PAGINA 0

CREATA PENTRU A PUTEA SEMNA ELECTRONIC DOCUMENTUL

MRI™ SureScan® pacemaker system

SureScan

G70DR

Specifications

Model G70A2
Dual chamber MRI™ SureScan®
pacemaker system

vitatron • The Pace Makers

G70DR Specifications

Model G70A2 Dual chamber pacemaker system

Mechanical

Model	G70A2
Size (HxWxD mm)	44.7x47.9x7.5
M (g)	27.1
V (cc)	12.1
Connector	IS-1 BI or UNI
Radiopaque ID	V5

Battery

Type	Lithium-iodine
Voltage	2.8 V
Average projected capacity	1.3 Ah

Longevity	11.4 years* 10.2 years†

Bradycardia Pacing

Programmable parameters

Pacing Modes	**DDDR**, DDD, DDIR, DDI, DVIR, DVI, DOOR, DOO, VDD, VVIR, VDIR, VVI, VDI, VVT, VOOR, VOO, AAIR, ADIR, AAI, ADI, AAT, AOOR, AOO, ODO, OVO, OAO
Mode Switch	**On**, Off
Lower Rate	30, 35, 40…**60**…170 min^{-1} (exc. 65, 85)
Upper Tracking Rate[a]	80, 90, 95…**130**…180 min^{-1}
Upper Sensor Rate	80, 90, 95…**130**…180 min^{-1}
A and RV Pulse Amplitude[b]	0.5, 0.75, 1.0…**3.5**…4, 4.5, 5, 5.5, 6, 7.5 V
A and RV Pulse Width	0.12, 0.15, 0.21, 0.27, 0.34, **0.4**, 0.46, 0.52, 0.64, 0.76, 1, 1.25, 1.5 ms
Atrial Sensitivity	0.18, 0.25, 0.35, **0.5**, 0.7, 1, 1.4, 2, 2.8, 4 mV
Ventricular Sensitivity	1, 1.4, 2, **2.8**, 4, 5.6, 8, 11.2 mV
Pacing Polarity (A and V)	Bipolar, Unipolar, Configure
Sensing Polarity (A and V)	Bipolar, Unipolar, Configure
Paced AV (PAV)	30, 40, 50…**150**…350 ms
Sensed AV (SAV)	30, 40, 50…**120**…350 ms
PVARP	**Auto**, Varied, 150, 160, 170…500 ms
Minimum PVARP	150, 160, 170…**250**…500 ms
PVAB	130, 140, 150…**180**…350 ms
Atrial Refractory Period	180, 190, 200…**400**…500 ms
Atrial Blanking Period	130, 140, 150…**180**…350 ms
Ventricular Refractory Period	150, 160, 170…**230**…500 ms
Ventricular Blanking (after atrial pace) (PAVB)	20, **28**, 36, 44 ms

Therapies to promote intrinsic activation

Reduced VP™+	**On**, Off
Max Increase to AV	10, 20, 30…**170**…250 ms
Sinus Preference™	**On**, Off
Sinus Preference Zone	3, 5, **10**, 15, 20 min^{-1}
Search Interval	5, 10, 20, 30 min
Sleep	On, **Off**
Sleep Rate	30, 35, 40…**50**…90 min^{-1} (exc. 65, 85)
Bed Time	00:00, 00:15, 00:30… **22:00**…23:45
Wake Time	00:00, 00:15, 00:30… **8:00**…23:45
Single Chamber Hysteresis	Off, 40, 50, 60 min^{-1}

Rate Response Pacing

ADL Rate	60, 65, 70…**95**…175, 180 min^{-1}
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
Acceleration	15 s, **30 s**, 60 s
Deceleration	2.5 min, 5 min, 10 min, **Exercise**
RAAV	On, **Off**
Start Rate	50, 55, 60…**80**…175 min^{-1}
Stop Rate	55, 60, 65…**120** … 180 min^{-1}
Maximum Offset	-10, -20, -30…**-40** …-300 ms

Rate Drop Response

Detection Type	Low Rate, Drop, Both, **Off**
Intervention Rate	60, 70, 75, 80…**100**…180 min^{-1} (exc. 65, 85)
Intervention Duration	1, **2**, 3…15 min
Detection Beats	1, **2**, 3 beats
Drop Rate	30, 40, **50**…100 min^{-1}
Drop Size	10, 15, 20, **25**…50 min^{-1}
Detection Window	10, 15, 20, **25**, 30 s; 1, 1.5, 2, 2.5 min

Additional pacing features

PMT Intervention	On, **Off**
PVC Response	**On**, Off
Ventricular Safety Pacing	**On**, Off

MRI Pacing Parameters

SureScan® Pacing Mode	AOO, VOO, DOO,ODO
SureScan Lower Rate Interval	60, 70, 75, 80 … 115, 120[c] min^{-1}
SureScan PAV	50, 60 … 110 ms
SureScan Atrial Amplitude	5.0, 5.5, 6.0, 7.5 V
SureScan Atrial Pulse Width	1.0, 1.25, 1.5 ms
SureScan Atrial Sensitivity	0.18, 0.25, 0.35, 0.5, 0.7, 1.0, 1.4, 2.0, 2.8, 4.0 mV
SureScan Ventricular Amplitude	5.0, 5.5, 6.0, 7.5 V
SureScan Ventricular Sensitivity	1.0, 1.4, 2.0, 2.8, 4.0, 5.6, 8.0, 11.2 mV
SureScan Ventricular Pulse Width	1.0, 1.25, 1.5 ms
SureScan Timeout Duration	24 hr
SureScan MRI Compatibility	1.5 and 3 Tesla, full body scan

Atrial Tachyarrhythmia Therapies and Interventions

Mode Switch	**On**, Off
Detected Rate	120, 125…**175**…200 min^{-1}
Detect Duration	**No Delay**, 10, 20…60 sec
Blanked Flutter Search	**On**, Off

Atrial Preference Pacing (APP) parameters

APP	On, **Off**
Maximum Rate (min^{-1})	80, 90, 95, **100**…150
Interval Decrement (ms)	**30**, 40, 50…100, 150
Search Beats	5, 10…**20**, 25, 50

Post Mode Switch Overdrive Pacing (PMOP) parameters

PMOP	On, **Off**
Overdrive Rate (min^{-1})	70, 75, **80**, 90, 95…120
Overdrive Duration (min)	0.5, 1, 2, 3, 5, **10**, 20, 30, 60, 90, 120

Nominal values indicated in **bold**

Conducted AF Response[d]

Regularize V-V during AT/AF	On, **Off**
Maximum Rate (min^{-1})	80, 85, 90…**110**…130

Non-Competitive Atrial Pacing **On**, Off

Automatic Pacing, Sensing, and Lead Monitor

Implant Detection and Initialization

At the completion of the 30-minute Implant Detection period, Rate Profile Optimization is enabled; the appropriate pacing and sensing polarities are automatically selected by the device; Atrial and Ventricular Output Management is enabled and Amplitude and Pulse Width become adaptive. Sensing Assurance™ is enabled and Sensitivity becomes adaptive. Reduced VP™+ is enabled 60 minutes after Implant Detection is complete.

Implant Detection	On/Restart, Off/Complete
Lead Monitor (A and V)	Configure, Monitor Only, Adaptive (Auto Polarity Switch), Off
Notify If <	**200** Ω
Notify If >	1000, 2000, 3000, **4000** Ω
Monitor Sensitivity	2, 3, 4 … **8** … 16

Atrial Output Management

Atrial Output Management	Off, Monitor Only, **Adaptive**
Amplitude Margin	1.5x, **2x**, 2.5x, 3x, 4x (times)
Minimum Adapted Amplitude	0.5, 0.75…**1.5**…3.5 V
Capture Test Frequency	1, 2, 4, 8, 12 hours; Day at rest; **Day at**…; 7 days at
Capture Test Time	00:00, **1:00**…23:00
Acute Phase Days Remaining	Off, 7, 14, 21…84, **112**, 140, 168…252 days

Ventricular Output Management

Ventricular Output Management	Off, Monitor Only, **Adaptive**
Amplitude Margin	1.5x, **2x**, 2.5x, 3x, 4x (times)
Minimum Adapted Amplitude	0.5, 0.75…**2.0**…3.5 V
Capture Test Frequency	15, 30 min; 1, 2, 4, 8, 12 hours; **Day at rest**; Day at…; 7 days at
Capture Test Time	00:00, 1:00…23:00
Acute Phase Days Remaining	Off, 7, 14, 21…84, **112**, 140, 168…252 days
V. Sensing During Search	Unipolar, Bipolar, **Adaptive**

Sensing Assurance

Sensing Assurance (A and V)	**On**, Off

Diagnostics

Cardiac Dashboard II

Highlights significant events, AT/AF and pacing summary, threshold and impedance trends

Atrial and ventricular pacing threshold trends
Battery longevity
Pacing summary and access to rate histogram
Atrial and ventricular lead impedance trends
Number of hours/day in atrial arrhythmia, percentage of time
Access to atrial arrhythmia diagnostics
Observations
P-wave/R-wave amplitudes and access to A and V sensitivity trends

CardioTrend™

Trend data compiles up to 6 months of daily clinical information in an easy-to-interpret graphic format

Histogram reports

Heart rate histograms
AV conduction histograms
Reduced VP™+ histogram
Sensor indicated rate profile

Atrial and ventricular episodes

Atrial and ventricular high rate episodes
Ventricular rate during atrial arrhythmias
Atrial arrhythmia durations
Multiple EGM episodes
Rate drop response episodes

Clinician selected diagnostics

Custom rate trend
Rate drop response detail
Atrial output management detail
Ventricular Output Management detail
High Rate Detail

Patient data stored in device

Patient identification
Leads implanted
Device implanted
Clinician's stored notes

Data management

Automatic printing of initial interrogation report
Full page printing
Save-to-Disk capacity for electronic file management

Follow-up and Troubleshooting

Telemetry features	
Transtelephonic monitor	On, Off
Extended telemetry	On, Off
Extended marker	Standard, Therapy Trace

Key parameter history
Initial interrogation report
Strength duration threshold test
Ventricular threshold test
Marker Channel™
Threshold margin test
Exercise test
EP studies
Magnet test
Underlying rhythm test
Sensing test
Temporary test

Magnet mode operation

	BOS	ERI
Dual chamber mode	DOO 85 min^{-1}	65
Single chamber atrial mode	AOO 85 min^{-1}	65
Single chamber ventricular mode	VOO 85 min^{-1}	65

Recommended Replacement Time (RRT) and Elective Replacement Indicator (ERI)

Replacement message on programmer (Cardiac Dashboard II)

Battery/lead information	Replacement message and battery voltage displayed on programmer
RRT and ERI initiation date	Displayed on programmer

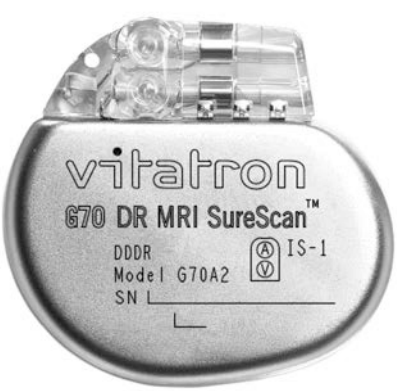
Vitatron. The Pace Makers

Vitatron - based in Europe - is the only medical device company that specializes exclusively in pacemakers. Since 1962, Vitatron pacemakers have helped restore more than 1,000,000 people in more than 60 countries to a full life. We strive to achieve perfection in everything we do. This results in unique patient-focused therapies, as well as highly cost-effective pacemakers that are easy to use.

Head Office: Vitatron Holding BV

Endepolsdomein 5,
Maastricht
NL 6229 GW
The Netherlands
www.vitatron.com

UC201708586 EE



G70DR • Dual chamber

References

*DDDR or DDD 50%, 1.5 V and 2.0 V, 60 min^{-1}, 0.4 ms, 500 OHM. For Atrial Output Management the Minimum Adapted Amplitude is 1.5 V (nominal). For Ventricular Output Management, the Minimum Adapted Amplitude is 2.0 V (nominal).

†DDDR or DDD 100%, 1.5 V and 2.0 V, 60 min^{-1}, 0.4 ms, 500 OHM. For Atrial Output Management the Minimum Adapted Amplitude is 1.5 V (nominal). For Ventricular Output Management, the Minimum Adapted Amplitude is 2.0 V (nominal).

[a] The atrial and ventricular Rate Limit is 200 min^{-1} (± 20 min^{-1}).

[b] Tolerance for amplitudes from 0.5 V through 6.0 V is ± 10%, and for 7.5 V is -20/+0%. Tolerances are based on 37 ºC and a 500 Ω load. Amplitude is determined 200 µs after the leading edge of the pace.

[c] User selection will not include 65 min^{-1} or 85 min^{-1}.

[d] Conducted AF Response is functional during Mode Switch episodes, DDIR, VVIR and VDIR modes.

vitatron • The Pace Makers