TELIGEN™

Specifications

TELIGEN: Models E102, E110

The TELIGEN family of high-energy implantable cardioverter defibrillators (ICDs) are designed to detect and terminate ventricular tachycardia (VT) and ventricular fibrillation (VF) and provide bradycardia therapy (atrial and ventricular pacing). TELIGEN ICDs are the smallest (31.5 cc) and thinnest (9.9 mm) high-energy ICDs, and offer extended battery longevity*, self-correcting software, and improved programming technology. In addition, TELIGEN hardware includes Safety Core™ technology, which is intended to provide lifesaving shock therapy and basic pacing functionality in the event the main system fails.

* 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)	Case Electrode Surface Area (mm^3)
E102 (VR) E110 (DR)	6.17 x 7.45 x 0.99	72	31.5	IS-1/DF-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)

BRADYCARDIA PACING PARAMETERS (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 (DR); VVI (VR)
Lower Rate Limit (LRL) (ppm)	30, 35, ..., 185	60 (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 ± NB 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 ± NB 100 mV) (whichever is greater)

Boston Scientific

Delivering what's next.™

BRADYCARDIA PACING PARAMETERS (normal, post-therapy, and temporary) continued

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)
V-Blank After A-Pace (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-Pace (ms)	45, 65, 85, Smart	Smart (Tolerance ± 5 ms)
A-Blank After V-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, ..., 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay (ms)	30, 40, ..., 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay (ms)	30, 40, ..., 400	150 (Tolerance ± 5 ms)
Minimum Sensed AV Delay (ms)	30, 40, ..., 400	65 (Tolerance ± 5 ms)
AV Search +	Off, On	Off
AV Search + Search Interval (cycles)	32, 64, 128, 256, 512, 1024	32 (Tolerance ± 1 cycle)
AV Search + Search AV Delay (ms)	30, 40, ..., 400	300 (Tolerance ± 5 ms)
Respiratory Sensor	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)

VENTRICULAR ANTITACHYCARDIA PACING (ATP)

2-, and 3-Zone Configurations

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 (ms)	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 (ms)	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) continued

2-, and 3-Zone Configurations

Parameters		VT-1 Zone	VT Zone	VF Zone	Nominal
Right Ventricular ATP Amplitude (V)	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 ± 1 cardiac cycle)
	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 ± 60% for ≤ 0.3 J, ± 40% for ≤ 0.6–3 J, ± 20% for 5–36 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 (for 1-, 2-, and 3-zone configurations)

		Programmable Values			
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	Rhythm ID

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 (DR); 30 (VR) (Tolerance ± 5 ms)
	2 zones		Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	
Shock If Unstable (ms)	3 zones		Off, 6, 8, ..., 32 35, 40, ..., 60 70, 80, ..., 120	Not available	30 (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	On
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		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	On
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	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 (DR); 30 (VR) (Tolerance ± 5 ms)
	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 (DR); 30 (VR) (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, On	On
ATR Maximum Pacing Rate (ppm)	30, 35, ..., 185	130
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, On	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 (HE), 41 (HE)	41 (Tolerance ± 60% for ≤ 0.3 J; ± 40% for ≤ 0.6–3 J; ± 20% for 5–36 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 ± 60% for ≤ 0.3 J; ± 40% for ≤ 0.6–3 J; ± 20% for 5–36 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

ICD Systems from Boston Scientific CRM

ICD Indications and Usage
ICDs are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening ventricular arrhythmias. ICDs with atrial therapies are also intended to provide atrial antitachycardia pacing and atrial defibrillation treatment in patients who have or are at risk of developing atrial tachyarrhythmias.

Contraindications
Use of ICD systems are contraindicated in: Patients whose ventricular tachyarrhythmias may have reversible cause, such as 1) digitalis intoxication, 2) electrolyte imbalance, 3) hypoxia, or 4) sepsis, or whose ventricular tachyarrhythmias have a transient cause, such as 1) acute myocardial infarction, 2) electrocution, or 3) drowning. Patients who have a unipolar pacemaker.

Warnings
Refer to the product labeling thoroughly before implanting the pulse generator to avoid damage to the ICD 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 post-mortem 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 cardiopulmonary resuscitation (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 the device and cause injury to the patient. Do not subject a patient with an implanted pulse generator to diathermy since diathermy may cause fibrillation, burning of the myocardium, and irreversible damage to the pulse generator. Do not use atrial tracking modes (or an AVT device) in patients with chronic refractory atrial tachyarrhythmias. Tracking of atrial arrhythmias could result in VT or VF. (Applies to dual-chamber devices only.) 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. Do not kink leads. Kinking leads may cause additional stress on the leads, possibly resulting in lead fracture. 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.

Precautions
For information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization, storage and handling; implantation 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.

Potential Adverse Events
Potential adverse events from implantation of the ICD 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.
(Rev. K)

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