

# FORMIO™ Pacing System

## ImageReady™\* MR Conditional Pacing System

The FORMIO™ pacing system from Boston Scientific provides an ImageReady™\* MR conditional pacing system. FORMIO™ offers RightRate™ – the newest generation of MV sensor technology, and the only MV sensor clinically proven to restore chronotropic competence<sup>a</sup> and RYTHMIQ™, designed to minimize unnecessary RV pacing without clinically significant pauses, therefore reducing the risk of HF development. FORMIO™ also offers enhanced features and diagnostics, including AP Scan™, HRV platform, and Respiratory Rate Trend, designed to provide you with greater insight into your patient's disease progression. FORMIO™ has been designed to maximize efficiency and ease of use with PaceSafe™ in both the atrium and ventricle, providing dynamic adjustment of pacing outputs to ensure capture. FORMIO™ is LATITUDE™ NXT Remote Patient Management enabled, the only system to meet ESC Class 1 Recommendations<sup>b</sup>, offering the opportunity for convenient remote patient monitoring and follow-up.



a. Chronotropic competence is defined by the Model of the Cardiac Chronotropic Response to Exercise. Wilkoff B, Corey J, Blackburn G. A mathematical model of the cardiac chronotropic response to exercise. Journal of Electrophysiology. 1989;3:176-180.  
 b. To date Dec 2012.

### Mechanical Specifications

Model	Type	Size (mm) (H × W × D)	Mass (g)	Volume (cc)	Projected Longevity (yrs)**	Connector
J279	DR	47 x 44.5 x 7.5	24.5	12	8.2	IS-1

### FORMIO™ MRI

<b>Pulse Generator</b>	Designed with minimized use of ferromagnetic materials which can interact with the fields generated during a typical MRI scan.
<b>Circuitry</b>	Designed to tolerate voltages that may be induced during MRI scans.
<b>Power Supply</b>	Lithium-carbon-monofluoride-silver Vanadium Oxide Cell.
<b>MRI Lead Compatibility</b>	Pulse Generator compatible with all FINELINE™ II Sterox and FINELINE™ II Sterox EZ Pacing Leads models.
<b>MRI Conditions</b>	Full body scan at 1.5T (SAR 2W/Kg) for all FINELINE™ II models.***
<b>Pulse Generator X-ray ID tag</b>	▲BSC011
<b>MRI Protection Mode</b>	Modifies the behavior of the pulse generator and has been designed to accommodate the MRI scanner electromagnetic environment.
<b>MRI Protection Time-out</b>	Automatic timeout function that returns Pulse Generator to original pacing settings. Options: off, 12, 24, 48 - Nominal: 24 hours

### AP Scan™

Diagnostic	Programmable Parameters
AP Scan™	Sleep Start Time, Sleep Duration

### ZIP Telemetry Settings

Parameter	Programmable Values	Nominal Setting
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)

### Device Mode

Parameter	Programmable Values	Nominal Setting
Device Mode	Exit Storage, Enable Electrocautery Protection, Enable MRI Protection	Storage

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\*\* Longevity projections as described in device user manual. Settings: 60 (min-1), A=2.0 V, V=1.0 V, 500 ohms, 100% paced, MV blended sensor On, Onset EGM On, Right Ventricular Automatic Capture On and Right Atrial Automatic Threshold On.

\*\*\* Please refer to the Pacing System MRI Technical Guide as the system is designated as MR Conditional in accordance with specified conditions.

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### Pacing Therapy Parameters (Specified into 750Ω load)

Parameter	Programmable Values	Nominal Setting
Mode <sup>a, b, d</sup>	DDD(R), DDI(R), DOO, VDD(R), VVI(R), VOO, AAI(R), AOO, Off; Temporary: DDD, DDI, DOO, VDD, VVI, VOO, AAI, AOO, Off	DDD
Lower Rate Limit (LRL) <sup>a, c, d</sup> (min <sup>-1</sup> )	30, 35, ..., 185	60 (Tolerance ± 5 ms)
Maximum Tracking Rate (MTR) <sup>a, d</sup> (min <sup>-1</sup> )	50, 55, ..., 185	130 (Tolerance ± 5 ms)
Maximum Sensor Rate (MSR) <sup>f</sup> (min <sup>-1</sup> )	50, 55, ..., 185	130 (Tolerance ± 5 ms)
Pulse Amplitude (atrium) <sup>a, d, e</sup> (V)	Auto, 0.1, 0.2, ..., 3.5, 4.0, ..., 5.0; Temporary: 0.1, 0.2, ..., 3.5, 4.0, ..., 5.0	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude (right ventricle) <sup>a, d, e</sup> (V)	Auto, 0.1, 0.2, ..., 3.5, 4.0, ..., 7.5; Temporary: 0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	3.5 (Tolerance ± 15% or 100 mV, whichever is greater)
Pulse Amplitude Daily Trend (independently programmable in each chamber) <sup>a</sup>	Disabled, Enabled	Disabled
Pulse Width (atrium, right ventricle) <sup>a, d, e, h</sup> (ms)	0.1, 0.2, ..., 2.0	0.4 (Tolerance ± 0.03 ms at < 1.8 ms; ±0.08 ms at ≥ 1.8 ms)
Accelerometer <sup>f</sup>	On, Passive	Passive
Accelerometer Activity Threshold	Very Low, Low, Medium Low, Medium, Medium High, High, Very High	Medium
Accelerometer Reaction Time (sec)	10, 20, ..., 50	30
Accelerometer Response Factor	1, 2, ..., 16	8
Accelerometer Recovery Time (min)	2, 3, ..., 16	2
Minute Ventilation <sup>f</sup>	On, Passive, Off	Passive
Minute Ventilation Response Factor	1, 2, ..., 16	3
Minute Ventilation Fitness Level	Sedentary, Active, Athletic, Endurance Sports	Active
Patient's Age	≤5, 6–10, 11–15, ..., 91–95, ≥ 96	56–60
Patient's Gender	Male, Female	Male
Ventilatory Threshold (min <sup>-1</sup> )	30, 35, ..., 185	120 (Tolerance ± 5 ms)
Ventilatory Threshold Response (%)	Off, 85, 70, 55	70
Respiration-related Trend <sup>i</sup>	Off, On	On
Rate Hysteresis Hysteresis Offset <sup>f</sup> (min <sup>-1</sup> )	-80, -75, ..., -5, Off	Off (Tolerance ± 5 ms)
Rate Hysteresis Search Hysteresis <sup>f</sup> (cycles)	Off, 256, 512, 1024, 2048, 4096	Off (Tolerance ± 1 cycle)
Rate Smoothing (up, down) <sup>f</sup> (%)	Off, 3, 6, 9, 12, 15, 18, 21, 25	Off (Tolerance ± 1%)
Rate Smoothing Maximum Pacing Rate (min <sup>-1</sup> )	50, 55, ..., 185	130 (Tolerance ± 5 ms)
Sudden Brady Response (SBR) <sup>f</sup>	Off, On	Off
SBR Atrial Paces Before Therapy	1, 2, ..., 8	3
SBR Atrial Pacing Rate Increase (min <sup>-1</sup> )	5, 10, ..., 40	20
SBR Therapy Duration (min)	1, 2, ..., 15	2
SBR Inhibit During Rest	Off, On	On
Atrial Pace/Sense Configuration <sup>a, d</sup>	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar, Unipolar/Off, Bipolar/Off	Unipolar
Right Ventricle Pace/Sense Configuration <sup>a, d</sup>	Unipolar, Bipolar, Bipolar/Unipolar, Unipolar/Bipolar	Unipolar
Safety Switch (independently programmable in each chamber)	Off, On	On
Maximum Paced AV Delay <sup>a, d</sup> (ms)	30, 40, ..., 400	180 (Tolerance ± 5 ms)
Minimum Paced AV Delay <sup>a, d</sup> (ms)	30, 40, ..., 400	80 (Tolerance ± 5 ms)
Maximum Sensed AV Delay <sup>a, d</sup> (ms)	30, 40, ..., 400	150 (Tolerance ± 5 ms)

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### Pacing Therapy Parameters (Specified into 750Ω load) (continued)

Parameter	Programmable Values	Nominal Setting
AV Search+ <sup>f</sup>	Off, On	Off
AV Search+ Search AV Delay (ms)	30, 40, ..., 400	300 (Tolerance ± 5 ms)
AV Search+ Search Interval (cycles)	32, 64, 128, 256, 512, 1024	32 (Tolerance ± 1 cycle)
RYTHMIQ <sup>g</sup>	AAI(R) with VVI Backup, Off	Off
Maximum A-Refractory (PVARP) <sup>a, d</sup> (ms)	150, 160, ..., 500	280 (Tolerance ± 5 ms)
Minimum A-Refractory (PVARP) <sup>a, d</sup> (ms)	150, 160, ..., 500	240 (Tolerance ± 5 ms)
Maximum V-Refractory (VRP) <sup>a, d</sup> (ms)	150, 160, ..., 500	250 (Tolerance ± 5 ms)
Minimum V-Refractory (VRP) <sup>a, d</sup> (ms)	150, 160, ..., 500	230 (Tolerance ± 5 ms)
PVARP After PVC <sup>a</sup> (ms)	Off, 150, 200, ..., 500	400 (Tolerance ± 5 ms)
A-Blank after V-Pace <sup>a, d</sup> (ms)	Smart, 45, 65, 85, 105, 125, 150, 175, 200	125 (Tolerance ± 5 ms)
A-Blank after RV-Sense <sup>a, d</sup> (ms)	Smart, 45, 65, 85	45 (Tolerance ± 5 ms)
RV-Blank after A-Pace <sup>a, d</sup> (ms)	45, 65, 85	65 (Tolerance ± 5 ms)
Noise Response <sup>a</sup>	A00, V00, D00, Inhibit Pacing	D00 for DDD(R) and DDI(R) modes; V00 for VDD(R) and VVI (R) modes; A00 for AAI(R) mode
Magnet Response	Off, Store EGM, Pace Async	Pace Async

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.

b. Refer to the NASPE/BPEG codes below for an explanation of the programmable values. The identification code of the North American Society of Pacing and Electrophysiology (NASPE) and the British Pacing and Electrophysiology Group (BPEG) is based on the categories listed in the table.

c. The basic pulse period is equal to the pacing rate and the pulse interval (no hysteresis). Runaway protection circuitry inhibits bradycardia pacing above 205 min<sup>-1</sup>. Magnet application may affect pacing rate (test pulse interval).

d. Separately programmable for Temporary Brady.

e. Values are not affected by temperature variation within the range 20°C–43°C.

f. This parameter is disabled during Temporary Brady.

g. This parameter is automatically enabled if Auto is selected for the Pulse Amplitude.

h. When the Pulse Amplitude is set to Auto or Pulse Amplitude Daily Trend is enabled the pulse width is fixed at 0.4 ms.

i. This value is located on the Lead Setup screen.

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## Brady Mode Values Based on NASPE/BPEG Codes

Position	I	II	III	IV	V
<b>Category</b>	<b>Chambers Paced</b>	<b>Chambers Sensed</b>	<b>Response to Sensing</b>	<b>Programmability, rate modulation</b>	<b>Antitachyarrhythmia Functions</b>
<b>Letters</b>	0–None	0–None	0–None	0–None	0–None
	A–Atrium	A–Atrium	T–Triggered	P–Simple Programmable	P–Pacing (Antitachyarrhythmia)
	V–Ventricle	V–Ventricle	I–Inhibited	M–Multiprogrammable	S–Shock
	D–Dual (A&V)	D–Dual (A&V)	D–Dual (T&I)	C–Communicating	D–Dual (P&S)
	--	--	--	R–Rate Modulation	--
<b>Mfrs. Designation Only</b>	S–Single (A or V)	S–Single (A or V)	--	--	--

## MRI Protection Parameters

Parameter	Programmable Values	Nominal Setting
MRI Brady Mode	Off, VOO, AOO, DOO	DOO for DDD(R), DDI(R), or DOO normal Brady modes; VOO for VDD(R), VVI(R), or VOO normal Brady modes; AOO for AA(R) or AOO normal Brady mode; Off for normal Brady mode Off
MRI Lower Rate Limit (LRL) (min <sup>-1</sup> )	30, 35, ..., 100	20 min <sup>-1</sup> above the normal mode LRL
MRI Atrial Amplitude (V)	2.0, 2.1, ..., 3.5, 4.0, ..., 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
MRI Ventricular Amplitude (V)	2.0, 2.1, ..., 3.5, 4.0, ..., 5.0	5.0 (Tolerance ± 15% or ± 100 mV, whichever is greater)
MRI Protection Time-out (hours)	Off, 12, 24, 48	24
MRI Pulse Width (atrial and ventricular) (ms)	1.0 (non-programmable)	1.0 (Tolerance ± 0.03 ms)

## Sensor Trending

Parameter	Programmable Values	Nominal Setting
Recording Method	Beat To Beat, Off, 30 Second Average	30 second average
Data Storage	Continuous, Fixed	Continuous

## Ventricular Tachy EGM Storage

Parameter	Programmable Values	Nominal Setting
Ventricular Tachy EGM Storage	Off, On	On
VT Detection Rate <sup>a</sup> (min <sup>-1</sup> )	90, 95, ..., 210, 220	160 (Tolerance ± 5 ms)

a. The VT Detection Rate must be ≥ 5 min<sup>-1</sup> higher than the Maximum Tracking Rate, Maximum Sensor Rate, and the Maximum Pacing Rate, and must be ≥ 15 min<sup>-1</sup> higher than the Lower Rate Limit.

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## Atrial Tachy Parameters

Parameter	Programmable Values	Nominal Setting
ATR Mode Switch <sup>a</sup>	Off, On	On
ATR Trigger Rate <sup>a, c</sup> (min <sup>-1</sup> )	100, 110, ..., 300	170 (Tolerance ± 5 ms)
ATR Duration <sup>a</sup> (cycles)	0, 8, 16, 32, 64, 128, 256, 512, 1024, 2048	8 (Tolerance ± 1 cardiac cycle)
Entry Count <sup>a</sup> (cycles)	1, 2, ..., 8	8
Exit Count <sup>a</sup> (cycles)	1, 2, ..., 8	8
ATR Fallback Mode <sup>d</sup>	VDI, DDI, VDIR, DDIR	DDI
ATR Fallback Time <sup>a</sup> (min:sec)	00:00, 00:15, 00:30, 00:45, 01:00, 01:15, 01:30, 01:45, 02:00	00:30
ATR Fallback LRL <sup>a</sup> (min <sup>-1</sup> )	30, 35, ..., 185	70 (Tolerance ± 5 ms)
ATR Ventricular Rate Regulation (VRR) <sup>a</sup>	Off, On	On
ATR Maximum Pacing Rate (MPR) <sup>a, d</sup> (min <sup>-1</sup> )	50, 55, ..., 185	130 (Tolerance ± 5 ms)
Atrial Flutter Response <sup>b</sup>	Off, On	On
Atrial Flutter Response Trigger Rate <sup>c</sup> (min <sup>-1</sup> )	100, 110, ..., 300	170 (Tolerance ± 5 ms)
PMT Termination <sup>b</sup>	Off, On	On
Ventricular Rate Regulation (VRR) <sup>b</sup>	Off, On	Off
BiV/VRR Maximum Pacing Rate (MPR) (min <sup>-1</sup> )	50, 55, ..., 185	130 (Tolerance ± 5 ms)
APP/ProACt <sup>b</sup>	Off, On	Off
APP/ProACt Max Pacing Rate (min <sup>-1</sup> )	50, 55, ..., 185	80 (Tolerance ± 5 ms)

a. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.

b. This parameter gets disabled during Temporary Brady.

c. ATR Trigger Rate and Atrial Flutter Response Trigger Rate are linked. If either of these rates is reprogrammed, the other will automatically change to the same value.

d. If Normal Brady ATR Fallback Mode is DDIR or DDI, then Temporary Brady ATR Fallback Mode is DDI and If Normal Brady ATR Fallback Mode is VDIR or VDI, then Temporary Brady ATR Fallback Mode is VDI.

## Sensitivity

Parameter <sup>a, b, c</sup>	Programmable Values	Nominal Setting
Sensing Method <sup>d</sup>	AGC, Fixed	Fixed
Atrial Sensitivity (AGC)	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)	AGC 0.15, AGC 0.2, AGC 0.25, AGC 0.3, AGC 0.4, ..., AGC 1.0, AGC 1.5	AGC 0.6
Atrial Sensitivity (Fixed)	Fixed 0.15, Fixed 0.25, Fixed 0.5, Fixed 0.75, Fixed 1.0, Fixed 1.5, ..., Fixed 8.0, Fixed 9.0, Fixed 10.0	Fixed 0.75
Right Ventricular Sensitivity (Fixed)	Fixed 0.25, Fixed 0.5, Fixed 0.75, Fixed 1.0, Fixed 1.5, ..., Fixed 8.0, Fixed 9.0, Fixed 10.0	Fixed 2.5

a. Separately programmable for Temporary Brady.

b. The programmed Normal Brady values will be used as the nominal values for Temporary Brady pacing.

c. In single-chamber models, the chamber chosen determines the nominal value.

d. The programmed value for Sensing Method determines the applicable values (AGC or Fixed) in each chamber.

## Daily Lead Measurements

Parameter	Programmable Values	Nominal Setting
Atrial Intrinsic Amplitude	On, Off	On
Ventricular Intrinsic Amplitude	On, Off	On
Atrial Pace Impedance	On, Off	On
Ventricular Pace Impedance	On, Off	On
Atrial Pace Impedance Alert Range Minimum (Ω)	200, 250, ..., 500	200
Ventricular Pace Impedance Alert Range Minimum (Ω)	200, 250, ..., 500	200

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### Backup EP Test

Parameter	Programmable Values	Nominal Setting
Backup Pacing Mode <sup>a</sup>	Off, On	On
Backup Pacing Lower Rate Limit <sup>a, b</sup> (min <sup>-1</sup> )	30, 35, ..., 185	60 (Tolerance ± 5 ms)
Backup Pacing V Refractory <sup>a, b</sup> (ms)	150, 160, ..., 500	250 (Tolerance ± 5ms)
EP Test Pacing Outputs Atrial Amplitude (when test is in the atrium) (V)	Off, 0.1, 0.2, ..., 3.5, 4.0, ..., 5.0	5.0 (Tolerance ± 15% or 100 mV, whichever is greater)
EP Test Pacing Outputs V Amplitude (V)	Off, 0.1, 0.2, ..., 3.5, 4.0, ..., 7.5	7.5 (Tolerance +/- 15% or 100 mV, whichever is greater)
EP Test Pacing Outputs Atrial Pulse Width (when test is in the atrium) (ms)	0.1, 0.2, ..., 2.0	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)
EP Test Pacing Outputs V Pulse Width (ms)	0.1, 0.2, ..., 2.0	1.0 (Tolerance ± 0.03 ms at < 1.8 ms; ± 0.08 ms at ≥ 1.8 ms)

a. This parameter only applies when the test is in the atrium.

b. The programmed Normal Brady value will be used as the nominal value.

### PES (Programmed Electrical Stimulation)

Parameter <sup>a</sup>	Programmable Values	Nominal Setting
Number of S1 Intervals (pulses)	1, 2, ..., 30	8
S2 Decrement (ms)	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)

a. Applied to the atrium or ventricle as commanded by the programmer.

### Manual Burst Pacing

Parameter <sup>a</sup>	Programmable Values	Nominal Setting
Burst Interval (ms)	100, 110, ..., 750	600 (Tolerance ± 5 ms)
Minimum Interval (ms)	100, 110, ..., 750	200 (Tolerance ± 5 ms)
Decrement (ms)	0, 10, ..., 50	50 (Tolerance ± 5 ms)

a. Applied to the atrium or ventricle depending on the chamber selected.

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