ADVISA SR MRI™ SURESCAN™

A3SR01

Digital single chamber pacemaker with SureScan™ Technology (VVIR)

Product Specifications

Physical Characteristics

Volume[a]	11.9 cm^3
Mass	21 g
H x W x D[b]	51 mm x 42 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

Device parameters

Emergency VVI 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 Polarity	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.

Medtronic

Tachyarrhythmia detection parameters

Parameter	Programmable values
VT Monitor	Monitor ◈; Off
VT Monitor Interval (Rate)[a]	280; 290 ... 360 ◈ ... 500 ms
RV Sensitivity[b,c,d]	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: 0.90 ◈ mV Unipolar: 2.80 ◈ 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] 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] 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.

Pacing parameters

Modes, rates, and intervals

Parameter	Programmable values
Mode	VVIR ◈; VVI; VOO; OVO
Lower Rate[a]	30; 35 ... 60 ◈; 70; 75 ... 150 bpm (± 2 bpm)

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

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 (± 50%) 0.90; 1.20; 2.00; 2.80; 4.00; 5.60; 8.00; 11.30 mV (± 30%) 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] 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.
[e] This setting applies to all sensing in this chamber for both tachyarrhythmia detection and bradycardia pacing operations.
[f] When RV Amplitude is 8 V, RV Pulse Width must be less than 1.3 ms.

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
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 (± 2 bpm)
ADL Rate	60; 65 ... 95 ◈ ... 170 bpm (± 2 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

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

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

MRI SureScan parameters

Parameter	Programmable values
MRI SureScan	On; Off
MRI Pacing Mode	VOO; OVO
MRI Pacing Rate	30; 35 ... 60; 70; 75 ... 120 bpm

Additional pacing features

Parameter	Programmable values
Rate Hysteresis	Off ◆; 30; 40 ... 80 bpm

Data collection parameters

Data collection parameters

Parameter	Programmable values
EGM 1 Source	Can 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	Can to RVring ◆; RVtip to RVring; RVtip to Can
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]	(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	RV
Decrement after	2; 3 ... 15 pulses
Mode[a] (RV test)	VVI; VOO
Lower Rate	30; 35 ... 60; 70; 75 ... 150 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
V. Pace Blanking	150; 160 ... 320 ms
Pace Polarity	Unipolar; Bipolar
Sensing test parameters	
Mode[a]	VVI; OVO
Lower Rate	30; 35 ... 60; 70; 75 ... 120 bpm

[a] The selectable values for this parameter depend on the programmed pacing mode.

EP study parameters

Fixed Burst induction parameters

Parameter	Selectable values
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

PES induction parameters

Parameter	Selectable values
#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

Shared Manual ATP therapy parameters

Parameter	Selectable values
Minimum Interval (ventricular ATP)	150; 160 ... 200 ◆ ... 400 ms
Amplitude	1; 2 ... 6 ◆, 8 V
Pulse Width	0.10; 0.20 ... 1.50 ◆ ms

Manual Ramp therapy parameters

Parameter	Selectable values
Chamber	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

Manual Burst therapy parameters

Parameter	Selectable values
# Pulses	1; 2 ... 8 ◆ ... 15
%RR Interval	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%

Nonprogrammable parameters

Nonprogrammable parameters

Parameter	Value
Premature event threshold for counting PVCs and Runs of PVCs	69%
Hardware parameters	
Pacing rate limit[a] (protective feature)	171 bpm[b]
Input impedance	150 k Ω minimum
Recommended Replacement Time (RRT)	
Battery Voltage Threshold	≤ 2.83 V

[a] Does not apply during ATP therapies.
[b] If Upper Sensor Rate is programmed to a value greater than 150 bpm, the pacing rate limit is set to 200 bpm.

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
Patient-activated episode log	50 entries
Flashback memory interval data before each of the following events: Interrogation, VT monitor episode	2,000 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), PVC runs (2-4 beats), PVC singles, runs of VRS paces, single VRS paces

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
Lead impedance	RV pacing
Sensing	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.

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

Cardiac Compass® trend data

Cardiac Compass trends data is available on the Programmer screen or 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; percent pacing per day; average ventricular rate (day and night rates); patient activity; heart rate variability

Rate Histograms data

Rate histogram data is available on the Programmer screen or as a printed report. The report shows the distribution of 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 event sequences	VS, VP

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[b]	3.5 V[b]	2.5 V[b]	3.5 V[b]	2.5 V[b]	3.5 V[b]
VVI, 0%	Off	13.9	13.9	13.9	13.9	13.9	13.9
	On	13.6	13.6	13.6	13.6	13.6	13.6
VVI, 15%	Off	13.5	13.1	13.5	13.2	13.6	13.4
	On	13.3	12.9	13.3	13.0	13.4	13.2
VVI, 50%	Off	12.7	11.5	12.8	11.8	13.1	12.4
	On	12.5	11.3	12.6	11.6	12.9	12.2
VVI, 100%	Off	11.7	9.8	11.9	10.2	12.5	11.1
	On	11.5	9.6	11.8	10.1	12.3	11.0

[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.
[b] 0.4 ms pulse width, 60 bpm when pacing and 70 bpm when sensing, and 5-month shelf life.

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

Pacing	500 Ω ± 1% pacing impedance	
	2.5 V	5.0 V
VVIR, 100%	10.8[a]	5.7[a]

[a] Data storage and diagnostic functions applicable to the pacing mode are On. Pulse width is set at 0.5 ms and pacing rate is 70 bpm.

Brief Statement: Advisa SR MRI™ SureScan™ Pacing System
The Advisa SR MRI™ SureScan™ pacing system is MR Conditional and as such is designed to allow patients to undergo MRI under the specified conditions for use. When programmed to On, the MRI SureScan™ mode allows the patient to be safely scanned while the device continues to provide appropriate pacing. A complete SureScan™ system, which is a SureScan™ device with appropriate SureScan™ lead, 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.

Indications
The Advisa SR MRI™ SureScan™ system is indicated 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.

Contraindications
The Advisa SR MRI™ SureScan™ system is 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. Asynchronous pacing is contraindicated in the presence (or likelihood) of competition between paced and intrinsic rhythms

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. Pace polarity parameters are set to Bipolar for programming MRI SureScan™ to On; or a SureScan™ pacing system is implanted with a lead impedance value of ≥ 200 Ω and ≤ 1,500 Ω. It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks).

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.

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. B_{1+RMS} must be ≤ 2.8 μT when the isocenter (center of the bore) is inferior to the C7 vertebra. Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra. Continuous patient monitoring is required 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 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/adverse events. For further information, call Medtronic at 1-800-328-2518 and/or consult the Medtronic website at www.medtronic.com.

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

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