

AZURE™ S DR MRI SURESCAN™

Model W3DR01

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 ⚡; AAIR<=>DDD; DDIR; DDI; AAIR; AAI; VVIR; VVI; DOO; AOO; VOO; ODO
Mode Switch	On ⚡; Off
Lower Rate ^a	30; 35 ... 60 ⚡; 70; 75 ... 150 min ⁻¹ (±2 min ⁻¹)
Upper Tracking Rate	80; 85 ... 130 ⚡... 175 min ⁻¹ (± 2 min ⁻¹); 180; 190 ... 210 min ⁻¹ (+2/-11 min ⁻¹)
Paced AV	30; 40 ... 180 ⚡ ... 350 ms (± 4 ms)
Sensed AV	30; 40 ... 150 ⚡ ... 350 ms (+ 30; - 2 ms)



- Bluetooth® wireless telemetry
- Updated MVP™ algorithm
- Approved for 1.5T and 3T MRI use

Medtronic

Modes, rates, and intervals, cont'd.

Parameter	Programmable values
Maximum AV Interval Limit	Off \diamond ; 256; 260 ... 500
PVARP	Auto \diamond ; 150; 160 ... 500 ms (+ 5; - 30 ms)
Minimum PVARP	150; 160 ... 250 \diamond ... 500 ms (+ 5; - 30 ms)
A. Refractory Period	150; 160 ... 310 \diamond ... 500 ms (+ 5; - 30 ms)

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

Atrial parameters

Parameter	Programmable values
Atrial Amplitude	0.5; 0.75 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 \diamond ... 5; 5.5; 6; 8 V (+15% /-33%) ^a
Atrial Pulse Width	0.03; 0.06 ms (\pm 10 μ s); 0.1; 0.2; 0.3; 0.4 \diamond ... 1.5 ms (\pm 25 μ s)
Atrial Sensitivity ^b	Off; 0.15 mV (\pm 75%); 0.3; 0.45; 0.6 mV (\pm 50%); 0.9; 1.2; 1.5; 1.8; 2.1; 4.0 mV (\pm 30%) Unipolar: 0.45 \diamond mV Bipolar: 0.3 \diamond mV
Atrial Pace Polarity	Bipolar; Unipolar
Atrial Sense Polarity	Bipolar; Unipolar
Atrial Lead Monitor	Monitor Only; Adaptive
Min Limit	200 \diamond ; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 \diamond 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 ... 1.25 V (+0.125 V/-33%) 1.50 ... 3.5 \diamond ... 5; 5.5; 6; 8 V (+15% /-33%) ^a
RV Pulse Width	0.03; 0.06 ms (\pm 10 μ s); 0.1; 0.2; 0.3; 0.4 \diamond ... 1.5 ms (\pm 25 μ s)
RV Sensitivity ^b	0.45; 0.60 mV (\pm 50%); 0.90 \diamond ; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (\pm 30%) Unipolar: 2.80 \diamond mV Bipolar: 0.90 \diamond mV
RV Pace Polarity	Bipolar; Unipolar
RV Sense Polarity	Bipolar; Unipolar
RV Lead Monitor	Monitor Only; Adaptive
Min Limit	200 \diamond ; 300; 400; 500 Ω
Max Limit	1,000; 1,500; 2,000; 3,000 \diamond 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 \diamond ; Monitor; Off
Atrial Amplitude Safety Margin	1.5x; 2.0x \diamond ; 2.5x; 3.0x
Atrial Minimum Adapted Amplitude	1.0; 1.5 \diamond ; 2.0; 2.5; 3.0; 3.5 V
Atrial Acute Phase Remaining	Off; 30; 60; 90; 120 \diamond ; 150 days

RV Capture Management™ parameters

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

Blanking periods

Parameter	Programmable values
PVAB Interval	10 ^a ; 20 ... 100; 110; 120 ... 150 \diamond ... 300 ms
PVAB Method	Partial \diamond ; Partial+; Absolute
A. Blank Post AP	150; 160 ... 200 \diamond ... 250 ms (+5; -30 ms)
A. Blank Post AS	100 \diamond ; 110 ... 170 ms (+2; -30 ms)
V. Blank Post VP	150; 160 ... 200 \diamond ... 320 ms (+5; -30 ms)
V. Blank Post VS	120 \diamond ; 130 ... 170; 200; 220; 250; 280; 300; 320 ms (+2; -30 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 \diamond ... 175 min ⁻¹ (\pm 2 min ⁻¹)
ADL Rate	60; 65 ... 95 \diamond ... 170 min ⁻¹ (\pm 2 min ⁻¹)
Rate Profile Optimisation	On \diamond ; Off
ADL Response	1; 2; 3 \diamond ; 4; 5
Exertion Response	1; 2; 3 \diamond ; 4; 5
Activity Threshold	Low \diamond ; Medium Low; Medium High; High
Activity Acceleration	15; 30 \diamond ; 60 s
Activity Deceleration	Exercise \diamond ; 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 \diamond ; On
Start Rate	50; 55 ... 90 \diamond ... 145 min ⁻¹
Stop Rate	55; 60 ... 130 \diamond ... 175 min ⁻¹
Minimum Paced AV	30; 40 ... 140 \diamond ... 200 ms
Minimum Sensed AV	30; 40 ... 110 \diamond ... 200 ms

Atrial preference pacing parameters

Parameter	Programmable values
A. Preference Pacing	On; Off
Maximum Rate	80; 85 ... 100 ... 150 min ⁻¹
Interval Decrement	30 ; 40; 50 ... 100; 150 ms
Search Beats	5; 10; 15; 20 ... 25; 50

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 min ⁻¹
Drop Rate	30; 40 ... 60 ... 100 min ⁻¹
Detection Window	10; 15; 20; 25; 30 s 1 ; 1.5; 2; 2.5 min

Low Rate Detection

Detection Beats	1; 2; 3 beats
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Intervention

Intervention Rate	70; 75 ... 100 ... 150 min ⁻¹
Intervention Duration	1; 2 ... 15 min

^a When Rate Drop Response is set to On, the lower rate is automatically set to 45 min⁻¹.

Sleep parameters

Parameter	Programmable values
Sleep	On; Off
Sleep Rate	30; 35 ... 50 ; 55; 60; 70; 75 ... 100 min ⁻¹
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 min ⁻¹

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 min ⁻¹

Tachyarrhythmia parameters

Tachyarrhythmia detection parameters

Parameter	Programmable values
AT/AF Detection	Monitor
AT/AF Interval (Rate) ^a	150; 160 ... 350 ... 450 ms
VT Monitor	Monitor ; Off
VT Monitor Interval (Rate) ^a	280; 290 ... 400 ... 500 ms 0.45; 0.60 mV (±50%); 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (±30%) Bipolar: 0.9 mV Unipolar: 2.80 mV
RV Sensitivity ^{b,c,d}	0.15 mV (±75%); 0.30; 0.45; 0.60 mV (±50%); 0.90; 1.20; 1.5; 1.8; 2.1; 4.0 mV (±30%); Off Bipolar: 0.3 mV Unipolar: 0.45 mV
Atrial Sensitivity ^{b,d,e}	0.15 mV (±75%); 0.30; 0.45; 0.60 mV (±50%); 0.90; 1.20; 1.5; 1.8; 2.1; 4.0 mV (±30%); 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 2.0 mV or higher.

^d Tolerances are based on bipolar polarity.

^e The device complies with the requirements of ISO 14708-2 when the sensitivity threshold is programmed to 1.8 mV or higher.

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
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.

^b The reset value may be set to Off if there is an issue with wireless communication that requires it to be disabled.

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 (hr/24hr)	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/24hr)	0.5; 1; 2; 6 ; 12; 24 hr/24 hr
Avg. V. Rate During AT/AF	90; 100 ... 150 min ⁻¹
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 min ⁻¹
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 min ⁻¹

^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 are based on pacing outputs programmed to the specified amplitude and 0.4 ms pulse width and 60 min⁻¹ 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.

IMPORTANT REMINDER

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Brief Statement

See the MRI SureScan™ technical manual before performing an MRI scan and the device manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at www.medtronic.com.



www.medtronic.com/manuals

Consult instructions for use on this website. Manuals can be viewed using a current version of any major Internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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