ADAPTA™ VDD
PACING SYSTEM
Model ADVDD01

Physical characteristics[1]

Physical characteristics	
Volume	11.1 cm^3
Mass	23.6 g
H x W x D	44.7 mm x 42.9 mm x 7.5 mm
Radiopaque ID	PWB
Connector	IS-1 BI or UNI
Battery	
Type	Lithium-iodine
Voltage	2.8 V
Usable Capacity[a]	0.93 Ah
Longevity[2b]	9.0 years[c]

[a] Capacity from Beginning of Service (BOS) to End of Service (EOS).
[b] Current serial number prefixes begin with "NW," older model serial number prefix is "PW." Clinician should consult labeling for relevant longevity information.
[c] VDD, 60 bpm, 100% pacing, 2.0 V, 0.4 ms pulse width, 1,000 Ω pacing impedance.

Medtronic

Bradycardia pacing[2]

Programmable parameters

Parameter	Programmable values
Pacing Modes	VDD ◆; VVIR; VDIR; VVI; VDI; VVT; VOOR; VOO; ODO; OVO; OAO
Mode Switch	On; Off ◆
Lower Rate	30; 35; 40 ... 50 ◆ ... 170 bpm (exc. 65, 85)
Upper Tracking Rate[a]	80; 90; 95 ... 130 ◆ ... 180; 190; 200; 210 bpm
Upper Sensor Rate	80; 90; 95 ... 130 ◆ ... 180 bpm
RV Pulse Amplitude[b]	0.5; 0.75; 1.0 ... 3.5 ◆ ... 4; 4.5; 5; 5.5; 6; 7.5 V
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 (V)	Bipolar; Unipolar; Configure
Sensing Polarity	V: Bipolar; Unipolar; Configure A: Bipolar
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
Ventricular Refractory Period	150; 160; 170 ... 230 ◆... 500 ms

[a] If the Upper Tracking Rate is set to 190 bpm or higher, the atrial and ventricular Rate Limit is 227 bpm (± 17 bpm). Otherwise, the atrial and ventricular Rate Limit is 200 bpm (± 20 bpm).
[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° C and a 500 Ω load. Amplitude is determined 200 µs after the leading edge of the pace.

Therapies for intrinsic activation

Parameter	Programmable values
Search AV™+	On ◆; Off
Max increase to AV	10; 20; 30 ... 170 ◆ ... 250 ms
Sleep	On; Off ◆
Sleep Rate	30; 35; 40 ... 50 ◆... 90 bpm (exc. 65, 85)
Bed Time	12:00 am, 12:15 am, 12:30 am ... 10:00 pm ◆ ... 11:45 pm
Wake Time	12:00 am, 12:15 am, 12:30 am ... 8:00 am ◆ ... 11:45 pm
Single Chamber Hysteresis	Off; 40; 50; 60 bpm

Rate Response Pacing

Parameter	Programmable values
ADL Rate	60; 65; 70 ... 95 ◆ ... 175 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
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 bpm
Stop Rate	55; 60; 65 ... 120 ◆ ... 180 bpm
Maximum Offset	-10; -20; -30 ... -40 ◆ ... -300 ms

Additional pacing features

Parameter	Programmable values
PMT Intervention	On; Off ◆
PVC Response	On ◆; Off

Atrial tachyarrhythmia therapies and interventions[2]

Mode switch

Parameter	Programmable values
Mode Switch	On; Off ◆
Detected rate	120; 125 ... 175 ◆ ... 200; 210; 220 bpm
Detect duration	NO Delay ◆; 10; 20 ... 60 sec
Blanked Flutter Search	On ◆; Off

Conducted AF response[a]

Parameter	Programmable values
Regularize V-V During AT/AF	On; Off ◆
Maximum Rate	80; 85; 90 ... 110 ◆ ... 130 bpm

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

Automatic pacing, sensing, and lead monitor[2]

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; Ventricular Capture Management™ is enabled and Amplitude and Pulse width become Adaptive. Sensing Assurance is enabled and sensitivity becomes Adaptive. SAV+ is enabled 60 minutes after implant detection is complete.

Parameter	Programmable values
Implant Detection	On/Restart; Off/Complete
Lead Monitor (V)	Configure; Monitor Only; Adaptive (Auto Polarity Switch); Off
Notify If <	200 Ω
Notify If >	1,000; 2,000; 3,000; 4,000 Ω ◈
Monitor Sensitivity	2; 3; 4 ... 8 ◈ ... 16

Ventricular Capture Management™

Parameter	Programmable values
Ventricular Capture Management™	Off; Monitor Only; Adaptive ◈
Amplitude Margin	1.5x; 2x ◈; 2.5x; 3x; 4x (times)
Minimum Adapted Amplitude	0.5; 0.75 ... 2 ◈ ... 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	12:00 am; 1:00 am ... 11:00 pm
Acute Phase Days Remaining	Off; 7; 14; 21 ... 84; 112 ◈; 140; 168 ... 252 days
V. Sensing During Search	Unipolar, Bipolar, Adaptive ◈

Sensing Assurance

Parameter	Programmable values
Sensing Assurance (A and V)	On ◈; Off

Diagnostics[2]

Quick Look™ II

Highlights significant events, AT/AF and Pacing Summary, Threshold and Impedance Trends
Ventricular Pacing Threshold Trends
Battery Longevity
Pacing Summary and Access to Rate Histogram
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

Cardiac Compass™ Trends

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
Search AV™+ 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

Clinician Selected Diagnostics

Custom Rate Trend
Ventricular Capture Management™ Detail
High Rate Detail

Patient Data Management[2]

TherapyGuide™ — Patient Condition Based Programming

TherapyGuide™ Fields
Atrial Status
AV Conduction
Heart Failure
Age
Activity Level

Patient Data Stored in Device

Patient Identification
Leads Implanted
Indication for Implant
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[2]

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/RRT
Single Chamber Ventricular Mode	VOO 85 bpm	65
ERI-RRT	Initiation date	

Recommended Replacement Time (RRT/ERI)

Replacement Message on programmer (Quick Look™ II)	
Battery/Lead Information	Replacement message and displayed battery voltage on programmer
RRT/ERI Initiation Date	Displayed on programmer

References

[1] Medtronic Adapta Implant Manual. M960725A001. Accessed July 10, 2017.

[2] Medtronic Adapta™, Versa™, Sensia™, Relia™ Pacemaker Reference Guide, M965319A001 C. Accessed June 26, 2017.

Brief Statement

IPGs

Indications

Implantable pulse generators (IPGs) are indicated for rate adaptive pacing in patients who may benefit from increased pacing rates concurrent with increases in activity. Pacemakers 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 and VVI intolerance (e.g., pacemaker syndrome) in the presence of persistent sinus rhythm. See device manuals for the accepted patient conditions warranting chronic cardiac pacing. Antitachycardia pacing (ATP) is indicated for termination of atrial tachyarrythmias in patients with one or more of the above pacing indications. For the MR-conditional IPGs, a complete SureScan™ pacing system, which consists of an approved combination (see mrisurescan.com/) MRI SureScan device with SureScan lead(s), is required for use in the MR environment.

Contraindications

IPGs are contraindicated for concomitant implant with another bradycardia device and concomitant implant 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. Antitachycardia pacing (ATP) therapy is contraindicated in patients with an accessory antegrade pathway.

Warnings/Precautions

Changes in a 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.

For MR-conditional IPG Systems, before performing an MRI scan, refer to the SureScan pacing system technical manual for additional information, patients and their implanted systems must be screened to meet the MRI Conditions of Use. Do not scan patients who do not have a complete SureScan pacing system consisting of an approved combination MRI SureScan device with SureScan lead(s); patients who have broken, abandoned, or intermittent leads; or patients who have a lead impedance value of < 200 Ω or > 1,500 Ω.

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, and surgical complications such as hematoma, infection, inflammation, and thrombosis.

SureScan systems have 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 manual for detailed information regarding the implant procedure, indications, contraindications, warnings, precautions, and potential complications/adverse events. For further information, please 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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