ADVISA DR MRI™ SURESCAN™

A2DR01

Digital dual chamber pacemaker
with SureScan Technology (OAE-DDDR)

Product Specifications

MR Conditional

Initial Implant	
Existing Implant	

Physical characteristics

Volume[a]	12.7 cm^3
Mass	22 g
H x W x D[b]	45 mm x 51 mm x 8 mm
Radiopaque ID[c]	PVX
Surface area of titanium device can	32.2 cm^2
Materials in contact with human tissue[d]	Titanium, polyurethane, silicone rubber
Battery	Lithium silver vanadium oxide with carbon monofluoride

[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)	≤ 2.83 V on 3 consecutive daily automatic measurements
Elective Replacement Indicator (ERI)	3 months after RRT
End of Service (EOS)	3 months after ERI

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	11.8	11.8	11.8	11.8	11.8	11.8
	On	11.6	11.6	11.6	11.6	11.6	11.6
DDD, 15%	Off	11.2	10.6	11.3	10.8	11.4	11.0
	On	11.0	10.4	11.1	10.6	11.2	10.9
DDD, 50%	Off	10.0	8.6	10.3	8.9	10.7	9.7
	On	9.9	8.5	10.1	8.8	10.5	9.5

Medtronic

AAI <=> DDD (MVP® Mode) 50% Atrial, 5% Ventricular	Off	10.8	9.8	10.9	10.1	11.2	10.5
	On	10.6	9.7	10.7	9.9	11.0	10.4
DDD, 100%	Off	8.7	6.7	9.1	7.2	9.8	8.2
	On	8.6	6.6	8.9	7.1	9.6	8.0

[a] The data provided for programming Pre-arrhythmia EGM storage to On is 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 27% or 3.2 months per year.
* Projected service life estimates are based on accelerated battery discharge data and device modeling as specified. Do not interpret these values as precise numbers.

Note: These projections are based on typical shelf storage time. Assuming worst-case shelf storage time (18 months), longevity is reduced by approximately 10.1%.

Projected service life in years per conditions specified in EN 45502-2-1:2003

Pacing	500 Ω pacing impedance	
	2.5 V	5.0 V
DDDR, 100%	7.9[a]	3.3[a]

Stored data and diagnostics

Arrhythmia episode data storage

Episode type	Capacity
Monitored VT episode log	100 entries
Monitored VT episode EGM, markers, and intervals	5 min
Nonsustained VT episode log	15 entries
Nonsustained VT episode EGM, markers, and intervals	2 min
Fast A and V episode log	15 entries
Fast A and V episode EGM, markers, and intervals	2 min
Treated AT/AF episode log	100 entries
Treated AT/AF episode EGM, markers, and intervals	8.25 min
Monitored AT/AF episode log	50 entries
Monitored AT/AF episode EGM, markers, and intervals	3 min
SVT episode log	25 entries
SVT episode EGM, markers, and intervals	2.5 min
Rate Drop Response episode log, markers, and intervals	10 entries
Patient-activated episode log	50 entries
Flashback memory interval data before each of the following events: Interrogation, VT monitor episode, Fast A and V episode, AT/AF episode	2,000 events (includes both A and V-events)

VT/VF episode counters

The VT/VF episode counters are maintained for the current follow-up session and the previous follow-up session.

Counts of each type of VT/VF episode	VT, VT-NS (> 4 beats), Fast A&V, PVC runs (2-4 beats), PVC singles, runs of VRS paces, single VRS paces

AT/AF episode counters

The AT/AF episode counters are maintained for the current follow-up session and the previous follow-up session.

AT/AF summary data	% of time AT/AF, average AT/AF time/day, monitored AT/AF episodes, treated AT/AF episodes, pace-terminated episodes, % of time atrial pacing, % of time atrial intervention, AT-NS (> 6 beats)
Number of AT/AF episodes	Grouped by duration[a] Grouped by start time[a]

[a] This counter includes any instance when the device identifies AT/AF Onset. Therefore, the total number of episodes in this counter may exceed the number of detected AT/AF episodes recorded by the device.

AT/AF therapy counters

The AT/AF therapy counters are maintained for the current follow-up session and the previous follow-up session.

Number of AT/AF episodes treated and the percentage of episodes terminated	▪ Grouped by detection zone and therapy ▪ Grouped by atrial cycle length
Counts of different types of AT/AF therapy	▪ ATP sequences: – delivered – aborted

Battery and lead measurement data

The device automatically and continuously monitors its battery and lead status throughout the life of the device. You may print and view the following data:

Battery voltage	
Remaining Longevity	Estimated at, Minimum, Maximum
Sensing integrity counter	Short V-V intervals
Atrial lead position check	
Lead impedance	A. Pacing, RV pacing
Sensing	P-wave and R-wave amplitudes

Lead performance trend data

For 14 days, the device stores daily measurements. After 14 days, the device compresses each full week of data into a weekly sample for up to 80 weeks. Beyond 82 weeks, data is maintained on a first-collected, first-deleted basis.

A. pacing impedance	Bipolar, Unipolar, Uni/Bi
RV pacing impedance	Bipolar, Unipolar, Uni/Bi
Capture Threshold	Atrial, RV
P/R Wave Amplitude	P-wave, R-wave

Cardiac Compass® trend data

Cardiac Compass trend data is available only as a printed report. The report shows up to 14 months of long-term clinical trends. Each report contains the following information:

Programming, interrogation, and remote session events with date and event annotations; AT/AF total minutes or hours per day; ventricular rate during AT/AF; percent pacing per day; average ventricular rate (day and night rates); patient activity; heart rate variability

Rate Histograms data

Rate histogram data is available only as a printed report. The report shows the distribution of atrial and ventricular rates recorded since the last patient session and in the period before the last session.

The histograms show the percentage of total time paced or sensed for the following events and event sequences[a]	Total VP, AS-VS, AS-VP, AP-VS, AP-VP
The histograms show the rate distribution of paced and sensed events for the following conditions:	Atrial rate,[b] ventricular rate, ventricular rate during AT/AF

[a] If the programmed pacing mode during the reporting period was a dual chamber mode, the report displays the AS-VS, AS-VP, AP-VS, and AP-VP event sequence data. If a single chamber mode was programmed, the report displays the percent of time spent pacing and sensing. MVP modes (AAIR<=>DDDR and AAI<=>DDD) are considered dual chamber modes for this purpose.

[b] If more than 2% of atrial sensed events are identified as far-field R-waves, the general percentage range (either "2% to 5%" or "> 5%") is reported above the atrial rate histogram.

Device parameters

Emergency settings

Parameter	Selectable values
Pacing Mode	VVI
Lower Rate	70 bpm
RV Amplitude[a]	6 V
RV Pulse Width[a]	1.5 ms
RV Pace Polarty	Unipolar
V. Blank Post VP	240 ms
Rate Hysteresis	Off
V. Rate Stabilization	Off
MRI SureScan	Off

[a] If the programmed RV Amplitude is 8 V, VVI pacing is delivered at 8 V with a pulse width of 1.2 ms.

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] (Bipolar sensing polarity)	0.45; 0.60; 0.9 ◈; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV
RV Sensitivity[b] (Unipolar sensing polarity)	0.45; 0.60; 0.9; 1.20; 2.00; 2.80 ◈; 4.00; 5.60; 8.00; 11.30 mV
Atrial Sensitivity[b,c] (Bipolar sensing polarity)	0.15; 0.3 ◈; 0.45; 0.60; 0.90; 1.20; 1.5; 1.80; 2.10; 4.00 mV
Atrial Sensitivity[b,c] (Unipolar sensing polarity)	0.15; 0.3; 0.45 ◈; 0.60; 0.90; 1.20; 1.50; 1.80; 2.10; 4.00 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] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in bipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of section 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 1.8 mV. The device complies with the requirements of section 27.5.1 when the sensitivity threshold is programmed to 1.8 mV or higher.

Atrial tachyarrhythmia therapy parameters

Parameter	Programmable values
Antitachy 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 ◈
Burst+ parameters	
Initial # S1 Pulses	1; 2 ... 15 ◈; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◈; 94; 97%
S1-S2 (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66; 69 ... 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 ... 6 ◈ ... 10
Ramp parameters	
Initial # S1 Pulses	1; 2 ... 6 ◈ ... 15; 20; 25
A-S1 Interval (%AA)	28; 31; 34; 38; 41 ... 59; 63; 66 ... 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; 3; 4; 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; 120; 130 ◆ ... 400 ms
A. Pacing Amplitude	1; 2 ... 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.

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
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.

Atrial parameters

Parameter	Programmable values
Atrial Amplitude[a]	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V[f]
Atrial Pulse Width[b]	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
Atrial Sensitivity[c,d,e]	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 tested per CENELEC standard EN 45502-2-1:2003, the tolerance (+ 40%/- 30% for voltages less than 2.0, and ± 30% for voltages greater than or equal to 2.0) is applied not to the programmed setting, but to the calculated amplitude A, which depends on the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times (0.9 - [W_p \times 0.145\ ms^{-1}])$.

[b] When tested per CENELEC standard EN 45502-2-1:2003, the measured pulse width W depends on the load Rload (in Ohms) and programmed pulse width W_p (in seconds): $W \le W_p + 34\ \mu s$ and $W \ge$ the smaller of (W_p - 16 µs) or (124 µs + [4 µs x Rload]).

[c] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[d] With a 20 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.4 times the rated sine^2 sensing threshold.

[e] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in bipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-2:2008, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the minimum value of 0.15 mV. The device complies with the requirements of section 27.5.1 when the sensitivity threshold is programmed to 0.3 mV or higher. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 1.8 mV. The device complies with the requirements of section 27.5.1 when the sensitivity threshold is programmed to 1.8 mV or higher.

[f] When Atrial Amplitude is 8 V, Atrial Pulse Width must be less than 1.3 ms.

RV parameters

Parameter	Programmable values
RV Amplitude[a]	0.5; 0.75 ... 3.5 ◆ ... 5; 5.5; 6; 8 V[f]
RV Pulse Width[b]	0.03; 0.06; 0.1; 0.2; 0.3; 0.4 ◆ ... 1.5 ms
RV Sensitivity[c,d,e]	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 tested per CENELEC standard EN 45502-2-1:2003, the tolerance (+ 40%/- 30% for voltages less than 2.0, and ± 30% for voltages greater than or equal to 2.0) is applied not to the programmed setting, but to the calculated amplitude A, which depends on the programmed amplitude A_p and programmed pulse width W_p: $A = A_p \times (0.9 - [W_p \times 0.145\ ms^{-1}])$.

[b] When tested per CENELEC standard EN 45502-2-1:2003, the measured pulse width W depends on the load Rload (in Ohms) and programmed pulse width W_p (in seconds): $W \le W_p + 34\ \mu s$ and $W \ge$ the smaller of (W_p - 16 µs) or (124 µs + [4 µs x Rload]).

[c] With a 40 ms sine^2 waveform. When using the CENELEC waveform, the rated sensing threshold value will be 1.5 times the rated sine^2 sensing threshold..

[d] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.

[e] Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to the more sensitive settings. When susceptibility to interference in unipolar sensing mode is tested under the conditions specified in CENELEC standard EN 45502-2-1:2003, clause 27.5.1, the device may sense the interference if the sensitivity threshold is programmed to the values below 2.0 mV. The device complies with the requirements of section 27.5.1 when the sensitivity threshold is programmed to 2.0 mV or higher.

[f] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

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; 20 ... 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

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 Setpoint	5; 6 ... 40; 42 ... 80
UR Setpoint	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 ◈ ... 25; 50

Post Mode Switch Overdrive 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	Off ◈; On
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 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
Detection Beats	1; 2; 3 ◈ beats
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	30; 35 ... 60; 70; 75 ... 120 bpm

Note: See the SureScan pacing system technical manual for information about SureScan programmable parameters.

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

Data collection parameters

Data collection parameters

Parameter	Programmable values
EGM 1 Source	Can to RVring; Can to Aring; RVtip to RVring; Atip to RVring; Atip to Aring ◈ ; Aring to RVring; RVtip to Can; Atip 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	Can to RVring ◈; Can to Aring; RVtip to RVring; Atip to RVring; Atip 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
Avg V. Rate During AT/AF Daily Burden	0.5; 1; 2; 6 ◈; 12; 24 hr
Avg V. Rate During AT/AF V. Rate	90; 100 ◈ ... 150 bpm
Device Date/Time[a]	(enter time and date)
Holter Telemetry	Off ◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr

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

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.

EP study parameters

50 Hz Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◈; Disabled
Amplitude	1; 2; 3; 4 ◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◈ ... 1.50 ms
VOO Backup	On; Off ◈
Pacing Rate	60; 70 ◈ ... 120 bpm
V. Amplitude[a]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Fixed Burst induction parameters

Parameter	Selectable values
Resume at Burst	Enabled ◈; Disabled
Chamber	RV; Atrium
Interval	100; 110 ... 600 ◈ ms
Amplitude	1; 2; 3; 4 ◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◈ ... 1.50 ms
VVI Backup (for atrial Fixed Burst)[b]	On; Off ◈
Pacing Rate	60; 70 ◈ ... 120 bpm
V. Amplitude[a]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[b] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

PES induction parameters

Parameter	Selectable values
Resume at Deliver	Enabled ◈; Disabled
Chamber	RV; Atrium
#S1	1; 2 ... 8 ◈ ... 15
S1S1	100; 110 ... 600 ◈ ... 2,000 ms
S1S2	Off; 100; 110 ... 400 ◈ ... 600 ms
S2S3	Off ◈; 100; 110 ... 600 ms
S3S4	Off ◈; 100; 110 ... 600 ms
Amplitude	1; 2; 3; 4 ◈; 5; 6; 8 V
Pulse Width	0.10; 0.20 ... 0.50 ◈ ... 1.50 ms
VVI Backup (for atrial PES)[b]	On; Off ◈
Pacing Rate	60; 70 ◈ ... 120 bpm
V. Amplitude[a]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[a]	0.10; 0.20 ... 1.50 ms

[a] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.
[b] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

Shared manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (atrial ATP)	100; 110; 120; 130 ◈ ... 400 ms
Minimum Interval (ventricular ATP)	150; 160 ... 200 ◈ ... 400 ms
Amplitude	1; 2 . . . 6 ◈; 8 V
Pulse Width	0.10; 0.20 ... 1.50 ◈ ms
VVI Backup (for atrial ATP therapy)[a]	On; Off ◈
Pacing Rate	60; 70 ◈ ... 120 bpm
V. Amplitude[b]	0.50; 0.75 ... 5.00; 5.50; 6.00; 8.00 V
V. Pulse Width[b]	0.10; 0.20 ... 1.50 ms

[a] Crosstalk may occur when atrial pacing amplitude is greater than 6.0 V.

[b] The default value for this parameter is set according to the permanently programmed settings for bradycardia pacing.

Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	Atrium; RV
RV Ramp therapy parameters	
# Pulses	1; 2 ... 6 ◈ ... 15
%RR Interval	50; 53; 56; 59; 63; 66 ... 84; 88; 91; 94; 97 ◈ %
Dec/Pulse	0; 10 ◈; 20; 30; 40 ms
Atrial Ramp Therapy parameters	
# Pulses	1; 2 ... 6 ◈ ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91; 94; 97 ◈ %
Dec/Pulse	0; 10 ◈; 20; 30; 40 ms

Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8 ◈ ... 15
%RR Interva	50; 53; 56; 59; 63; 66 ... 84; 88 ◈ ; 91; 94; 97%

Manual Ramp+ therapy parameters

Parameter	Selectable values
# Pulses	1; 2; 3 ◈ ... 15
R-S1 (%RR)	50; 53; 56; 59; 63; 66 ... 75 ◈ ... 84; 88; 91; 94; 97%
S1-S2 (%RR)	50; 53; 56; 59; 63; 66; 69 ◈ ... 84; 88; 91; 94; 97%
S2-SN (%RR)	50; 53; 56; 59; 63; 66 ◈ ... 84; 88; 91; 94; 97%

Manual Burst+ therapy parameters

Parameter	Selectable values
# S1 Pulses	1; 2 ... 6 ◈ ... 15; 20; 30 ... 100
%AA Interval	28; 31; 34; 38; 41 ... 59; 63; 66 ... 84; 88; 91 ◈; 94; 97%
S1S2	Off; 28; 31; 34; 38; 41 ... 59; 63; 66 ... 84 ◈; 88; 91; 94; 97%
S2S3 Dec	Off; 0; 10; 20 ◈ ... 80 ms

Nonprogrammable parameters

Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
Fixed blanking periods	
Atrial blanking after a paced ventricular event (bipolar atrial sensing)	30 ms
Atrial blanking after a paced ventricular event (unipolar atrial sensing)	40 ms
Ventricular blanking after a paced atrial event (bipolar ventricular sensing)	30 ms[a]
Ventricular blanking after a paced atrial event (bipolar ventricular sensing)	40 ms
Fixed bradycardia pacing parameters	
Ventricular Safety Pacing intervals[b]	110 ms
PVARP value applied by PVC Response and PMT Intervention[c]	400 ms
NCAP value applied by PVC Response and PMT Intervention[d]	400 ms
Fixed automatic atrial ATP therapy parameters	
VVI Backup Pacing amplitude	6 V
VVI Backup Pacing pulse width	1.5 ms
Fixed EP study parameters	
50 Hz burst pacing interval	20 ms
Hardware parameters	
Pacing rate limit[e] (protective feature)	171 bpm[f]
Input impedance	150 k Ω minimum
Recommended Replacement Time (RRT)	
Battery Voltage Threshold	≤ 2.83 V

[a] 35 ms when the ventricular pacing amplitude is programmed to 8 V.

[b] The VSP interval may be shortened from 110 ms to 70 ms automatically by the device at higher pacing rates when necessary to help support ventricular tachycardia detection.

[c] PVARP is extended to 400 ms only if the current PVARP is less than 400 ms.

[d] The NCAP extension applies only if NCAP is enabled.

[e] Does not apply during ATP therapies or ventricular safety pacing.

[f] If either the Upper Tracking Rate or Upper Sensor Rate (whichever is greatest) is programmed to a value greater than 150 bpm and less than or equal to 180 bpm, the pacing rate limit is 200 bpm. If the Upper Tracking Rate is programmed to a value greater than 180 bpm, the pacing rate limit is 230 bpm.

Brief Statement: Advisa DR MRI™ SureScan™ Pacing System

The Advisa DR MRI™ SureScan™ pacing system is MR Conditional and as such is designed to allow patients to undergo MRI under the specified conditions for use. A complete SureScan pacing system, which consists of an approved combination (see http://www.mrisurescan.com/) MRI SureScan device with SureScan lead(s), is required for use in the MRI environment. Consult the device manuals to ensure all system components are MR Conditional.

Indications

The Advisa DR MRI™ SureScan™ Model A2DR01 IPG is indicated for use as a system consisting of an Advisa DR MRI™ SureScan IPG implanted with two SureScan leads. A complete system is required for use in the MRI environment. The Advisa DR MRI™ SureScan system is indicated for the following:

- 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
  - Bradycardia-tachycardia syndrome to prevent symptomatic bradycardia or some forms of symptomatic tachyarrhythmias

The Advisa DR MRI™ device is 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
- 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.

Contraindications

The Advisa DR MRI™ SureScan system is contraindicated for concomitant implantation with another bradycardia device or with an implantable cardioverter defibrillator. There are no known contraindications for the use of pacing as a therapeutic modality to control heart rate. The patient's age and medical condition, however, may dictate the particular pacing system, mode of operation, and implant procedure used by the physician.

- 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/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; pace polarity parameters set to Bipolar for programming MRI SureScan to On; or a SureScan pacing system with a lead impedance value of ≥ 200 Ω and ≤ 1,500 Ω. The device must be operating within the projected service life and the system must be implanted in the left or right pectoral region. For pacemaker-dependent patients, it is not recommended to perform an MRI scan if the right ventricular (RV) lead pacing capture threshold is greater than 2.0 V at 0.4 ms. Patients whose device will be programmed to an asynchronous pacing mode when MRI SureScan is on must have no diaphragmatic stimulation at a pacing output of 5.0 V and at a pulse width of 1.0 ms. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).
Patients may be scanned using a horizontal field, cylindrical bore, clinical 1.5T or 3T MRI system for hydrogen proton imaging, maximum spatial gradient ≤ 20 T/m, and maximum gradient slew rate performance per axis ≤ 200 T/m/s. 1.5T scanners must be operated in Normal Operating Mode (whole body averaged specific absorption rate (SAR) ≤ 2.0 W/kg, head SAR ≤ 3.2 W/kg. 3T scanners must be operated in First Level Controlled Operating Mode or Normal Operating Mode. $B1_{+RMS}$ must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without $B1_{+RMS}$ restriction when the isocenter is at or superior to the C7 vertebra. Proper patient monitoring must be provided during the MRI scan.

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. The SureScan system has been designed to minimize potential complications in the MRI environment. 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 Advisa MRI™ SureScan Technical Manual before performing an MRI Scan and see the device manuals for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com *or* www.mrisurescan.com.

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

Medtronic
710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1.763.514.4000

medtronic.com

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