Allure Quadra™ RF

Cardiac Resynchronisation Therapy Pacemaker

Merlin@home™ Transmitter Compatible

Product Highlights

- The Allure Quadra™ CRT-P and quadripolar LV pacing lead features four pacing electrodes and 14 pacing vectors to provide more options and greater control to address complications at and post implant to improve CRT response
- 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 unitilization from Day 1 when paired with the Merlin@home™ transmitter at point of care
- AT/AF Alerts can be programmed to notify patients and their 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 8 years of service life supported by a 6 year warranty*

Ordering Information

Contents: Cardiac pulse generator

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM3242	56 x 59 x 6	27	15	IS4-LLLL, IS-1

*Longevity calculated based on the following settings: 2.5 V, 500 Ohm, 60 BPM, 100% DDD-BiV Pacing, 0.4ms, Cap Confirm Off, and Stored EGM On

Indications: Implantation of Allure and Allure RF devices is indicated for: maintaining synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic atrial fibrillation and have NYHA Class II or III heart failure, the reduction of the symptoms of moderate to severe heart failure (NYHA Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of Assurity, Endurity and Allure family of devices is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation, or any combination of those symptoms. ***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***. Anthem 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.

Customer Support: 46-8-474-4756

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 St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies.

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Allure Quadra™ RF

Cardiac Resynchronisation Therapy Pacemaker

Product Specifications

PHYSICAL SPECIFICATIONS	
Model	**PM3242**
Telemetry	RF
Dimensions (mm)	56 x 59 x 6
Weight (g)	27
Volume (cc)[1]	15
Connector	IS4-LLLL, IS-1

PARAMETER	SETTINGS
Resynchronisation Therapy	
QuickOpt™ Timing Cycle Optimisation	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
VectSelect Quartet™ LV Pulse Configuration	Unipolar; Bipolar; Distal Tip 1 - Mid 2;Distal Tip 1 - Proximal 4; Distal Tip 1 - RV Ring;Mid 2 - Proximal 4; Mid 2 - RV Ring; Mid 3 - Mid 2; Mid 3 - Proximal 4;Mid 3 - RV Ring; Proximal 4 - Mid 2; Proximal 4 - RV Ring; Distal Tip 1 - Can; Mid 2- Can; Mid 3 - Can; Proximal 4 - Can
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
Interventricular Pace Delay (ms)	10–80 in steps of 5
Output/Sensing	
Negative AV Hysteresis Search (ms)	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
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

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.

Rate-Modulated	
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
of the 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 Impedance Out of Range; AT/AF Burden; AT/AF Episode Duration; High V Rate During AT/AF, High V Rate, Percent BiV/RV Pacing Alert CorVue Congestion Monitoring 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

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Item GMCRM1096EN

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