AZURE™ XT DR MRI SURESCAN™

Model W1DR01

Physical characteristics

Physical characteristics	
Volume[a]	12.75 cm^3
Mass	22.5 g
H x W x D[b]	46.6 mm x 50.8 mm x 7.4 mm
Radiopaque ID[c]	RNA
Surface area of titanium device can	33.48 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium-hybrid CFx silver vanadium oxide

[a] Volume with connector holes unplugged.
[b] Grommets may protrude slightly beyond the can surface.
[c] The radiopaque ID, which includes a Medtronic-identifier symbol, can be viewed in a fluoroscopic image of the device.
[d] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

Replacement indicators	
Recommended Replacement Time (RRT)	≤ 2.63 V on 3 consecutive daily automatic measurements
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

Pacing parameters

Modes, rates, and intervals	
Parameter	**Programmable values**
Mode	DDDR; DDD; AAIR<=>DDDR◈; AAI<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On◈; Off
Lower Rate[a]	30; 35 ... 60◈; 70; 75 ... 150 bpm
Upper Tracking Rate	80; 85 ... 130◈... 175; 180; 190 ... 210 bpm
Paced AV	30; 40 ... 180◈ ... 350 ms
Sensed AV	30; 40 ... 150◈ ... 350 ms
Maximum AV Interval Limit	Off◈; 250; 260 ... 500
PVARP	Auto◈; 150; 160 ... 500 ms
Minimum PVARP	150; 160 ... 250◈... 500 ms
A. Refractory Period	150; 160 ... 310◈... 500 ms

[a] The corresponding Lower Rate Interval can be calculated as follows: Lower Rate Interval (ms) = 60,000/Lower Rate.

- BlueSync™ ready
- Over 10 years longevity[a]
- Updated MVP™ algorithm
- Simple Reactive ATP™ programming
- Approved for 1.5T and 3T MRI use[a]

[a] Medtronic Azure XT DR MRI SureScan W1DR01 Device Manual. M964338A001 B. Accessed September 13, 2017.

Medtronic

Atrial parameters

Parameter	Programmable values
Atrial Amplitude	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V[a]
Atrial Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
Atrial Sensitivity[b]	Off; 0.15; 0.3; 0.45; 0.6; 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV Unipolar: 0.45 ◆ mV Bipolar: 0.3 ◆ mV
Atrial Pace Polarity	Bipolar; Unipolar
Atrial Sense Polarity	Bipolar; Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆ ; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.
[b] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

RV parameters

Parameter	Programmable values
RV Amplitude	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V[a]
RV Pulse Width	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
RV Sensitivity[b]	0.45; 0.60; 0.90 ; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Unipolar: 2.80 ◆ mV Bipolar: 0.90 ◆ mV
RV Pace Polarity	Bipolar; Unipolar
RV Sense Polarity	Bipolar; Unipolar
RV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 ◆ ; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 ◆ Ω

[a] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.
[b] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

Atrial Capture Management™ parameters

Parameter	Programmable values
Atrial Capture Management™	Adaptive ◆; Monitor; Off
Atrial Amplitude Safety Margin	1.5x; 2.0x ◆; 2.5x; 3.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5 ◆; 2.0; 2.5; 3.0; 3.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120 ◆; 150 days

RV Capture Management™ parameters

Parameter	Programmable values
RV Capture Management™	Adaptive ◆; Monitor; Off
RV Amplitude Safety Margin	1.5x; 2.0x ◆; 2.5x; 3.0x
RV Minimum Adapted Amplitude	1.0; 1.5; 2.0 ◆; 2.5; 3.0; 3.5 V
RV Acute Phase Remaining	Off; 30; 60; 90; 120 ◆; 150 days

Blanking periods

Parameter	Programmable values
PVAB Interval	10[a]; 20 ... 100; 110; 120 ...150 ◆ ... 300 ms
PVAB Method	Partial ◆; Partial+; Absolute
A. Blank Post AP	150; 160 ... 200 ◆ ... 250 ms
A. Blank Post AS	100 ◆; 110 ... 170 ms
V. Blank Post VP	150; 160 ... 200 ◆ ... 320 ms
V. Blank Post VS	120 ◆; 130 ... 170; 200; 220; 250; 280; 300; 320 ms

[a] If the PVAB Method is set to Partial, the minimum selectable value for the PVAB Interval is 100 ms.

Rate response pacing parameters

Parameter	Programmable values
Upper Sensor Rate	80; 85 ... 130 ◆ ... 175 bpm
ADL Rate	60; 65 ... 95 ◆ ... 170 bpm
Rate Profile Optimization	On ◆; Off
ADL Response	1; 2; 3 ◆; 4; 5
Exertion Response	1; 2; 3 ◆; 4; 5
Activity Threshold	Low ◆; Medium Low; Medium High; High
Activity Acceleration	15; 30 ◆; 60 s
Activity Deceleration	Exercise ◆; 2.5; 5; 10 min
ADL Set Point	5; 6 ... 40; 42 ... 80
UR Set Point	15; 16 ... 40; 42 ... 80; 85 ... 180

Rate Adaptive AV parameters

Parameter	Programmable values
Rate Adaptive AV	Off ◆; On
Start Rate	50; 55 ... 90 ◆ ... 145 bpm
Stop Rate	55; 60 ... 130 ◆ ... 175 bpm
Minimum Paced AV	30; 40 ... 140 ◆ ... 200 ms
Minimum Sensed AV	30; 40 ... 110 ◆ ... 200 ms

Atrial rate stabilization parameters

Parameter	Programmable values
A. Rate Stabilization	On; Off ◆
Maximum Rate	80; 85 ... 100 ◆ ... 150 bpm
Interval Percentage Increment	12.5; 25 ◆; 50%

Atrial preference pacing parameters

Parameter	Programmable values
A. Preference Pacing	On; Off ◆
Maximum Rate	80; 85 ... 100 ◆ ... 150 bpm
Interval Decrement	30 ◆; 40; 50 ... 100; 150 ms
Search Beats	5; 10; 15; 20 ◆ ... 25; 50

Post mode switch pacing (PMOP) parameters

Parameter	Programmable values
Post Mode Switch	On; Off ◆
Overdrive Rate	70; 75; 80 ◆ ... 120 bpm
Overdrive Duration	0.5; 1; 2; 3; 5 ◆; 10; 20; 30; 60; 90; 120 min

Conducted AF response parameters

Parameter	Programmable values
Conducted AF Response	On; Off ◆
Response Level	Low; Medium ◆; High
Maximum Rate	80; 85 ... 110 ◆ ... 130 bpm

Ventricular rate stabilization parameters

Parameter	Programmable values
V. Rate Stabilization	On; Off ◆
Maximum Rate	80; 85 ... 100 ◆ ... 120 bpm
Interval Increment	100; 110 ... 150 ◆ ... 400 ms

Rate drop response parameters

Parameter	Programmable values
Rate Drop Response[a]	On; Off ◆
Detection Type	Drop ◆; Low Rate; Both
Drop Detection	
Drop Size	10; 15 ... 25 ◆ ... 50 bpm
Drop Rate	30; 40 ... 60 ◆ ... 100 bpm
Detection Window	10; 15; 20; 25; 30 s 1 ◆; 1.5; 2; 2.5 min
Low Rate Detection	
Detection Beats	1; 2; 3 ◆ beats
Intervention	
Intervention Rate	70; 75 ... 100 ◆ ... 150 bpm
Intervention Duration	1; 2 ◆ ... 15 min

[a] When Rate Drop Response is set to On, the lower rate is automatically set to 45 bpm.

Sleep parameters

Parameter	Programmable values
Sleep	On; Off ◆
Sleep Rate	30; 35 ... 50 ◆; 55; 60; 70; 75 ... 100 bpm
Bed Time	00:00; 00:10 ... 22:00 ◆ ... 23:50
Wake Time	00:00; 00:10 ... 07:00 ◆ ... 23:50

Non-Competitive atrial pacing (NCAP) parameters

Parameter	Programmable values
Non-Comp Atrial Pacing	On ◆; Off
NCAP Interval	200; 250; 300 ◆; 350; 400 ms

MRI SureScan™ parameters

Parameter	Programmable values
MRI SureScan™	On; Off
MRI Pacing Mode	DOO; AOO; VOO; ODO
MRI Pacing Rate	60; 70; 75; 80 ... 120 bpm

Additional pacing features

Parameter	Programmable values
PMT Intervention	On; Off ◆
PVC Response	On ◆; Off
V. Safety Pacing	On ◆; Off
Rate Hysteresis	Off ◆; 30; 40 ... 80 bpm

Tachyarrhythmia parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
AT/AF Detection	On; Monitor ◆
Zones	1 ◆; 2
AT/AF Interval (Rate)[a]	150; 160 ... 350 ◆ ... 450 ms
Fast AT/AF Interval (Rate)[a]	150; 160 ... 200 ◆ ... 250 ms
VT Monitor	Monitor ◆; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 400 ◆ ... 500 ms
RV Sensitivity[b,d]	0.45; 0.60; 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV Bipolar: 0.9 ◆ mV Unipolar: 2.80 ◆ mV
Atrial Sensitivity[b,c]	0.15; 0.30; 0.45; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.0 mV; Off Bipolar: 0.3 ◆ mV Unipolar: 0.45 ◆ mV

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.
[b] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[c] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.
[d] The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 2.0 mV or higher.

Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values
Anti-Tachy Pacing (ATP)	
Fast AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆ Rx3: Ramp ◆
AT/AF Rx Status	On; Off ◆
Therapy Type	Ramp; Burst+ Rx1: Ramp ◆; Rx2: Burst+ ◆ Rx3: Ramp ◆

Atrial tachyarrhythmia therapy parameters, cont'd.

Parameter	Programmable values
Burst+ parameters	
Initial # S1 Pulses	1; 2; 3 ... 11 ◆; 15; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 84 ◆; 88; 91; 94; 97%
S1-S2 (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 81 ◆; 84; 88; 91; 94; 97%; Off
S2-S3 Decrement	0; 10; 20 ◆ ... 80 ms; Off
Interval Decrement	0; 10 ◆; 20; 30; 40 ms
# Sequences	1; 2; 3 ... 10 ◆
Ramp parameters	
Initial # S1 Pulses	1; 2; 3... 13 ◆... 14; 15; 20; 25
A-S1 Interval (%AA)	
Rx1	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx2	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◆; 94; 97%
Rx3	28; 31; 34; 38; 41 ... 59; 63; 66 ... 81 ◆; 84; 88;91; 94; 97%
Interval Decrement	0; 10 ◆ ...40 ms
# Sequences	1; 2 ... 8; 9; 10 ◆
Stop Atrial Rx After (shared)	
Rx/Lead Suspect...	
Disable Atrial ATP if it accelerates V. rate?	Yes ◆ ; No
Disable all atrial therapies if atrial lead position is suspect? (Atrial Lead Position Check)	Yes ◆ ; No
Duration to Stop	12; 24; 48 ◆ ; 72 hr; None
Episode Duration Before Rx Delivery	
Episode Duration Before ATP	0; 1 ◆; 2 ... 5; 7; 10; 15; 20; 25; 30; 40; 50 min; 1; 2; 3; 4; 5; 6; 12; 24 hr
Reactive ATP™	
Rhythm Change	On ◆; Off
Time Interval	Off ◆; 2; 4; 7; 12; 24; 36; 48 hr
Shared A. ATP	
A-A Minimum ATP Interval[a]	100; 110 ... 150 ◆ ... 400 ms
A. Pacing Amplitude	1; 2; 3 ... 6 ◆; 8 V
A. Pacing Pulse Width	0.1; 0.2 ... 1.5 ◆ ms
VVI Backup Pacing	Off; On (Always); On (Auto-Enable) ◆
VVI Backup Pacing Rate	60; 70 ◆ ... 120 bpm

[a] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

Data collection parameters

Data collection parameters

Parameter	Programmable values
EGM 1 Source	Can to Aring; Can to RVring; Atip to Aring ◆; Atip to RVring; Atip to Can; Aring to RVring; RVtip to RVring; RVtip to Can
EGM 1 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
EGM 2 Source	Can to RVring; RVtip to RVring ◆; RVtip to Can
EGM 2 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
EGM 3 Source	RVtip to RVring; Can to RVring ◆; Atip to RVring; Atip to Aring; Can to Aring
EGM 3 Range	±1; ±2; ±4; ±8 ◆; ±12; ±16; ±32 mV
Monitored	EGM1 and EGM2 ◆; EGM1 and EGM3; EGM2 and EGM3
Pre-arrhythmia EGM	Off ◆; On – 1 month; On – 3 months; On Continuous
AT/AF Daily Burden	0.5; 1; 2; 6 ◆; 12; 24 hr/24 hr
Avg. V. Rate During AT/AF Burden	0.5; 1; 2; 6 ◆; 12; 24 hr/24 hr
Avg. V. Rate During AT/AF V. Rate	90; 100 ◆ ... 150 bpm
Device Date/Time[a]	(select Time Zone)
Holter Telemetry	Off ◆; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr
Wireless Telemetry with Monitor	On; Off

[a] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

Medtronic CareAlert™ parameters

Clinical management alerts

Parameter	Programmable values
AT/AF Burden and Rate Settings	
AT/AF Alerts	
AT/AF Daily Burden Enable	Off ◆; On
Daily AT/AF Burden	0.5; 1; 2; 6 ◆; 12; 24 hr/24 hr
Avg. V. Rate During AT/AF Enable	Off ◆; On
Daily Burden for Avg. V. Rate (hr/24 hr)	0.5; 1; 2; 6 ◆; 12; 24 hr/24 hr
Avg. V. Rate During AT/AF	90; 100 ◆ ... 150 bpm
Monitored VT Episode Detected	Off ◆; On
Cumulative Right Ventricular Pacing > 40%[a]	Off ◆; On[b]

[a] There is no observation for Cumulative Right Ventricular Pacing > 40%.
[b] Alert triggered if cumulative percent of right ventricular pacing exceeds 40% for 7 consecutive days.

Lead/Device integrity alerts

Parameter	Programmable values
Low Battery Voltage RRT	On ◈; Off
Lead Impedance Out of Range	
Lead Impedance	
A. Pacing Enable	On ◈; Off
A. Pacing Less than	200 ◈; 300; 400; 500 Ω
A. Pacing Greater than	1,000; 1,500; 2,000; 3,000 ◈ Ω
RV Pacing Enable	On ◈; Off
RV Pacing Less than	200 ◈; 300; 400; 500 Ω
RV Pacing Greater than	1,000; 1,500; 2,000; 3,000 ◈ Ω
Capture Management™ High Threshold	
High Threshold	
A. Capture Enable[a]	Off ◈; On
RV Capture Enable[b]	Off ◈; On

[a] If programmed to On, alert notification is sent if A. capture management™ has measured high thresholds for 3 consecutive days.
[b] If programmed to On, alert notification is sent if RV capture management™ has measured high thresholds for 3 consecutive days.

System test parameters

System test parameters

Parameter	Selectable values
Pacing Threshold Test parameters	
Test Type	Amplitude; Pulse Width
Chamber	Atrium; RV
Decrement after	2; 3 ... 15 pulses
Mode[a] (RV Test)	VVI; VOO; DDI; DDD; DOO
Mode[a] (Atrium Test)	AAI; AOO; DDI; DDD; DOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150[c] bpm
RV Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
RV Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
A. Amplitude	0.25; 0.5 ... 5; 5.5; 6; 8 V
A. Pulse Width	0.03; 0.06; 0.1; 0.2 ... 1.5 ms
AV Delay[b]	30; 40 ... 350 ms
V. Pace Blanking	150; 160 ... 320 ms
A. Pace Blanking	150; 160 ... 250 ms
PVARP	150; 160 ... 500 ms
Pace Polarity	Unipolar; Bipolar
Sensing Test parameters	
Mode[a]	AAI; DDD; DDI; VVI; ODO
AV Delay[b]	30; 40 ... 350 ms
Lower Rate[c]	30; 35 ... 60; 70; 75 ... 120 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.
[b] The selectable values for this parameter depend on the programmed Lower Rate.
[c] When performing the test in DDD mode, the Lower Rate must be less than the programmed Upper Tracking Rate.

Longevity

Projected service life in years

Pacing	Pre-arrhythmia EGM storage[a]	500 Ω pacing impedance		600 Ω pacing impedance		900 Ω pacing impedance	
		2.5 V	3.5 V	2.5 V	3.5 V	2.5 V	3.5 V
DDD, 0%	Off	15.8	15.8	15.8	15.8	15.8	15.8
	On	15.7	15.7	15.7	15.7	15.7	15.7
DDD, 15%	Off	14.6	13.6	14.8	13.9	15.1	14.4
	On	14.5	13.5	14.7	13.8	15.0	14.3
DDD, 50%	Off	12.4	10.2	12.8	10.8	13.6	11.9
	On	12.3	10.1	12.7	10.7	13.5	11.9
AAI<=>DDD (MVP™ Mode) 50% Atrial, 5% Ventricular	Off	13.7	12.1	14.0	12.6	14.5	13.4
	On	13.6	12.1	13.9	12.5	14.4	13.3
DDD, 100%	Off	10.2	7.5	10.8	8.1	12.0	9.6
	On	10.1	7.4	10.7	8.1	11.9	9.5

[a] The data provided for programming Pre-arrhythmia EGM storage to On are based on a 6-month period (two 3-month follow-up intervals) over the life of the device. Additional use of Pre-arrhythmia EGM storage reduces projected service life by approximately 12.1% or 1.4 months per year.

Note: These projections are based on typical shelf storage time (5 months). Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 7%.

The data is based on pacing outputs programmed to the specified amplitude and 0.4 ms pulse width and 60 bpm pacing rate. The service life of the device is affected by the programmed settings for certain features, such as Pre-arrhythmia EGM storage. Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. These values should not be interpreted as precise numbers. Delivery of atrial antitachycardia pacing therapy does not appreciably alter the longevity, considered with the inhibition of atrial pacing during the AT/AF episode.

Note: Medtronic Azure XT DR MRI SureScan W1DR01 Device Manual. M964338A001 B. Accessed September 13, 2017.

Brief Statement
Azure™ MRI SR and DR IPG
Indications

The Azure DR MRI and Azure SR MRI SureScan™ systems are indicated for the rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Accepted patient conditions warranting chronic cardiac pacing include symptomatic paroxysmal or permanent second- or third-degree AV block, symptomatic bilateral bundle branch block, symptomatic paroxysmal or transient sinus node dysfunctions with or without associated AV conduction disorders, or bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias.

The Azure DR MRI devices are also indicated for dual chamber and atrial tracking modes in patients who may benefit from maintenance of AV synchrony. Dual chamber modes are specifically indicated for treatment of conduction disorders that require restoration of both rate and AV synchrony, which include various degrees of AV block to maintain the atrial contribution to cardiac output, VVI intolerance (for example, pacemaker syndrome) in the presence of persistent sinus rhythm, or vasovagal syndromes or hypersensitive carotid sinus syndromes. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrhythmias in bradycardia patients with one or more of the above pacing indications.

MRI Conditions for Use: Medtronic SureScan pacing systems are MR conditional, and as such are designed to allow patients to undergo MRI under the specified conditions for use. Pacemaker SureScan system patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan pacing system, which is a SureScan device with appropriate SureScan lead(s), is required for use in the MR environment. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com/. Any other combination may result in a hazard to the patient during an MRI scan.

Contraindications: The Azure DR MRI and Azure SR MRI SureScan systems are contraindicated for concomitant implantation with another bradycardia device or with an implantable cardioverter defibrillator. Rate-responsive modes may be contraindicated in those patients who cannot tolerate pacing rates above the programmed Lower Rate. Dual chamber sequential pacing is contraindicated in patients with chronic or persistent supraventricular tachycardias, including atrial fibrillation or flutter. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms. Single chamber atrial pacing is contraindicated in patients with an AV conduction disturbance. ATP therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings and Precautions: Changes in patient's disease and/or medications may alter the efficacy of the device's programmed parameters. Patients should avoid sources of magnetic and electromagnetic radiation to avoid possible underdetection, inappropriate sensing and/or therapy delivery, tissue damage, induction of an arrhythmia, device electrical reset, or device damage. Do not place transthoracic defibrillation paddles directly over the device. Use of the device should not change the application of established anticoagulation protocols.

Patients and their implanted systems must be screened to meet the following requirements for MRI: no lead extenders, lead adaptors, or abandoned leads present; no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history; the device must be operating within the projected service life, and the system must be implanted in the left or right pectoral region.

Potential Adverse Events or Potential Complications: Potential complications include, but are not limited to, rejection phenomena, erosion through the skin, muscle or nerve stimulation, oversensing, failure to detect and/or terminate arrhythmia episodes, acceleration of tachycardia, and surgical complications such as hematoma, infection, inflammation, and thrombosis. Potential lead complications include, but are not limited to, valve damage, fibrillation, thrombosis, thrombotic and air embolism, cardiac perforation, heart wall rupture, cardiac tamponade, pericardial rub, infection, myocardial irritability, and pneumothorax. Other potential complications related to the lead may include lead dislodgement, lead conductor fracture, insulation failure, threshold elevation, or exit block. Potential MRI complications include, but are not limited to, lead electrode heating and tissue damage resulting in loss of sensing or capture or both, or induced currents on leads resulting in continuous capture, VT/VF, and/or hemodynamic collapse.

See the device manuals before performing an MRI Scan for detailed information regarding the implant procedure, indications, MRI conditions of use, contraindications, warnings, precautions, and potential complications. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at medtronic.com.

Caution: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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