacing Configurations	bipolar, tip-coil, ring-coil	bipolar, tip-coil, ring-coil	bipolar, tip-coil, ring-coil
Resynch Therapy - Multisite Pacing	No	No	No
Resynch Therapy - CRT Sensing Options	RV	RV	RV
Capture Confirmation - RV	Yes	No	No
Capture Confirmation - LV	Yes	Yes	Yes
Capture Confirmation - Atrial	Yes	No	No
Capture Confirmation - Follow-up EGMs	No	No	No
Sensing - T-wave Oversensing Programmability	No	No	No
Discrimination - Morphology Discrimination	Wavelet™ algorithm - in the RV only	Wavelet algorithm - in the RV only	Wavelet algorithm - in the RV only
Discrimination – A-V Rate Branch	Yes - PR Logic®	Yes - PR Logic	Yes - PR Logic
HF Diagnostics - Thoracic Impedance	Yes - OptiVol® fluid status monitoring	Yes - OptiVol fluid status monitoring	No
HF Diagnostics - Heart Rate Variability	Yes	Yes	Yes
HF Diagnostics - Exercise Trend	No	No	No
HF Diagnostics - Day and Night Heart Rate	Yes	Yes	Yes
HF Diagnostics - Weight / Blood Pressure	No	No	No
HF Diagnostics - Hemodynamic / Pressure	No	No	No
HF Diagnostics - % Pacing	Yes	Yes	Yes
HF Diagnostics - Ischemia Trending	No	No	No
Rhythm Diagnostic - AT/AF Burden Trend	Yes	Yes	Yes
Rhythm Diagnostic - AT/AF Alert	Yes	Yes	Yes
IEGM Storage - Capacity (min)	23.5 - 1 ch, 14 - 2 ch	23.5 - 1 ch, 14 - 2 ch	23.5 - 1 ch, 14 - 2 ch
System Diagnostics - HV Lead Impedance	Yes	Yes	Yes
Remote Management - Remote Monitoring	Yes - CareLink® RF	Yes - CareLink RF	Yes - CareLink RF
Battery	SVO		
Wireless Telemetry	Yes - Conexus MICS band RF	Yes - Conexus MICS band RF	Yes - Conexus MICS band RF
Patient Alert	Yes - audible	Yes - audible	Yes - audible
Safety Platform	No	No	No
Full Page 8-1/2" x 11" Printouts	No	No	No

Boston Scientific – Selling Against Boston Scientific CRT-D Therapy

What Boston Scientific is saying about their products

Discover Innovation

Cognis® CRT-D – The smallest, thinnest high-energy CRT-D in the world, featuring innovative new technologies with exceptional longevity. This full-featured device was designed, built and tested with patient safety and reliability in mind.

In addition to Livian® CRT-D:
- Quick Convert delivers a burst of ATP in the VF zone to avoid painful shocks
- Choice of rhythm discriminators between onset/stability or Rhythm ID to tailor therapy
- Remote monitoring and follow-up with the LATITUDE patient management system
- 9.9 mm thin and 32.5 cc volume

Livian® CRT-D – SmartDelay AV optimization, which quickly provides recommended settings for programming AV delay for optimally timed CRT

In addition to Contak Renewal® 4 RF CRT-Ds:
- SmartDelay AV optimization to deliver the accuracy of a catheter without the invasiveness
- BiV triggers help deliver CRT as prescribed during atrial arrhythmias
- New hybrid battery technology for stable charge times throughout the life of the device and improved longevity

Renewal® 4 & Contak Renewal 4 RF CRT-Ds

- ZIP wandless telemetry enables wireless communication between the device and the programmer
- 41 J high-energy shock for HE models
- Ventricular Rate Regulation to reduce irregular ventricular intervals during conducted AF
- Patient-centric diagnostics (autonomic balance monitor, HRV footprint, activity log)
- Electronic repositioning provides additional programming flexibility to mitigate elevated thresholds and extracardiac stimulation

ACUITY® Steerable Lead The first LV lead with 3D tip control for enhanced maneuverability so you can deflect, push and torque

- Can be delivered either over-the-wire or with a stylet and is stabilized within the venous system by its pre-formed J shape

ACUITY® Spiral Lead The smallest lead tip profile of any LV lead on the market

- Increases lead placement options, allowing access to veins that may have been avoided in the past
- Unique helical design is intended to maximize vein tissue contact for reliable fixation in a range of vessel sizes and tortuosities
- Demonstrated reliability with redundant Insulation and limited lifetime warranty

St. Jude Medical Response

Feature	SJM Response
Size	▪ Although the Cognis CRT-D is the thinnest device available, the large footprint requires a larger incision ▪ Cognis CRT-D may be suboptimal for some patients' body type ▪ Boston Scientific highlights the size of the Cognis CRT-D because it's the only unique feature
AV delay optimization	▪ SmartDelay AV optimization is suboptimal, because the LV offset recommendations are based on retrospective clinical data rather than on the timing cycle recommendations tailored to the specific needs of each patient.
Electronic repositioning	▪ Cognis CRT-D is not compatible with quadripolar LV pacing ▪ Fewer options to change pacing vectors noninvasively
Reliable design	▪ Cognis CRT-D failure rates shown thus far appear to be consistent with products developed under the Guidant quality system ▪ Three advisories have been issued on Cognis CRT-D during 1.5 years after market release
Broad lead portfolio	▪ Customers must make trade-offs between size and polarity when selecting a Boston Scientific LV lead – ACUITY Spiral is the smallest LV lead, but unipolar only – Bipolar options, ACUITY Steerable and EasyTrak® are larger than comparable SJM leads ▪ SJM QuickFlex® µ LV lead is the smallest bipolar LV lead on the market and can be delivered through an inner catheter*

Key SJM features over Boston Scientific CRT-Ds

40 J safety shock, DeFT Response® technology, ATP while charging, Total Capture Confirmation, smaller footprint, 7 F lead, Optim® insulation.

	Boston Scientific	Boston Scientific	Boston Scientific
	Cognis® HE	**Contak Renewal® 4 HE RF**	**Livian®**
Model number	108. N120	H239	H227/H229
Volume (cc)	32.5	43	44
Weight (g)	72	90	87.5
H x W x D (mm)	79.5 x 61.7 x 9.9	82.6 x 63.0 x 11.5	82.5 x 67.0 x 14.5
Max Delivered Energy (J)	35	35	35
Charge Time to Max Delivered Energy (sec)	8.8	6.9	
Longevity (year)	**5.8** @ 100% BiV pacing, RV 3.5 V, LV 3.5 V, A 3.0 V, 0.4 ms, 60 ppm	**4.3** @ 100% BiV pacing, RV 3.5 V, LV 3.5 V, A 3.0 V, 0.4 ms, 60 ppm	
HV Therapy - ATP	RV only	RV only	RV only
ATP During Charge	No	No	No
Max Rate for ATP Zone	250 bpm	250 bpm	250 bpm
HV Therapy - Reverse Last Therapy	Yes	Yes	Yes
HV Therapy - Shock Vector Programmability	Yes - SVC On/Off	Yes	Yes
HV Therapy - Waveform Programmability	Polarity	Polarity	Polarity
Induction - DC Fibber	No	No	No
Pacing Options - Reduced V-pacing	No	No	No
Pacing Options - AV Optimization	Yes - SmartDelay AV confirmation	No	Yes - Expert Ease
AF Management - Prevention	No	No	No
Resynch Therapy - V-V Optimization	No - AV only	No	No - AV only
Resynch Therapy - V-V Interval (range)	0-100 ms (LV first only)	0-100 ms (LV first only)	0-100 ms (LV first only)
Resynch Therapy - V-V Interval (step)	10 ms	10 ms	10 ms
Resynch Therapy - Algorithm for Max CRT in AT	Yes - atrial tracking preference	Yes - atrial tracking preference	Yes - atrial tracking preference
Resynch Therapy - Algorithm for Max CRT in AF	Yes - ventricular rate regularization, Atrial Tachy Response Mode	Yes - ventricular rate regularization, Atrial Tachy	Yes - ventricular rate regularization, Atrial Tachy Response Mode
Resynch Therapy - Rate Smoothing	Yes	Yes	Yes
Resynch Therapy - LV Pacing Configurations	Yes - Expanded Electronic Repositioning; LV tip-can, LV tip-RV coil, LV ring-can, LV ring-RV coil, LV tip-LV ring, LV ring-LV tip (pace only)	Yes - Electronic Repositioning	Yes - Electronic Repositioning
Resynch Therapy - Multisite Pacing	No	No	No
Resynch Therapy - CRT Sensing Options	RV	RV	RV
Capture Confirmation - RV	No	No	No
Capture Confirmation - LV	No	No	
Capture Confirmation - Atrial	No	No	No
Capture Confirmation - Follow-up EGMs	No	No	No
Sensing - T-wave Oversensing Programmability	No	No	No
Discrimination - Morphology Discrimination	Yes	No	No
Discrimination – A-V Rate Branch	Yes, freq V> freq V, AFib rate threshold	Yes, freq V> freq V, AFib rate threshold	Yes, freq V> freq V, AFib rate threshold
HF Diagnostics - Thoracic Impedance	No	No	No
HF Diagnostics - Heart Rate Variability	Yes	Yes	Yes
HF Diagnostics - Exercise Trend	No	No	No
HF Diagnostics - Day and Night Heart Rate	Yes	No	No
HF Diagnostics - Weight / Blood Pressure	Yes - in LATITUDE	Yes - in LATITUDE	Yes - in LATITUDE
HF Diagnostics - Hemodynamic / Pressure	No	No	No
HF Diagnostics - % Pacing	Yes	Yes	Yes
HF Diagnostics - Ischemia Trending	No	No	No
Rhythm Diagnostic - AT/AF Burden Trend	Yes	Yes	Yes
Rhythm Diagnostic - AT/AF Alert	Yes	Yes	Yes
IEGM Storage - Capacity (min)	17	19 - 1 channel, 9.5 - 2 channels	19 - 1 channel, 9.5 - 2 channels
System Diagnostics - HV Lead Impedance	Yes	Yes	Yes
Remote Management - Remote Monitoring	Yes - LATITUDE	No	No
Battery	MnO2	SVO	QHR
Wireless Telemetry	Yes - ZIP Telemetry	Yes - ZIP Telemetry	Yes - ZIP Telemetry
Patient Alert	Yes - audible	Yes - audible	Yes - audible
Safety Platform	Yes - Safety Core feature	No	No

Biotronik – Selling Against Biotronik CRT-D Therapy

What Biotronik is saying about their products

Advanced Patient Management

Lumax® 540 CRT-D Series – Tomorrow's standard of care – The Lumax 540 Series with Biotronik Advanced Patient Management provides the cornerstones for comprehensive patient protection and care

In addition to Lumax 340 CRT-D:

- Extended lifetime for improved patient quality-of-life by prolonging intervals for device replacement

Lumax® 340 CRT-D – Heart failure therapy now has more options

- The most advanced Biotronik Home Monitoring® technology
- Heart Failure monitor (mean heart rate, patient activity, VES per hour, % BiV pacing, LV Capture, AF Burden, HRV)
- Enhanced painless therapy spares your patients the stress and anxiety of unnecessary shocks (ATP One Shot)
- Multiple LV pacing configurations to optimize the patient's hemodynamics and overcome phrenic nerve stimulation
- RV tracking to maintain CRT even at high ventricular rates such as AF with RVR
- Superior SVT discrimination with SMART Detection (93% Specificity, 100% Sensitivity)

Corox™ OTW Bipolar CRT Lead Performance. Versatility. Stability. – The Corox lead family helps you achieve your CRT goals.

- Corox leads offer industry-leading threshold performance for LV applications
- Corox leads can be used with a stylet or the over-the-wire implantation technology
- The everesT study, which evaluated the performance of the Corox OTW BP and Corox OTW BP-S leads from implant to 6 months, demonstrated a 1.5% dislodgement rate
- The access and placement versatility of the Corox family of LV leads allows you to place the lead where it can help resynchronize the failing heart—not just where anatomy permits
- There were fewer CRT "non-responders" in the everesT study than in conventional CRT trials with the average NYHA functional Class at three months improved 0.75 classes

St. Jude Medical Response

Feature	SJM Response
Painless therapy	▪ The Biotronik ATP One Shot is similar to the Boston Scientific Quick Convert in that it offers ATP before but not during charge in the VF zone, delaying the time to shock therapy when it is needed
Remote monitoring	▪ Merlin.net® PCN is the only CRM remote monitoring system to win an award for Medical Design Excellence and has the ability to link directly to electronic health record systems ▪ Biotronik has a unique wireless transmitter, and the company emphasizes it in corporate messages about its Biotronik Home Monitoring System ▪ However, ask physicians how many patients are willing to carry their monitor with them at all times
Longevity	▪ All products in the SJM ICD portfolio have longevity expectations that meet or exceed those of the Biotronik Lumax 540 ICD
Broad lead portfolio	▪ SJM QuickFlex LV leads range from XL versions to micro versions to accommodate varying patient anatomies ▪ The Biotronik Corox family of CRT leads does not have a comparable offering, and therefore does not offer the same versatility

Key SJM features over Biotronik CRT-Ds

40 J safety shock, DeFT Response® technology, ATP while charging, Total Capture Confirmation, smaller footprint

	Biotronik	Biotronik	Biotronik
	Lumax® 540 HF-T	**Lumax® 340 HF-T**	**Lumax® 300 HF-T**
Model number	540 HF-T	340 HF-T	300 HF-T
Volume (cc)	40	40	37
Weight (g)	94	94	83
H x W x D (mm)	66 x 59 x 13	66 x 59 x 13	66 x 59 x 13
Max Delivered Energy (J)	35	35	30
Charge Time to Max Delivered Energy (sec)	<10	6.9	
Longevity (year)	**6.3** @ RA/RV 2.5 V/0.4 ms; LV 4.8 V/ 0.4 ms; 60 ppm; 700 Ohm, RA	**5.2** @ 100% BiV pacing, 0% a pacing, 2.8 V, 0.5 ms (RV), 4.0 V, 0.4 ms (LV), 60 ppm, Q shocks, HM On and diagnostics On	**5.4** @ 100% BiV pacing, 0% a pacing, 2.8 V, 0.5 ms (RV), 4.0 V, 0.4 ms (LV), 60 ppm, Q shocks, HM On and diagnostics On
HV Therapy - ATP	RV/LV/BiV	RV/LV/BiV	RV/LV/BiV
ATP During Charge	No	No	No
Max Rate for ATP Zone			
HV Therapy - Reverse Last Therapy	Yes	Yes	Yes
HV Therapy - Shock Vector Programmability	No	No	No
HV Therapy - Waveform Programmability	Polarity	Polarity	Polarity
Induction - DC Fibber	No	No	No
Pacing Options - Reduced V-pacing	Yes - AV hysteresis	Yes - AV hysteresis	Yes - AV hysteresis
Pacing Options - AV Optimization	No	No	No
AF Management - Prevention	No	No	No
Resynch Therapy - V-V Optimization	No	No	No
Resynch Therapy - V-V Interval (range)	0-100 ms	0-100 ms	0-100 ms
Resynch Therapy - V-V Interval (step)	5 ms	5 ms	5 ms
Resynch Therapy - Algorithm for Max CRT in AT	Yes - Neg AV Hysteresis	Yes - Neg AV Hysteresis	Yes - Neg AV Hysteresis
Resynch Therapy - Algorithm for Max CRT in AF	Yes - AMS base rate, RV Sense Trigger (BiV trigger)	Yes - AMS base rate, RV Sense Trigger (BiV trigger)	Yes - AMS base rate, RV Sense Trigger (BiV trigger)
Resynch Therapy - Rate Smoothing	No	No	No
Resynch Therapy - LV Pacing Configurations	LV tip-LV ring, LV tip-RV ring, LV ring-LV tip, LV ring-RV ring)	LV tip-LV ring, LV tip-RV ring, LV ring-LV tip, LV ring-RV ring)	LV tip-LV ring, LV tip-RV ring, LV ring-LV tip, LV ring-RV ring)
Resynch Therapy - Multisite Pacing	No	No	No
Resynch Therapy - CRT Sensing Options	RV/LV	RV/LV	RV/LV
Capture Confirmation - RV	Yes	No	No
Capture Confirmation - LV	Yes	No	No
Capture Confirmation - Atrial	No	No	No
Capture Confirmation - Follow-up EGMs	No	No	No
Sensing - T-wave Oversensing Programmability	Yes - upper/lower threshold, hold of upper threshold	Yes - upper/lower threshold, hold of upper threshold	Yes - upper/lower threshold, hold of upper threshold
Discrimination - Morphology Discrimination	No	No	No
Discrimination – A-V Rate Branch	Yes - SMART Detection	Yes - SMART Detection	Yes - SMART Detection
HF Diagnostics - Thoracic Impedance	No	No	No
HF Diagnostics - Heart Rate Variability	Yes	Yes	Yes
HF Diagnostics - Exercise Trend	No	No	No
HF Diagnostics - Day and Night Heart Rate	No	No	No
HF Diagnostics - Weight / Blood Pressure	No	No	No
HF Diagnostics - Hemodynamic / Pressure	No	No	No
HF Diagnostics - % Pacing	Yes	Yes	Yes
HF Diagnostics - Ischemia Trending	No	No	No
Rhythm Diagnostic - AT/AF Burden Trend	Yes	Yes	Yes
Rhythm Diagnostic - AT/AF Alert	Yes	Yes	Yes
IEGM Storage - Capacity (min)	32 (3 ch)	32 (3 ch)	32 (3 ch)
System Diagnostics - HV Lead Impedance	Yes	Yes	Yes
Remote Management - Remote Monitoring	Yes - CardioMessenger feature	Yes - CardioMessenger feature	Yes - CardioMessenger feature
Battery	LiMnO2		
Wireless Telemetry	Yes	Yes	Yes
Patient Alert	No	No	No
Safety Platform	No	No	No
Full Page 8-1/2" x 11" Printouts	No	No	No

Sorin – Selling Against Sorin CRT-D Therapy

What Sorin is saying about their products

PARADYM CRT-D – Thanks to its active resynchronization, accurate therapies, and augmented energy, PARADYM CRT is changing the rules.

In addition to ELA Ovatio® CRT-D:
- Increased longevity (6.4 years)
- Highest shock energy (42 J stored / 37 J delivered)
- Larger size (34 cc) compared with Ovatio CRT-D

Ovatio CRT-D

- BTO delivers CRT during exercise and simultaneously protects from slow VTs
- The comfort of painless therapy (ATP up to 255 bpm) significantly improves quality of life
- Superior tachyarrhythmia discrimination to minimize inappropriate shocks (PARAD+ provides 94% overall specificity)
- Smallest CRT-D available (30 cc, 11 mm thin)

Situs® OTW

- Silicone screw design at the tip of the lead body "actively fixes" the lead in the lumen of the vein
- Polyurethane coating offers smooth handling within the guiding catheter

Situs LV Lead

- Exclusive dual-curve design allows the operator to position the lead in the proximal part of the lateral vein

St. Jude Medical Response

Feature	SJM Response
CRT assurance	▪ Clinical benefit of BTO is unproven and suspect given the small number of patients able to achieve sinus rates during exercise that are greater than VT rates
Appropriate therapy	▪ The capabilities of Sorin to ensure appropriate therapy are limited ■ PARAD rhythm discrimination is based on timing cycle data only, not morphology ▪ ATP is not available in the VF zone meaning that rhythms over 255 bpm can only be treated with shock therapy
Shock energy	▪ Unify™ CRT-Ds from SJM deliver a 40 J safety shock and have 45 J stored energy ▪ PARADYM CRT-D does not offer DeFT Response® technology to optimize the shocking waveform and maximize the defibrillation safety margin
Broad lead portfolio	▪ SJM provides an equivalent or superior solution to all of the Sorin LV lead options
Lead dislodgement	▪ SJM QuickFlex® LV leads have a proven 1% dislodgement rate*[1]
Lead durability	▪ QuickFlex µ LV leads are manufactured with Optim insulation for enhanced handling and performance*

1. QuickSite Lead Family data represents data pooled on QuickSite Model 1056K and QuickSite Model 1056T leads from the RHYTHM ICD/QuickSite Model 1056K Lead Study (162 patients) and the RHYTHM ICD/QuickSite Model 1056T Lead Study (144 patients) [QuickSite Models 1056K and 1056T Lead User's Manual]. © 2005 St. Jude Medical, Inc.

Key SJM features over Biotronik Sorin CRT-Ds

40 J safety shock, DeFT Response® technology, ATP while charging, Total Capture Confirmation, smaller footprint

*Pending FDA approval

ELA/Sorin	
	ELA Ovatio CRT
Model number	6750
Volume (cc)	30
Weight (g)	87
Thickness (mm)	11
Max Delivered Energy (J)	30
Charge Time to Max Delivered Energy (sec)	
Longevity (year)	**4.3** @ 100% BiV pacing, 3.3 V, 0.37 ms, 60 ppm, A = 500W, V=500W, Q shocks
HV Therapy - ATP	RV, LV, RV+LV
ATP During Charge	No
Max Rate for ATP Zone	
HV Therapy - Reverse Last Therapy	Yes
HV Therapy - Shock Vector Programmability	Yes - Can On/Off and SVC On/Off
HV Therapy - Waveform Programmability	Polarity
Induction - DC Fibber	No
Pacing Options - Reduced V-pacing	Yes - AAIsafeR
Pacing Options - AV Optimization	No
AF Management - Prevention	No
Resynch Therapy - V-V Optimization	No
Resynch Therapy - V-V Interval (range)	0-64 ms
Resynch Therapy - V-V Interval (step)	8 ms
Resynch Therapy - Algorithm for Max CRT in AT	BTO (Brady-tachy overlap)
Resynch Therapy - Algorithm for Max CRT in AF	Yes - FMS + AMS base rate
Resynch Therapy - Rate Smoothing	No
Resynch Therapy - LV Pacing Configurations	LV tip-LV ring, LV tip-RV ring, LV ring-LV tip, LV ring-RV ring)
Resynch Therapy - Multisite Pacing	No
Resynch Therapy - CRT Sensing Options	RV
Capture Confirmation - RV	No
Capture Confirmation - LV	No
Capture Confirmation - Atrial	No
Capture Confirmation - Follow-up EGMs	No
Sensing - T-wave Oversensing Programmability	Yes - upper/lower threshold, hold of upper threshold
Discrimination - Morphology Discrimination	No
Discrimination – A-V Rate Branch	Yes
HF Diagnostics - Thoracic Impedance	No
HF Diagnostics - Heart Rate Variability	Yes
HF Diagnostics - Exercise Trend	No
HF Diagnostics - Day and Night Heart Rate	No
HF Diagnostics - Weight / Blood Pressure	No
HF Diagnostics - Hemodynamic / Pressure	No
HF Diagnostics - % Pacing	Yes
HF Diagnostics - Ischemia Trending	No
Rhythm Diagnostic - AT/AF Burden Trend	Yes
Rhythm Diagnostic - AT/AF Alert	Yes
IEGM Storage - Capacity (min)	19 (15 episodes, 1 and 2 channels)
System Diagnostics - HV Lead Impedance	No
Remote Management - Remote Monitoring	No
Battery	SVO
Wireless Telemetry	No
Patient Alert	No
Safety Platform	No
Full Page 8-1/2" x 11" Printouts	No

	St. Jude Medical	St. Jude Medical	St. Jude Medical
	Unify™ (SJ4-LLHH)	**Promote Accel® (SJ4-LLHH)**	**Promote® Plus (SJ4-LLHH)**
Model number	CD3231-40(Q)	CD3215-36(Q)	CD3211-36(Q)
Volume (cc)	36	43(42)	43(42)
Weight (g)	78(77)	82	82
H x W x D (mm)	79(73) x 40 x 14	81 x 50 x 14	75 x 50 x 14
Max Delivered Energy (J)	40	36	36
Charge Time to Max Delivered Energy (sec)	10.0 to 40 J (8.2 to 36 J)	9.2	9.2
Longevity (year)	**10** @ 100% RA, RV and LV pacing, 2.5 V, 0.5 ms, 60 ppm, 500 ohms, 3 max shocks	**6.2** @ 100% RV and LV pacing, 2.5 V, 0.5 ms, 60 ppm, 500 ohms, 4 max shocks	**6.2** @ 100% RV and LV pacing, 2.5 V, 0.5 ms, 60 ppm, 500 ohms, 4 max shocks
HV Therapy - ATP	**RV only**	**RV only**	**RV only**
ATP During Charge	Yes	No	No
Max Rate for ATP Zone	300 bpm	214 bpm	214 bpm
HV Therapy - Reverse Last Therapy	No - RV anode nominal	No - RV anode nominal	No - RV anode nominal
HV Therapy - Shock Vector Programmability	Yes - SVC On/Off	Yes - SVC On/Off	Yes - SVC On/Off
HV Therapy - Waveform Programmability	Pulse width, polarity, tilt	Pulse width, polarity, tilt	Pulse width, polarity, tilt
Induction - DC Fibber	Yes	Yes	Yes
Pacing Options - Reduced V-pacing	Yes - VIP if RV only pacing	Yes - VIP if RV only pacing	Yes - VIP if RV only pacing
Pacing Options - AV Optimization	Yes - QuickOp® Timing Cycle Optimization	Yes - QuickOpt Timing Cycle Optimization	Yes - QuickOpt Timing Cycle Optimization
AF Management - Prevention	Yes - AF Suppression™ Algorithm	Yes - AF Suppression Algorithm	Yes - AF Suppression Algorithm
Resynch Therapy - V-V Optimization	Yes - QuickOpt Timing Cycle Optimization	Yes - QuickOpt Timing Cycle Optimization	Yes - QuickOpt Timing Cycle Optimization
Resynch Therapy - V-V Interval (range)	10-80 ms	10-80 ms	10-80 ms
Resynch Therapy - V-V Interval (step)	5 ms	5 ms	5 ms
Resynch Therapy - Algorithm for Max CRT in AT	Yes - Neg AV Hysteresis	Yes - Neg AV Hysteresis	Yes - Neg AV Hysteresis
Resynch Therapy - Algorithm for Max CRT in AF	Yes -AMS base rate, RV Sense Trigger (BiV Trigger Mode)	Yes -AMS base rate, RV Sense Trigger (BiV Trigger Mode)	Yes -AMS base rate, RV Sense Trigger (BiV Trigger Mode)
Resynch Therapy - Rate Smoothing	No	No	No
Resynch Therapy - LV Pacing Configurations	bipolar, tip-coil, ring-coil	bipolar, tip-coil, ring-coil	bipolar, tip-coil, ring-coil
Resynch Therapy - Multisite Pacing	No	No	No
Resynch Therapy - CRT Sensing Options	RV	RV	RV
Capture Confirmation - RV	Yes	Yes	Yes
Capture Confirmation - LV	Yes	No	No
Capture Confirmation - Atrial	Yes	No	No
Capture Confirmation - Follow-up EGMs	Yes	No	No
Sensing - T-wave Oversensing Programmability	Yes - Sense*Ability*®; Threshold Start, Decay Delay, Low Frequency Attenuation	Yes - Sense*Ability*; Threshold Start, Decay Delay	Yes - Sense*Ability*; Threshold Start, Decay Delay
Discrimination - Morphology Discrimination	Yes	Yes	Yes
Discrimination – A-V Rate Branch	Yes	Yes	Yes
HF Diagnostics - Thoracic Impedance	No	No	No
HF Diagnostics - Heart Rate Variability	Yes	No	No
HF Diagnostics - Exercise Trend	Yes	Yes	Yes
HF Diagnostics - Day and Night Heart Rate	No	No	No
HF Diagnostics - Weight / Blood Pressure	No	No	No
HF Diagnostics - Hemodynamic / Pressure	No	No	No
HF Diagnostics - % Pacing	Yes	Yes	Yes
Rhythm Diagnostic - AT/AF Burden Trend	Yes	Yes	Yes
Rhythm Diagnostic - AT/AF Alert	Yes	Yes	Yes
IEGM Storage - Capacity (min)	45 - up to 3 channels	45 - up to 3 channels	45 - up to 3 channels
System Diagnostics - HV Lead Impedance	Yes, multivector, automatic, daily	Yes, multivector, automatic, daily	Yes, multivector, automatic, daily
Remote Management - Remote Monitoring	Yes - Merlin@home® transmitter	Yes - Merlin@home transmitter	Yes - Merlin@home transmitter
Battery	QHR	SVO	SVO
Wireless Telemetry	Yes - InvisiLink	Yes - InvisiLink	Yes - InvisiLink
Patient Alert	Yes - vibratory	Yes - vibratory	Yes - vibratory
Safety Platform	Multiple system safeguards	Multiple system safeguards	Multiple system safeguards
Full Page 8-1/2" x 11" Printouts	Yes	Yes	Yes

Frequently Asked Questions

Frequently Asked Questions

ATP While Charging

Question: How does ATP in the VF zone in SJM devices compare to the competition?

Answer: The Unify™ CRT-D, and Fortify™ ICDs are capable of delivering ATP in the VF zone for arrhythmias detected at up to 300 bpm either prior to or while charging. Medtronic is the only other company that offers ATP either before or during charging in the VF zone.

Boston Scientific (Quick Convert feature) and Biotronik (ATP One Shot feature) only offer ATP prior to charging which may delay shock therapy when needed. Further, the Boston Scientific Quick Convert feature can only deliver ATP if the rhythm is < 250 bpm.

Question: How is ATP prior to or while charging programmed?

Answer: ATP While Charging is nominally on as the first therapy in the VF zone. When selecting the first therapy in the VF zone, the user can choose Defib, ATP While Charging or ATP Prior to Charging. If the user selects ATP, the maximum rate can be selected between 150 and 300 bpm. The ATP scheme for ATP prior to or while charging is equal to either the nominal for all ATP therapies or the scheme that has been programmed for the most aggressive zone.

Battery

Question: Why did SJM change the battery chemistry for these devices?

Answer: The QHR® battery, which is manufactured by Greatbatch Medical, was chosen in part because its higher current density allows for a reduction in size without compromising longevity. The QHR battery chemistry also provides more consistent charge times throughout the device life. Finally, changing to QHR battery chemistry supports advanced technology such as the unique 40 J safety shock feature from SJM.

Question: What kind of testing has been done on the QHR battery?

Answer: Since 2006, SJM has been designing and testing the QHR battery with Greatbatch Medical. A comprehensive range of quality, performance and reliability tests were completed to ensure SJM, Greatbatch Medical, and the Medical Device Regulating Bodies (FDA and TUV Product Services) of a safe, reliable and long-term battery solution.

Throughout the development process, more than 1,000 cells were used for component-level and device-level engineering testing. In addition, more than 300 QHR batteries endured a series of electrical, mechanical and environmental tests. These included the following:

- short-circuit tests
- high-current capability tests
- thermal shock
- external pressure
- vibration and mechanical shock
- high and low temperature exposure
- life testing

This testing verifies that the QHR battery supports device performance that ensures patient safety and reliability, even under extreme conditions.

Frequently Asked Questions cont'd

Battery cont'd

Question: Do any other companies use QHR batteries?

Answer: Boston Scientific uses QHR batteries in their Confient® ICD and Livian® CRT-D devices. With Teligen® ICD and Cognis® CRT-D, Boston Scientific has gone to an in-house manufactured MnO2 battery with similar properties. Sorin uses QHR batteries in their PARADYM™ ICDs and CRT-Ds. We don't have definitive knowledge of other companies using QHR batteries in their ICD or CRT-D products at this time; however, the industry in general is moving towards more advanced battery technologies with higher current density to enable smaller sizes and feature enhancements.

Question: Are there any changes in device behavior due to the new battery?

Answer: Besides the ability to extend longevity vs. SVO batteries and maintain more consistent charge times, the only change to device behavior due to the QHR battery is a new method for tracking and displaying longevity. Monitoring voltage will no longer be viewable by the end user. Longevity remaining calculations performed by the device and displayed on the programmer are more accurate for assessing remaining service life using QHR batteries.

Capture and Sensing

Question: Does the Ventricular AutoCapture™ pacing system improve the longevity of devices in the high voltage portfolio?

Answer: The primary benefit of the AutoCapture pacing system feature in any device is to ensure the proper delivery of pacing therapy. Additional benefits include an acceleration of the follow-up exam by eliminating manual capture tests as well as an increase in longevity. Although the improved longevity in ICD and CRT devices is not as significant as in pacemakers, most devices and pacing configurations will realize some benefit.

There are limited circumstances under which a longevity benefit would not be realized, such as a patient with very little to no ventricular pacing. In this case, the energy required to run the AutoCapture™ pacing system feature might exceed the energy potentially saved from properly adjusting the pacing output. This may be a consideration in whether to turn on the feature in these patients.

Question: How does Capture Confirmation in SJM devices compare to the Medtronic Complete Capture Management® feature?

Answer: Both the SJM Capture Confirmation and Medtronic Complete Capture Management are designed to ensure patient safety by automatically measuring and adjusting pacing thresholds according to changing patient needs. However, there are two important differences to note when comparing capture confirmation algorithms.

Frequently Asked Questions cont'd

First, only the SJM AutoCapture™ pacing system feature (available in Fortify™ ICD & Current Accel™ ICD) provides Beat-by-Beat™ RV capture verification and a backup safety pulse, and adjusts ventricular output accordingly to ensure the highest patient safety available. On the contrary, the Medtronic Complete Capture Management® system checks RV capture only once daily, potentially leaving the patient without effective pacing therapy.

Second, in the case of a failed automated atrial or BiV threshold test, the Medtronic Capture Management algorithms automatically go to high output until the device can be reprogrammed at the next follow-up visit (possibly weeks or months later). As a result, unnecessary battery drainage may occur in these devices. On the contrary, the St. Jude Medical ACap® Confirm algorithm (St. Jude Medical Accel™ family, Unify™ CRT-D and Fortify ICD) and BiVCap® confirm capture confirmation (Unify CRT-D and Promote Accel™ CRT-D) features monitor and adjust thresholds every 8 or 24 hours as programmed. If a threshold test fails in a St. Jude Medical device, the Capture Confirmation feature will go to high output only until the next automatic interval of 8 or 24 hours, when it will adjust as appropriate.

Question: Has implementation of the Sense*Ability*® algorithm changed with Unify CRT-D and Fortify ICD devices?

Answer: While the Sense*Ability* algorithm itself has not been changed, device sensing in the Unify CRT-D and the Fortify ICDs has been enhanced with low frequency attenuation to significantly reduce the risk of T-wave oversensing. This is a filter-based approach to reducing or eliminating inappropriate therapy due to T-wave oversensing. The new filter works in concert with the existing Sense*Ability* algorithm to provide the most accurate sensing. Bench testing has shown significant reduction in T-wave oversensing by adding the new filter.

Question: Can the new filter (low frequency attenuation) be turned off?

Answer: Yes. The enhanced filter is the default filter at shipped setting. It can be switched to the standard Tachy filter (the filter on our current devices) via the "Low Frequency Attenuation Filter" parameter. "ON" indicates enhanced filter is in effect. The parameter is located at Parameters > Brady > Capture & Sense > SenseAbility Settings > Advanced Settings > Low Frequency Attenuation.

Device Comparison

Question: How does the Fortify ICD differ from the Current Accel ICD?

Answer: The Fortify ICD is 6 cc smaller; delivers 40 J vs. 36 J; has a low frequency attenuation filter designed to reduce T-wave oversensing; ATP prior to or while charging in the VF zone; a % RV pacing alert and QHR® battery technology.

Question: How does the Unify CRT-D differ from the Promote® Plus RF CRT-D?

Answer: The Unify CRT-D, is 7 cc smaller; delivers 40 J vs. 36 J; has a low frequency attenuation filter to reduce T-wave oversensing; a % BiV pacing alert; ATP prior to or while charging in the VF zone; and QHR battery technology.

Device Size/Shape

Question: How was the device shape chosen for the Unify CRT-D and Fortify ICD? Why isn't it thinner?

Answer: The form factor of the Unify CRT-D and Fortify ICD devices was selected through consideration of many important factors with particular focus on patient safety and an improved implant experience. While some customers have indicated they value a thin shape, they also recognize that the consequence of a thin shape is a larger footprint.

A smaller footprint also allows the physician to make a smaller incision, which saves time both in creating the pocket as well as when suturing the incision at the end of the procedure. Also, wider footprints create a problem for change-out procedures when the new device footprint is larger than the device being replaced.

Frequently Asked Questions cont'd

High Voltage Therapy

Question: What are the maximum stored and delivered energy capabilities of devices in the high voltage portfolio?

	Unify™ CRT-D, Fortify ™ ICD	St. Jude Medical Accel™ and Promote® Plus families of ICDs and CRT-Ds
	Safety Shock	**Safety Shock**
Stored	45 J	41 J
Delivered	40 J	36 J

Question: How is the 40 J safety shock programmed?

Answer: The 40 J shock can only be delivered following a 30 J or higher shock in normal use condition (no ATP).

In all but one case, a 40 J safety shock can never be programmed as first therapy in any zone. However, It can be programmed as second, third or last therapy if the previous therapy in the same zone is programmed to 30 J or higher.

The one exception is for commanded shock, where it is all selectable. However, this will be a rare case.

Question: What technology changes enable the 40 J shock?

Answer: Higher rated components (feedthrus, IGBTs, SCRs, Diodes, FETs and Transformers), QHR® battery and caps that have higher surge voltage rating.

Question: How do charge times compare between a 36 J and 40 J shock?

Answer: Beginning of Life (BOL) charge times between 36 and 40 J shocks are very similar. The average BOL charge time for a 36 J shock in a Unify CRT-D or Fortify ICD is 8 seconds, with a range of 7-10 seconds. The average BOL charge time for a 40 J shock is also 8 seconds, with a range of 8-14 seconds. At ERI, charge times for a 36 J shock can be up to 12 seconds, while charge times for a 40 J shock can be up to 15 seconds.

Maximum Charge time (seconds)			
	36 J	**40 J (2nd charge)**	**40 J (6th charge)**
BOL	8.4 ± 0.3	10.1 ± 0.2	13.1 ± 1.1
MOL	9.2 ± 0.3	11.7 ± 0.2	11.7 ± 0.4
ERI	11.4 ± 0.7	14.2 ± 0.8	14.2 ± 1.4
EOS	12.0 ± 0.6		

Longevity

Question: What are the projected longevities for the various models at nominal settings?

Answer: Device longevity at the noted settings is as follows:

Fortify ICD longevity estimates with AutoCapture™ Pacing System Off:			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Fortify DR* ICD	CD2231-40(Q)	7.4	9.5
Fortify VR* ICD	CD1231-40(Q)	9.1	10.5

*2.5 V, 0.5 ms, 60 ppm, 500 ohms, 3 max charges per year

Fortify™ ICD longevity estimates with AutoCapture™ Pacing System Off:			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Fortify DR* ICD	CD2231-40(Q)	7.5	9.0
Fortify VR** ICD	CD1231-40(Q)	9.0	9.9

*RV = 1.0 V, A = 2.0 V, 0.5 ms, 60 ppm, 500 ohms, 3 max charges per year
** RV = 1.0 V, 0.5 ms, 60 ppm, 500 ohms, 3 max charges per year

Current® Plus ICD			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Current Plus DR* ICD	CD2211-36(Q)	6.1	8.2
Current Plus VR* ICD	CD1211-36(Q)	7.0	8.4

*2.5 V, 0.5 ms, 60 ppm, 500 ohms, 4 max charges per year

Unify™ CRT-D longevity estimates with BiVCap® Confirm Off:			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Unify* CRT-D	CD3231-40Q)	6.6	9.5

*RV = 2.5 V, LV = 2.5 V, A = 2.5 V, 0.5 ms, 60 ppm, 500 ohms, 3 max charges per year, 100% BiV pacing

Unify CRT-D longevity estimates with BiVCap Confirm Off:			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Unify* CRT-D	CD3231-40(Q)	7.0	9.5

*RV = 2.0 V, LV = 2.0 V, A = 2.0 V, 0.5 ms, 60 ppm, 500 ohms, 3 max charges per year, 100% BiV pacing

Promote® Plus CRT-D			
	Model#	**Estimated Longevity 100% Pacing All Chambers**	**Estimated Longevity 0% Pacing All Chambers**
Promote Plus* CRT-D	CD3211-36(Q)	6.5	10.2

*RV = 2.5 V, LV = 2.5 V, A = 2.5 V, 0.5 ms, 60 ppm, 500 ohms, 4 max charges per year, 100% BiV pacing

Percent Pacing Alerts

Question: How are the %V pacing and %BiV pacing alerts programmed?

Answer: The percent pacing alerts are programmed on the Parameters > Alert Notification screen. The clinician also can specify the moving time window (1, 7, 30 or 90 days) over which the pacing percentage is calculated. If the average percent pacing value exceeds the threshold during the specified window, the system, at the clinician's option, will log an alert to be displayed at the next remote or in-clinic device interrogation.

For those patients with CRT devices, the clinician can set the threshold such that pacing below the threshold will trigger an alert. The programmable range for the CRT alert is 60 to 80% in steps of 5% and 81 to 100% in steps of 1%, with a nominal setting of 90%.

For patients with dual– or single-chamber devices, the clinician can set the threshold such that pacing above the threshold will trigger an alert. The programmable range for the single– and dual-chamber alert is 0 to 95% in steps of 5%, with a nominal setting of 40%.

Frequently Asked Questions cont'd

SJ4 Header

Question: What header connector options will be available with the high voltage portfolio devices?

Answer: The devices will be available in IS-1/DF-1 and SJ4 inline connector header options.

Question: Why don't we label the devices with the DF-4 standard?

Answer: SJ4 is an interim label for the St. Jude Medical product designed to meet the requirements of the DF-4 standard approved by ISO in January 2010.

St. Jude Medical is focused on reducing risk by continuously finding ways to put more control into the hands of those who save and enhance lives.

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