Allure™ RF

Cardiac Resynchronization Therapy Pacemaker

Merlin@home™ Transmitter Compatible

Product Highlights

- Angled header and physiologic tear drop shape provide better lead wrap
- CorVue™ Congestion Monitoring feature monitors the intrathoracic impedance and provides the option for both patient and physician alerts
- The DirectTrend™ Report provides a summary of three month daily, one year weekly or one year daily diagnostic trends
- Better patient utilization from day one when paired with the Merlin@home™ transmitter at point of care[1]
- AT/AF Alerts can be programmed to notify clinics when a programmed AT/AF threshold or continuous episode duration has been exceeded, or when a high ventricular rate accompanies the AT/AF episode
- Exclusive AF Suppression™ algorithm is clinically proven to suppress episodes of paroxysmal and persistent AF
- AT/AF burden trend provides a graphical representation of the percentage of time in AT/AF and the number of AT/AF episodes in the previous 52 weeks
- Up to 14 minutes of stored electrograms help identify key intrinsic and pacemaker-related events and simplify the diagnosis of complex ECG rhythms associated with heart failure
- Industry-leading longevity offers eight years of service life supported by a six-year warranty*

Ordering Information

Contents: Cardiac Pulse Generator

MODEL NUMBER	DIMENSIONS (H × W × T, MM)	WEIGHT (G)	VOLUME (CC)	CONNECTOR
PM3222	55 × 59 × 6	24	14	IS-1

1. Ren X et al. Patient adherence in remote follow-up of cardiovascular implantable electronic devices. *J Am Coll Cardiol.* 2012;59:E645, doi: 10.1016/SO735-10097(12)60646-9.

*Longevity calculated based on the following settings: 2,5V @ 0,4 ms (RA/RV/LV), 500 ohms, DDD, 60 BPM, 100% Bi-V Pacing, 100% Atrial Pacing and Stored EGMS on

Indications: Implantation of a CRT-P is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combinations of those symptoms. Implantation of a CRT-P is indicated for patients who would benefit from resynchronization of the right and left ventricles of have one or more conventional indications for the implantation of a pacemaker. ***Rate-Modulated Pacing*** is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. ***Dual-Chamber Pacing*** is indicated for those patients exhibiting: sick sinus syndrome, chronic, symptomatic second- and third-degree AV block, recurrent Adams-Stokes syndrome, symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. ***Atrial Pacing*** is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. ***Ventricular Pacing*** is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of A-V block or sinus arrest, chronic atrial fibrillation, severe physical disability. ***AF Suppression*** algorithm is indicated for suppression of paroxysmal or persistent atrial fibrillation episodes in patients with one or more of the above pacing indications.

Contraindications: Implanted Cardioverter-Defibrillator (ICD). Devices are contraindicated in patients with an implanted cardioverter-defibrillator. Rate-Adaptive Pacing may be inappropriate for patients who experience angina or other symptoms of myocardial dysfunction at higher sensor-driven rates. An appropriate Maximum Sensor Rate should be selected based on assessment of the highest stimulation rate tolerated by the patient. AF Suppression™ stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. ***Dual-Chamber Pacing***, though not contraindicated for patients with chronic atrial flutter, chronic atrial fibrillation, or silent atria, may provide no benefit beyond that of single-chamber pacing in such patients. ***Single-Chamber Ventricular Demand Pacing*** is relatively contraindicated in patients who have demonstrated pacemaker syndrome, have retrograde VA conduction or suffer a drop in arterial blood pressure with the onset of ventricular pacing. ***Single-Chamber Atrial Pacing*** is relatively contraindicated in patients who have demonstrated compromise of AV conduction. ***Atrial Fibrillation.*** Allure™ devices are contraindicated in patients having chronic atrial fibrillation or intermittent atrial fibrillation that does not terminate. For specific contraindications associated with individual modes, refer to the programmer's on-screen help.

Potential Adverse Events: The following are potential complications associated with the use of any pacing system: air embolism, body rejection phenomena, cardiac tamponade or perforation, hematoma, bleeding hematoma, seroma, formation of fibrotic tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pulse generator function due to electrical interference, either electromyogenic or electromagnetic, lead malfunction due to conductor fracture or insulation degradation, loss of capture or sensing due to lead dislodgement or reaction at the electrode/tissue interface, loss of desired pacing and/or sensing due to lead displacement, body reaction at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker migration or pocket erosion, pectoral muscle or diaphragmatic stimulation, phrenic nerve stimulation, pneumothorax/hemothorax, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, pulmonary edema, rise in threshold and exit block, valve damage, cardiac/coronary sinus dissection, cardiac/coronary sinus perforation, coronary sinus or cardiac vein thrombosis.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Allure™ RF

Cardiac Resynchronization Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS

Models	PM3222
Telemetry	RF
Dimensions (mm)	55 x 59 x 6
Weight (g)	24
Volume (cc)[1]	14
Connector	IS-1

PARAMETER	SETTINGS
Resynchronization Therapy	
QuickOpt™ Timing Cycle Optimization	Sensed/Paced AV Delay; Interventricular Paced Delay
RV and LV Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RV and LV Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
RV Pulse Configuration	Unipolar; Bipolar
LV Pulse Configuration	Unipolar; Bipolar; LV Tip–RV Ring; LV Ring–RV Ring
Ventricular Sense Configuration	BV Unipolar Tip; BV Bipolar; RV Unipolar Tip; RV Bipolar; Distal Tip 1–Mid 2; Distal Tip 1–Can; and Distal Tip 1–RV Tip
First Chamber Paced	Simultaneous[2]; RV; LV
SyncAV™ CRT Delta	Off; -10 to -120 in steps of 10
Shortest AV/PV Delay (ms)	25–50 in steps of 5; 60–120 in steps of 10
Output/Sensing	
Atrial ACap™ Confirm	On; Off; Monitor
Primary Pulse Confirmation	Bipolar
Backup Pulse Confirmation	Bipolar
Backup Pulse Amplitude (V)	5,0
Searchable Intervals (hrs)	8; 24
Atrial Pulse Configuration	Unipolar (tip–case); Bipolar (tip–ring)
Atrial Sense Configuration	Unipolar Tip (tip–case); Bipolar (tip–ring); Unipolar Ring (ring–case)
Atrial Sensitivity[3,4] (Fixed) (mV)	0,1–0,5 in steps of 0,1; 0,75–2,0 in steps of 0,25; 2,5–5,0 in steps of 0,5
Atrial Pulse Amplitude (V)	0,25–4,0 in steps of 0,25; 4,5–7,5 in steps of 0,5
Atrial Pulse Width (ms)	0,05; 0,1–1,5 in steps of 0,1
RVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
LVCap™ Confirm	On; Off; Monitor
Searchable Interval (hrs)	8; 24
Sense*Ability*™ Technology	Off; On (Automatic Sensitivity Control adjustment for atrial and ventricular events)
A Max Sensitivity (mV)	0,2–1,0 in steps of 0,1
V Max Sensitivity (mV)	0,2–2,0 in steps of 0,1
Threshold Start	(Atrial and Ventricular Post-Sense) 50; 62,5; 75; 100% (Atrial Post-Pace) 0,2–3,0 in steps of 0,1 mV (Ventricular Post-Pace) Auto; 0,2–3,0 in steps of 0,1 mV
Decay Delay (ms)	(Atrial and Ventricular Post-Sense) 0; 30; 60; 95; 125; 160; 190; 220 (Atrial Post-Pace) 0; 30; 60; 95; 125; 160; 190; 220 (Ventricular Post-Pace) Auto; 0; 30; 60; 95; 125; 160; 190; 220
Ventricular Sensitivity (fixed) (mV)	0,5–12,5 in steps of 0,5[3,4]
Rate/Timing	
Mode	A00(R); AAI(R); AAT(R); VOO(R); VVI(R); VVT(R); DOO(R); DVI(R); DDI(R); DDT(R); DDD(R); VDD(R); Pacing Off
DDT Trigger[5]	R wave
DDT Timing[5]	DDI
Base Rate (min^{-1})	30–130 in steps of 5; 140–170 in steps of 10
Hysteresis Rate (min^{-1})	Off; 30–150 in steps of 5[6]
Search Interval (min)	Off; 1; 5; 10; 15; 30
Cycle Count	1–16
Intervention Rate (min^{-1})	Off; Same Base Rate; 80–120 in steps of 10 (Intrinsic +0; Intrinsic +10; Intrinsic +20; Intrinsic +30)
Intervention Duration (min^{-1})	1–10
Recovery Time	Fast; Medium; Slow; Very Slow
Rest Rate (min^{-1})	Off; 30–150 in steps of 5
Maximum Tracking Rate (min^{-1})	90–130 in steps of 5; 140–180 in steps of 10
Sensed AV Delay (ms)	25; 30–200 in steps of 10; 225–325 in steps of 25
Paced AV Delay (ms)	25; 30–200 in steps of 10; 225–300 in steps of 25; 350
Ventricular Pace/Sense Refractory[7] (Fixed) (ms)	125; 160–400 in steps of 30; 440; 470[8]
Atrial Pace Refractory	190–400 in steps of 30; 440; 470[8]
Atrial Sense Refractory	93; 125; 157; 190–400 in steps of 30; 440; 470[8]
PVARP (ms)	125–500 in steps of 25
Atrial Protection Interval (ms)[5]	125
Far-Field Protection Interval (ms)[5]	16
Rate-Modulated Parameters	
Rate Responsive AV/PV Delay	Off; Low; Medium; High
Rate Responsive PVARP/VREF	Off; Low; Medium; High
Shortest PVARP/VREF	125–475 in steps of 25
Sensor	On; Off; Passive
Max Sensor Rate (min^{-1})	80–150 in steps of 5; 160–180 in steps of 10
Threshold	Auto (-0,5); Auto (+0,0); Auto (+0,5); Auto (+1,0); Auto (+1,5); Auto +(2,0); 1–7 in steps of 0,5
Slope	Auto (-1); Auto (+0); Auto (+1); Auto (+2); Auto (+3); 1–16
Reaction Time	Very Fast; Fast; Medium; Slow
Recovery Time	Fast; Medium; Slow; Very Slow

AF Management	
AF Suppression™ Algorithm	Off; On
Lower Rate Overdrive (min^{-1})[5]	10
Upper Rate Overdrive (min^{-1})[5]	5
No. of Overdrive Pacing Cycles	15–40 in steps of 5
Rate Recovery (ms)	8; 12
Auto Mode Switch	Off; DDD(R) to DDI(R); DDD(R) to DDT(R); DDD(R) to VVI(R); DDD(R) to VVT(R); VDD(R) to VVI(R); VDD(R) to VVT(R)
AMS Base Rate (min^{-1})	40–170 in steps of 5
Stored Electrograms	
Options	
Priority Options	Off; Low; High
Channel	1; 2; 3
Triggers	
Advanced Hysteresis	Off; Low; High
AMS Entry/AMS Exit/ AMS Entry and Exit	Off; Low; High
AT/AF Detection	Off; Low; High
Magnet Response	Off; Low; High
High Atrial Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
High Ventricular Rate	Off; Low; High
Rate (min^{-1})	125–300 in steps of 25
No. of Consecutive Cycles	2; 3; 4; 5; 10; 15; 20
PMT Termination	Off; Low; High
Consecutive PVCs	Off; Low; High
No. of Consecutive PVCs	2; 3; 4; 5
Noise Reversion	Off; Low; High
Other	
Magnet Response	Off; Battery Test
Ventricular Intrinsic Preference, VIP™ (ms)	Off; 50–150 in steps of 25; 160–200 in steps of 10
VIP Search Interval	30 sec.; 1; 3; 5; 10; 30 min.
VIP Search Cycles	1; 2; 3
Atrial Tachycardia Detection Rate (min^{-1})	110–200 in steps of 10; 225–300 in steps of 25
Post Vent. Atrial Blanking PVAB (ms)	60–200 in steps of 10; 225; 250
Ventricular Safety Standby	Off; On
PVC Response	Off; Atrial Pace[8]
PMT Options	Off; Passive; Atrial Pace[8]
PMT Detection Rate (min^{-1})	90–180 in steps of 5
Lead Type	Uncoded; Unipolar; Bipolar
NIPS Options	
Stimulation Chamber	Atrial; Right Ventricular
Coupling Interval[9] (ms)	200–800 in steps of 10
S1 Count	2–25 in steps of 1
S1[10]; S2; S3 and S4 Cycle (ms)	Off; 100–800 in steps of 10 (Fixed or Adaptive)
Right Ventricular Support Rate (min^{-1})	Off; 30–95 in steps of 5
Sinus Node Recovery Delay (s)	1–5 in steps of 1
Diagnostic Trends	AT/AF Activity; Exercise; Lead Impedance; P and R Wave; A and V threshold; CorVue™ Congestion Monitoring
CorVue™ Congestion Monitoring	Off; On
CorVue Congestion Trigger	8–18 days
Patient Notifiers	
Programmable Notifiers (On; Off)	Device at ERI; Atrial Lead Impedance Out of Range; Ventricular Lead Impedance Out of Range; LV Lead ImpedanceOut of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF; High V Rate; Percent BiV/RV Pacing Alert; CorVue Alert
Device Reset	On
Entry into Backup VVI Mode	On
Audible Duration (sec)	2; 4; 6; 8; 10; 12; 14; 16
Number of Audible Alerts per Notification	2
Number of Notifications	1–16
Time Between Notifications (hours)	10; 22

1. ± 0.5 cc
2. LV first with 10 ms interventricular delay.
3. Sensitivity is with respect to a 20 ms haversine test signal.
4. Values 0,1–0,4 not available in a Unipolar Sense Configuration.
5. This parameter is not programmable.
6. The highest available setting for hysteresis rate is 5 min^{-1} below the programmed base rate.
7. In dual-chamber modes, the maximum Ventricular Refractory Period is 325 ms.
8. Programming options dependent on pacing mode.
9. During atrial NIPS in dual-chamber modes, the shortest Coupling Interval will be limited by the programmed AV/PV Delay.
10. S1 Burst Cycle is applied at the preprogrammed S1 cycle length.

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St. Jude Medical is now Abbott.

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your Abbott representative for product availability in your country.

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