COGNIS™

Specifications

COGNIS: Model N119

The COGNIS cardiac resynchronization therapy defibrillator (CRT-D) provides ventricular tachyarrhythmia therapy and cardiac resynchronization therapy (CRT) for the treatment of ventricular tachycardia, ventricular fibrillation, and heart failure. COGNIS CRT-Ds are the smallest (32.5 cc) and thinnest (9.9 mm) high-energy CRT devices, and offer extended battery longevity*, self-correcting software, and improved programming technology. In addition, COGNIS hardware includes Safety Core™ technology, which is intended to provide lifesaving shock therapy and basic pacing functionality in the event the main system fails.

Other advances in the COGNIS device include the SmartDelay™ algorithm, which quickly provides recommended settings for programming AV Delay/Sensed AV Offset with the intent of providing optimally timed CRT, enabling individualized pacing therapy. And Boston Scientific CRM's Electronic Repositioning™ feature has been expanded to provide six configurations for non-invasively stimulating the left side of the heart, even after implant.

* Compared with previous Boston Scientific devices based on internal bench testing data

MECHANICAL SPECIFICATIONS

Model	Size (cm) (W x H x D)	Mass (g)	Volume (cc)	Connector Type (RV : LV)	Case Electrode Surface Area (mm^3)
N119	6.17 x 7.95 x 0.99	72	32.5	IS-1/DF-1 : IS-1	6670

ZIP™ TELEMETRY

Parameter	Programmable Values	Nominal
Communication Mode	Enable use of ZIP telemetry (May require limited use of wand), Use wand for all telemetry	Enable use of ZIP telemetry (May require limited use of wand)

CARDIAC RESYNCHRONIZATION THERAPY

Pacing Therapy Parameter (normal, post-therapy and temporary)

Parameter	Programmable Values	Nominal
Mode	DDD(R), DDI(R), VDD(R), VVI(R), AAI(R), Off; Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off	DDD
Lower Rate Limit (LRL) (ppm)	30, 35, ..., 185	45 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR) (ppm)	30, 35, ..., 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR) (ppm)	30, 35, ..., 185	130 (Tolerance ± 5 ms)
Pulse Amplitude (atrium) (V)	0.1, 0.2, ... 3.5, 4.0, ..., 5.0	3.5 (5.0 post-therapy) (Tolerance ± 15% or ± 100 mV) (whichever is greater)
Pulse Amplitude (right ventricle) (V)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	3.5 (5.0 post-therapy) (Tolerance ± 15% or ± 100 mV) (whichever is greater)

Boston Scientific

Delivering what's next.™

CARDIAC RESYNCHRONIZATION THERAPY continued

Pacing Therapy Parameter (normal, post-therapy and temporary)

Parameter	Programmable Values	Nominal
Pulse Width (atrium, right ventricle) (ms)	0.1, 0.2, ..., 2.0	0.4 (1.0 post-therapy) (Tolerance ±0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
Atrial Pace/Sense Configuration	Bipolar, Off	Bipolar
Activity Threshold	Very High, High, Medium High, Medium, Medium Low, Low, Very Low	Medium
Reaction Time (sec)	10, 20, ..., 50	30
Response Factor	1, 2, ..., 16	8
Recovery Time (min)	2, 3, ..., 16	2
Maximum PVARP (ms)	150, 160, ..., 500	280 (Tolerance ± 5 ms)
Minimum PVARP (ms)	150, 160, ..., 500	240 (Tolerance ± 5 ms)
PVARP After PVC (ms)	Off, 150, 200, ..., 500	400 (Tolerance ± 5 ms)
RV-Blank After A-Pace (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-Pace (ms)	85, 105, 125, Smart	Smart (Tolerance ± 5 ms)
A-Blank After RV-Sense (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
Maximum VRP (right ventricle) (ms)	150, 160, 170, ..., 500	250 (Tolerance ± 7.5 ms)
Minimum VRP (right ventricle) (ms)	150, 160, ..., 500	230 (Tolerance ± 7.5 ms)
Maximum Paced AV Delay (ms)	30, 40, ..., 300	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay (ms)	30, 40, ..., 300	180 (Tolerance ± 5 ms)
Maximum Sensed AV Delay (ms)	30, 40, ..., 300	120 (Tolerance ± 5 ms)
Minimum Sensed AV Delay (ms)	30, 40, ..., 300	120 (Tolerance ± 5 ms)
Respiratory Sensor	Off, On	On
Tracking Preference	Off, On	On
Rate Hysteresis Hysteresis Offset (ppm)	-80, -75, ... ,-5, Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis (cycles)	Off, 256, 512, 1024, 2048, 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (up, down) (%)	Off, 3, 6, 9, 12, 15, 18, 21, 25	Off (Tolerance 1%)
Noise Response	AOO, VOO, DOO, Inhibit Pacing	DOO for DDD(R) and DDI(R) modes; VOO for VDD(R) and VVI(R) modes; AOO for AAI(R) mode
Maximum Pacing Rate (ppm)	30, 35, ... ,185	130 (Tolerance ± 5 ms)
Post-therapy Pacing Period (min:sec) (available post-shock only)	00:15, 00:30, 00:45, 01:00, 01:30, 02:00, 03:00, 04:00, 05:00, 10:00, 15:00, 30:00, 45:00, and 60:00	00:30 (Tolerance 0.5% ± 1 cardiac cycle)

Brady/CRT Left Ventricular Pacing

Parameter	Programmable Values	Nominal
Ventricular Pacing Chamber	RV Only, BiV	BiV
LV Offset (ms)	-100, -90, ..., 0	0 (Tolerance ± 5 ms for <> 0 ms; ±6 ms for = 0 ms)
Pulse Amplitude (left ventricle) (V)	0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	3.5 (5.0 post therapy) (Tolerance ± 15% or ± 100 mV) (whichever is greater)
Pulse Width (left ventricle) (ms)	0.1, 0.2, ..., 2.0	0.4 (1.0 post therapy) (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
LV-Blank After A-Pace (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
LVRP (ms)	250, 260, ..., 500	250 (Tolerance ± 7.5 ms)
LVPP (ms)	300, 350, ..., 500	400 (Tolerance ± 5 ms)
BiV Trigger	Off, On	Off
Left Ventricular Electrode Configuration	Dual, Single, None	None
Left Ventricular Pace Configuration	Single or Dual: LVtip>>Can, LVtip>>RV; Dual Only: LVring>>Can, LVring>>RV, LVtip>>Lvring, LVring>>Lvtip	Single: LVtip>>RV; Dual: LVtip>>LVring
Left Ventricular Sense Configuration	Single or Dual: LVtip>>Can, LVtip>>RV, Off; Dual Only: LVring>>Can, LVring>>RV, LVtip>>Lvring, Off	Single: LVtip>>RV; Dual: LVtip>>LVring

VENTRICULAR ANTITACHYCARDIA PACING (ATP) (specified into a 750Ω load)

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
ATP Type	3 zones	Off, Burst, Ramp, Scan, Ramp/Scan	Off, Burst, Ramp, Scan, Ramp/Scan	Not available	Off (VT-1); Burst (VT-ATP1); Ramp (VT-ATP2)
	2 zones		Off, Burst, Ramp, Scan, Ramp/Scan	Not available	Burst (VT-ATP1); Ramp (VT-ATP2)
Number of Bursts (per scheme)	3 zones	Off, 1, 2, ..., 30	Off, 1, 2, ..., 30	Not available	Off (VT-1); 2 (VT-ATP1); 1 (VT-ATP2)
	2 zones		Off, 1, 2, ..., 30	Not available	2 (ATP1); 1 (ATP2)
Initial Pulse (pulses)	3 zones	Off, 1, 2, ..., 30	Off, 1, 2, ..., 30	Not available	4 (VT-1); 10 (VT)
	2 zones		Off, 1, 2, ..., 30	Not available	10
Pulse Increment (pulses)	3 zones	0, 1, ..., 5	0, 1, ..., 5	Not available	0
	2 zones		0, 1, ..., 5	Not available	
Maximum Number of Pulses	3 zones	1, 2, ..., 30	1, 2, ..., 30	Not available	4 (VT-1); 10 (VT)
	2 zones		1, 2, ..., 30	Not available	10
Coupling Interval (% or ms)	3 zones	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	Not available	81% (Tolerance ± 5 ms)
	2 zones		50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	Not available	
Coupling Interval Decrement (ms)	3 zones	0, 2, ..., 30	0, 2, ..., 30	Not available	0 (Tolerance ± 5 ms)
	2 zones		0, 2, ..., 30	Not available	
Burst Cycle Length (BCL) (% or ms)	3 zones	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	Not available	81% (Tolerance ± 5 ms)
	2 zones		50, 53, 56, 59; 63, 66, ..., 84, 88, 91, 94, 97% or 120, 130, ..., 750 ms	Not available	
Ramp Decrement (ms)	3 zones	0, 2, ..., 30	0, 2, ..., 30	Not available	0 (VT-1); 0 (VT ATP1); 10 (VT ATP2) (Tolerance ± 5 ms)
	2 zones		0, 2, ..., 30	Not available	0 (ATP1); 10 (VT ATP2) (Tolerance ± 5 ms)
Scan Decrement (ms)	3 zones	0, 2, ..., 30	0, 2, ..., 30	Not available	0 (Tolerance ± 5 ms)
	2 zones		0, 2, ..., 30	Not available	
Minimum Interval	3 zones	120, 130, ..., 400	120, 130, ..., 400	Not available	220 (Tolerance ± 5 ms)
	2 zones		120, 130, ..., 400	Not available	
Right Ventricular ATP Pulse Width	3 zones	0.1, 0.2, ..., 2.0 ms	0.1, 0.2, ..., 2.0 ms	Not available	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
	2 zones		0.1, 0.2, ..., 2.0 ms	Not available	

VENTRICULAR ANTITACHYCARDIA PACING (ATP) (specified into a 750Ω load) continued

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Left Ventricular ATP Pulse Width (ms)	3 zones	0.1, 0.2, ..., 2.0 ..., 2.0 ms	0.1, 0.2, ..., 2.0 ..., 2.0 ms	Not available	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
	2 zones		0.1, 0.2, ..., 2.0 ..., 2.0 ms	Not available	
Right Ventricular ATP Amplitude (V) (one value for all zones)	3 zones	0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	Not available	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
	2 zones		0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	Not available	
Left Ventricular ATP Amplitude (V) (one value for all zones)	3 zones	0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	Not available	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
	2 zones		0.1, 0.2, ..., 3.0, 3.5, 4.0, ..., 7.5	Not available	
ATP Time-out (seconds)	3 zones	Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	Not available	60 (Tolerance ± 250 ms)
	2 zones		Off, 10, 15, ..., 60, 75, 90, ..., 120, 150, ..., 600, 900, ..., 3600	Not available	
QUICK CONVERT ATP (VF Only)	3 zones			Off, On	On
	2 zones			Off, On	

VENTRICULAR SHOCK

Parameter	Programmable Values	Nominal
Shocks 1 and 2 energy (J) (stored energy)	Off, 0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36, 41	41 J (Tolerance ± 40% for ≤ 2 J, ± 20% for 3–36 J, ± 10% for 41 J)
Energy of Remaining Shocks (J) (stored energy)	Off, 31, 41	41 J (Tolerance ± 10% for 41 J)
Lead Polarity	Initial, Reversed	Initial
Committed Shock	Off, On	Off
Shock Lead Vector	RV Coil to RA Coil and Can; RV Coil to Can; RV Coil to RA Coil	RV Coil to RA Coil and Can

TACHY MODE

Parameter	Programmable Values	Nominal
Tachy Mode	Off, Monitor Only, Monitor + Therapy, Enable Electrocautery Protection	Storage

VENTRICULAR DETECTION

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Rate (bpm) (intervals in ms)	3 zones	90, 95, ..., 200 (667–300)	110, 115, ..., 210 (545–286) 220 (273)	130, 135, ..., 210 (462–286), 220, 230, 240, 250 (273–240)	140 (Tolerance ± 5 ms) for VT-1 Zone 160 (Tolerance ± 5 ms) for VT Zone 200 (Tolerance ± 5 ms) for VF Zone
	2 zones		90, 95, ..., 210 (667–286) 220 (273)	110, 115, ..., 210 (545–286) 220, 230, 240, 250 (273–240)	160 (Tolerance ± 5 ms) for VT Zone 200 (Tolerance ± 5 ms) for VF Zone
	1 zone			90, 95, ..., 210 (667–286) 220 (273)	200 (Tolerance ± 5 ms)
Initial Duration (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, ..., 60	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1, 1.5, ..., 5, 6, 7, ..., 15	2.5 (Tolerance ± 1 cardiac cycle) for VT-1 Zone 2.5 (Tolerance ± 1 cardiac cycle) for VT Zone 1.0 (Tolerance ± 1 cardiac cycle) for VF Zone
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1, 1.5, ..., 5, 6, 7, ..., 15	2.5 (Tolerance ± 1 cardiac cycle) for VT Zone 1.0 (Tolerance ± 1 cardiac cycle) for VF Zone
	1 zone			1, 1.5, ..., 5, 6, 7, ..., 15	1.0 (Tolerance ± 1 cardiac cycle)
Redetection Duration (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15	1, 1.5, ..., 5, 6, 7, ..., 15	1 (nonprogrammable)	1 (Tolerance ± 1 cardiac cycle) for all zones
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15	1 (nonprogrammable)	
	1 zone			1 (nonprogrammable)	
Post-shock Duration (sec)	3 zones	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, ..., 60	1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1 (nonprogrammable)	1 (Tolerance ± 1 cardiac cycle) for all zones
	2 zones		1, 1.5, ..., 5, 6, 7, ..., 15, 20, 25, 30	1 (nonprogrammable)	
	1 zone			1 (nonprogrammable)	

VENTRICULAR DETECTION ENHANCEMENTS

Ventricular Detection Enhancement Type for 2-zone and 3-zone Configurations

Parameter	Programmable Values	Nominal
Detection Enhancement Type	Off, Rhythm ID, Onset/Stability	Onset/Stability

Onset/Stability Detection Enhancements for 2-zone and 3-zone Configurations

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
V Rate > A Rate	3 zones	Off, On	Not available	Not available	On
	2 zones		Off, On	Not available	
AFib Rate Threshold (bpm)	3 zones	Off, 100, 110, ..., 300	Not available	Not available	170 (Tolerance ± 5 ms)
	2 zones		Off, 100, 110, ..., 300	Not available	
Stability (ms)	3 zones	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	Not available	20 (Tolerance ± 5 ms)
	2 zones		Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	
Shock If Unstable (ms)	3 zones	Not available	Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	Off (Tolerance ± 5 ms)
	2 zones		Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	
Onset (% or ms)	3 zones	Off, 9, 12, 16, 19, ..., 37 41, 44, 47, 50% or 50, 60, ..., 250 ms	Not available	Not available	9% (Tolerance ± 5 ms)
	2 zones		Off, 9, 12, 16, 19, ..., 37 41, 44, 47, 50% or 50, 60, ..., 250 ms	Not available	
Stability And/Or Onset	3 zones	And, Or	Not available	Not available	And
	2 zones		And, Or	Not available	
Sustained Rate Duration (min:sec)	3 zones	Off, 00:10, 00:15, ..., 00:55 01:00, 01:15, ..., 02:00 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	Not available	Not available	03:00 (Tolerance ± 1 cardiac cycle)
	2 zones		Off, 00:10, 00:15, ..., 00:55 01:00, 01:15, ..., 02:00 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	Not available	
Detection Enhancement	3 zones	Off, On	Off, On	Not available	On (VT1) Off (VT)
	2 zones		Off, On	Not available	
Atrial Tachyarrhythmia Discrimination	3 zones	Off, On	Not available	Not available	On
	2 zones		Off, On	Not available	
Sinus Tachycardia Discrimination	3 zones	Off, On	Not available	Not available	On
	2 zones		Off, On	Not available	
Polymorphic VT Discrimination	3 zones	Not available	Off, On	Not available	Off
	2 zones		Off, On	Not available	

Rhythm ID Detection Enhancements for 2-zone and 3-zone Configurations

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Detection Enhancement	3 zones	Off, On	Off, On	Not available	On (VT-1) Off (VT)
	2 zones		Off, On	Not available	Off
Sustained Rate Duration (min:sec)	3 zones	Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Not available	03:00 (VT-1 and VT)
	2 zones		Off, 00:10, 00:15, ..., 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Not available	03:00
Passive Method	3 zones	Off, On	Off, On	Not available	On
	2 zones		Off, On	Not available	
Active Method	3 zones	Off, On	Off, On	Not available	On
	2 zones		Off, On	Not available	
Temp LRL (one value for all zones)	3 zones	Use Norm LRL, 30, 35, ..., 105	Use Norm LRL, 30, 35, ..., 105	Not available	Use Norm LRL
	2 zones		Use Norm LRL, 30, 35, ..., 105	Not available	
Atrial Tachy Discrimination	3 zones	Off, On	Off, On	Not available	On
	2 zones		Off, On	Not available	
AFib Rate Threshold	3 zones	100, 110, ..., 300	100, 110, ..., 300	Not available	170
	2 zones		100, 110, ..., 300	Not available	
Stability	3 zones	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	Not available	20
	2 zones		6, 8, ..., 32, 35, 40, ..., 60, 70, ..., 120	Not available	

POST-SHOCK DETECTION ENHANCEMENTS

Post-shock Onset/Stability Detection Enhancements for 2-zone and 3-zone Configurations

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock V Rate > A Rate	3 zones	Off, On	Not available	Not available	On
	2 zones		Off, On	Not available	
Post-shock Afib Rate Threshold (bpm)	3 zones	Off, 100, 110, ..., 300	Not available	Not available	170 (Tolerance ± 5 ms)
	2 zones		Off, 100, 110, ..., 300	Not available	
Post-shock Stability (ms)	3 zones	Off, 6, 8, ..., 32, 35, 40, ..., 60, 70, 80, ..., 120	Not available	Not available	20 (Tolerance ± 5 ms)
	2 zones		Off, 6, 8, ..., 32, 35, 40, ..., 60, 70, 80, ..., 120	Not available	
Post-shock Sustained Rate Duration (min:sec)	3 zones	Off, 00:10, 00:15, ..., 00:55, 01:00, 01:15, ..., 02:00, 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	Not available	Not available	00:15 (Tolerance ± 1 cardiac cycle)
	2 zones		Off, 00:10, 00:15, ..., 00:55, 01:00, 01:15, ..., 02:00, 02:30, 03:00, ..., 10:00, 15:00, 20:00, ..., 60:00	Not available	

Post-shock Rhythm ID Detection Enhancements for 2-zone and 3-zone Configurations

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Post-shock Rhythm ID Enable	3 zones	Off, On	Off, On	Not available	Off
	2 zones		Off, On	Not available	
Post-shock Sustained Rate Duration (min:sec)	3 zones	Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Not available	0:15
	2 zones		Off, 00:10, 00:15, 01:00, 01:15, ..., 02:00, 02:30, ..., 10:00, 15:00, ..., 60:00	Not available	

ATRIAL ARRHYTHMIA MANAGEMENT

Parameter	Programmable Values	Nominal
ATR Mode Switch	Off, On	On
ATR Trigger Rate (ppm)	100, 110, ..., 300	170 (Tolerance ± 5 ms)
ATR Duration (cycles)	0, 8, 16, 32, 64, 128, 256, 512, 1024, 2048	8 (Tolerance ± 1 cardiac cycle)
Entry Count (cycles)	1, 2, ..., 8	8
Exit Count (cycles)	1, 2, ..., 8	8
ATR Fallback Mode	VDI, DDI, VDIR, DDIR	DDI
ATR Fallback Time (min:sec)	0, 0:15, 0:30, 0:45, 1:00, 1:15, 1:30, 1:45, 2:00	0:30 (Tolerance ± 15%)
ATR/VTR Fallback LRL (ppm)	30, 35, ..., 185	70 (Tolerance ± 5 ms)
ATR VRR	Off, Min, Med, Max	Min
ATR Maximum Pacing Rate (ppm)	30, 35, ..., 185	130
ATR BiV Trigger	Off, On	On
Atrial Flutter Response	Off, On	Off
Atrial Flutter Response Rate (ppm)	100, 110, ..., 300	170 (Tolerance ± 5 ms)
PMT Termination	Off, On	On
VRR	Off, Min, Med, Max	Off

EP TEST FUNCTIONS

Ventricular Commanded ATP

Parameter	Programmable Values	Nominal
Commanded Ventricular ATP (Type)	Burst, Ramp, Scan, Ramp/Scan	Burst
Number Of Bursts	1, 2, ..., 30	30
Initial Pulses per Burst (pulses)	1, 2, ..., 30	4
Pulse Increment (pulses)	0, 1, .., 5	0
Maximum Number of Pulses	1, 2, ..., 30	4
Coupling Interval (% or ms)	50, 53, 56, 59; 63, 66, ..., 84; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81% (Tolerance ± 5 ms)
Coupling Interval Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Burst Cycle Length (BCL) (% or ms)	50, 53, 56, 59; 63, 66, ..., 84; 88, 91, 94, 97% or 120, 130, ..., 750 ms	81% (Tolerance ± 5 ms)
Ramp Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Scan Decrement (ms)	0, 2, ..., 30	0 (Tolerance ± 5 ms)
Minimum Interval (ms)	120, 130, ..., 400	200 (Tolerance ± 5 ms)

Manual Burst Pacing

Parameter	Programmable Values	Nominal
Burst Interval (ms)	20, 30, ..., 750	600 (Tolerance ± 5 ms)
Minimum Interval (ms)	20, 30, ..., 750	200 (Tolerance ± 5 ms)
Decrement (ms)	0, 10, ..., 50	50 (Tolerance ± 5 ms)

Ventricular Commanded Shock

Parameter	Programmable Values	Nominal
Shock (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36, 41	41 (Tolerance ± 40% for ≤ 2 J; ± 20% for 3–36 J, ± 10% for 41 J)
Coupling Interval (ms)	Sync, 50, 60, ..., 500	Sync

Ventricular Fibrillation Induction

Parameter	Values (nonprogrammable)
VFib High	15V (Tolerance 15 ± 10V)
VFib Low	9V (Tolerance 9 ± 7V)

Shock on T Induction

Parameter	Programmable Values	Nominal
Shock (stored energy) (J)	0.1, 0.3, 0.6, 0.9, 1.1, 1.7, 2, 3, 5, 6, 7, 9, 11, 14, 17, 21, 23, 26, 29, 31, 36, 41	1.1 J (Tolerance ± 40% for ≤ 2 J; ± 20% for 3–36 J, ±10% for 41 J)
Number of S1 Pulses	1, 2, ..., 30	8
S1 Interval (ms)	120, 130, ..., 750	400
Coupling Interval (ms)	Sync, 10, 20, , ..., 500	310

Programmable Electrical Stimulation (PES)

Parameter	Programmable Values	Nominal
Number of S1 Intervals (pulses)	1, 2, ..., 30	8
S2 Decrement	0, 10, ..., 50	0
S1 Interval (ms)	120, 130, ..., 750	600 (Tolerance ± 5 ms)
S2 Interval (ms)	Off, 120, 130, ..., 750	600 (Tolerance ± 5 ms)
S3 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)
S4 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)
S5 Interval (ms)	Off, 120, 130, ..., 750	Off (Tolerance ± 5 ms)

OTHER

Magnet/Beeper Functions

Parameter	Programmable Values	Nominal
Magnet Response	Off, Store EGM, Inhibit Therapy	Inhibit Therapy
Beep During Capacitor Charge	Off, On	Off
Beep When Explant is Indicated	Off, On	On

Sensitivity Adjustment

Parameter	Programmable Values	Nominal
Atrial Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 0.25
Right Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 0.6
Left Ventricular Sensitivity	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 1.0

CRT-D Systems and Leads from Boston Scientific CRM

Indications
Cardiac Resynchronization Therapy Defibrillators (CRT-Ds) are indicated for patients with moderate to severe heart failure (NYHA III/IV) who remain symptomatic despite stable, optimal heart failure drug therapy, and have left ventricular dysfunction (EF ≤ 35%) and QRS duration ≥ 120 ms. Left ventricular coronary venous, steroid-eluting, pace/sense leads are transvenous leads intended for chronic LV pacing and sensing via the coronary veins when used in conjunction with a compatible pulse generator. Extended bipolar pacing and sensing is available using dual-electrode LV leads with an RV pace/sense/defibrillation lead or a bipolar RV pace/sense lead.

Contraindications
There are no contraindications for the CRT-D device. Use of LV leads are contraindicated in patients with a hypersensitivity to a nominal dose of 0.7 or 1.0 mg dexamethasone acetate drug. Some LV lead models are contraindicated in patients with mechanical tricuspid heart valves, or obstructed or inadequate vasculature for intravenous catheterization.

Warnings
Refer to the product labeling thoroughly before implanting the pulse generator to avoid damage to the system. Such damage can result in injury to, or death of, the patient. Program the pulse generator Tachy Mode to Off during implant, explant or postmortem procedures to avoid inadvertent high voltage shocks. Always have sterile external and internal defibrillator protection available during implant. If not terminated in a timely fashion, an induced tachyarrhythmia can result in the patient's death. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Do not expose a patient to MRI device scanning. Strong magnetic fields may damage/interfere with the device and lead system and cause injury to the patient. Do not subject a patient with an implanted pulse generator and lead system to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator. Do not use atrial tracking modes in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. Do not use atrial only modes in patients with heart failure because such modes do not provide CRT. LV lead dislodgment to a position near the atria can result in atrial oversensing and LV pacing inhibition. Physicians should use medical discretion when implanting this device in patients who present with slow VT. Programming therapy for slow monomorphic VT may preclude CRT delivery at faster rates if these rates are in the tachyarrhythmia zones. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. Do not use defibrillation patch leads with the CRT-D system, or injury to the patient may occur. Do not use this pulse generator with another CRM pulse generator. This combination could cause pulse generator interaction resulting in patient injury or lack of therapy delivery. For specific models, when using a subpectoral implantation, place the pulse generator with the serial number facing away from the ribs. Implanting the pulse generator subpectorally with the serial number facing the ribs may cause repetitive mechanical stress to a specific area of the titanium case, potentially leading to a component failure and device malfunction. When using a RV pace/sense lead in conjunction with an LV pacing lead, it is recommended that a polyurethane-insulated lead be used. Failure to observe this warning could result in insulation damage of the RV lead, which can cause a periodic or continual loss of pacing, sensing or both. Lead fracture, dislodgment, abrasion or an incomplete connection can cause a periodic or continual loss of pacing, sensing or both. The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by leakage currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector must be insulated from any leakage currents that could arise from line-powered equipment. The lead is not designed to tolerate excessive flexing, bending, tension or injection pressure. This could cause structural weakness, conductor discontinuity or lead dislodgment. When using a finishing wire accessory kit, use the corresponding finishing wire model for the lead length If the wrong length finishing wire is used, the finishing wire tip may extend out of the distal end of the lead or not stabilize the lead properly. When placing the lead with a stylet, use only a stylet designed for use with the ACUITY Steerable lead. These stylets are specifically designed to prevent the stylet from extending past the lead tip. Extending the stylet past the lead tip may cause tissue damage.

Precautions
For information on precautions, refer to the following sections of the PG product labeling: clinical considerations, sterilization, storage and handling, implant and device programming, follow-up testing, explant and disposal, environmental and medical therapy hazards; home and occupational environments. Advise patients to avoid sources of electromagnetic interference (EMI) because EMI may cause the pulse generator to deliver inappropriate therapy or inhibit appropriate therapy. Refer to the following sections of the lead product labeling: sterilization and handling, and lead evaluation and implantation for cautions specific to handling, implanting, and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage/dislodgment, or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference.

Potential Adverse Events
Potential adverse events from implantation of the CRT-D system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure-related, psychologic intolerance to an ICD system – patients susceptible to frequent shocks despite antiarrhythmic medical management/imagined shocking, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.
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