Allure Quadra™ RF
Cardiac Resynchronisation Therapy Pacemaker

**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 utilisation from Day 1 when paired with the Merlin@home™ transmitter at point of care.
- ATAF 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.
- ATAF 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**

<table>
<thead>
<tr>
<th>Model Number</th>
<th>Dimensions (H x W x T, mm)</th>
<th>Weight (g)</th>
<th>Volume (cc)</th>
<th>Connector</th>
</tr>
</thead>
<tbody>
<tr>
<td>PM3242</td>
<td>56 x 59 x 6</td>
<td>27</td>
<td>15</td>
<td>IS4-LLL, IS-1</td>
</tr>
</tbody>
</table>

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

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**Indications:** Implantation of Allure and Allure RF devices is indicated for maintaining synchrony of the atria 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 a biventricular pacing system: Ventricular Pacing is indicated for patients with chronic atrial fibrillation 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:** Implantated Cardiowire-Defibrillator (ICD). Devices are contraindicated in patients with 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. AT/AF Suppression stimulation is not recommended in patients who cannot tolerate high atrial-rate stimulation. Dual-Chamber Pacing may not be suitable for patients with atrioventricular block, chronic atrial fibrillation, or sick sinus, and may provide no benefit beyond that of single-chamber pacing 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: All atrial devices are contraindicated in patients who have demonstrated compromise of AV conduction. Rate-Adaptive Pacing may be inappropriate for patients who remain symptomatic despite stable, optimal medical therapy, and have a left ventricular ejection fraction ≤ 35% and a prolonged QRS duration, implantation of a biventricular pacing system: Ventricular Pacing is indicated for patients with chronic atrial fibrillation 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.

**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, hemothema, seroma, formation of fibrinous tissue, local tissue reaction, inability to interrogate or program due to programmer or device malfunction, infection/erosion, interruption of desired pacemaker generator function due to electrical interference, off-target electrotherapy or therapeutic, 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 motion at electrode interface, or lead malfunction (fracture or damage to insulation), loss of normal device function due to battery failure or component malfunction, pacemaker ingrowth or pocket erosion, perforation injury or diaphragmatic stimulation, phrenic nerve stimulation, periaortic/periradicular, endocarditis, excessive bleeding, induced atrial or ventricular arrhythmias, myocardial irritability, pericardial effusion, pericardial rub, polynymy edema, rise in threshold and exit block, valve damage, cardiac/corony sinus dissection, cardio/corony sinus perforation, coronary sinus or cardiac ven thrombosis. Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.
## Allure Quadra™ RF Resynchronisation Therapy Pacemaker

### Product Specifications

#### PHYSICAL SPECIFICATIONS

- **Model**: PM2342
- **Screnology**: RF
- **Dimensions (mm)**: 56 x 99 x 6
- **Weight (g)**: 21
- **Volume (cc)**: 15
- **Connector**: LSL-LLL, IS-1

### Resynchronisation Therapy

<table>
<thead>
<tr>
<th>QuickStim™ Timing Cycle</th>
<th>Sensed/Paced AV Delay; Intraventricular Paced Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td>RV and LV Pulse Amplitude (V)</td>
<td>0.25–4.0 in steps of 0.25, 1.5–7.5 in steps of 0.5</td>
</tr>
<tr>
<td>RV and LV Pulse Configuration</td>
<td>Unipolar; Bipolar</td>
</tr>
<tr>
<td>LV Pulse Configuration</td>
<td>Unipolar; Bipolar; Distal Tip 1; Med 2; Distal Tip 2; Distal Tip 3; Med 2; Med 3</td>
</tr>
<tr>
<td>RV PVARP (ms)</td>
<td>15–30 in steps of 5</td>
</tr>
<tr>
<td>LV PVARP (ms)</td>
<td>15–30 in steps of 5</td>
</tr>
<tr>
<td>Ventricular Sense Configuration</td>
<td>RV Unipolar Tip; RV Bipolar Tip; RV Bipolar Tip/Distal Tip 1; Med 2; Distal Tip 1; Med 2; Med 3; Med 4; Proximal 4; Can</td>
</tr>
<tr>
<td>First Chamber Paced</td>
<td>Sensed/AV; LV</td>
</tr>
<tr>
<td>Intraventricular Pace Delay (ms)</td>
<td>10–80 in steps of 5</td>
</tr>
</tbody>
</table>

### Output/Sensing

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative RV</td>
<td>Off; ±20–120 in steps of 10</td>
</tr>
<tr>
<td>shortest AADP Delay</td>
<td>25–50 in steps of 5, 50–120 in steps of 10</td>
</tr>
<tr>
<td>Atrial Aca® Confirmation</td>
<td>Off; On, Moire</td>
</tr>
<tr>
<td>Primary Pacing Configuration</td>
<td>Bipolar; Unipolar</td>
</tr>
<tr>
<td>Atrial and Ventricular Pacing Configuration</td>
<td>Unipolar (tip–case), Bipolar (tip–ring), Unipolar (ring–case)</td>
</tr>
<tr>
<td>Atrial Sensitivity (Fixed) (mV)</td>
<td>0.1–1.5 in steps of 0.25, 0.25–3.0 in steps of 0.5</td>
</tr>
<tr>
<td>Atrial Pulse Width (ms)</td>
<td>0.05; 0.1–1.5 in steps of 0.1</td>
</tr>
<tr>
<td>Ventricular Sensitivity (Fixed) (mV)</td>
<td>0.5–1.25 in steps of 0.5</td>
</tr>
</tbody>
</table>

### Rate/Timing

<table>
<thead>
<tr>
<th>Mode</th>
<th>AV Delay (ms)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A00(R); AAT(R); AAI(R); DDI(R); DDT(R); DVI(R); DOO(R); DDD(R)</td>
<td>25–100 in steps of 5</td>
</tr>
<tr>
<td>AAT(R); AAI(R); DDI(R); DDT(R); DVI(R); DOO(R); DDD(R)</td>
<td>100–200 in steps of 5</td>
</tr>
<tr>
<td>AAI(R); DDI(R); DDT(R); DVI(R); DOO(R); DDD(R)</td>
<td>200–800 in steps of 10</td>
</tr>
</tbody>
</table>

### Magnet Response

- **AV Delay**: Off; 50–150 in steps of 10
- **Ventricular Intrinsic**: Off; 100–200 in steps of 10
- **VF Search**: Off; 300–2000 in steps of 10

### Other

- **Magnet Response**: Off; Battery Test
- **Ventricular Intrinsic Preference**: Off; Passive, Passive, Automatic, Automatic
- **VF Search**: Off; 100–1000 in steps of 10
- **Ventricular Intrinsic Preference**: Off; Passive, Automatic
- **ALV Blanking**: Off; 100–1000 in steps of 10
- **Lead Type**: Unipolar, Bipolar
- **NPS Options**: Off; Automatic, Manual, External
- **CorVue™ Congestion Monitoring**: Off; On, Off, On
- **CorVue Congestion Trigger**: Off; 10–20 mm

### Stored Electrogams

<table>
<thead>
<tr>
<th>Category</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device Reset</td>
<td>Off</td>
</tr>
<tr>
<td>Malfunction Reporting</td>
<td>Off</td>
</tr>
<tr>
<td>Device Data</td>
<td>Off</td>
</tr>
<tr>
<td>Programming Options</td>
<td>Off</td>
</tr>
<tr>
<td>Patient Notifiers</td>
<td>Off</td>
</tr>
<tr>
<td>Other</td>
<td>Off</td>
</tr>
</tbody>
</table>

#### Rate-Mediated

<table>
<thead>
<tr>
<th>Mode</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ativo (Fixed)</td>
<td>Off; 10, Low</td>
</tr>
<tr>
<td>Ativo (Adaptive)</td>
<td>Off; 10, High</td>
</tr>
</tbody>
</table>

### AF Management

- **AF Suppression™ Algorithm**: Off, On
- **Lower Rate Overdrive (ms)**: 10
- **Upper Rate Overdrive (ms)**: 5
- **No. of Overdrive Pacing Cycles**: 10–40 in steps of 5
- **Rate Recovery (ms)**: 40–170 in steps of 5

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<tr>
<th>Category</th>
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<tbody>
<tr>
<td>AF Suppression</td>
<td>Off; On</td>
</tr>
<tr>
<td>AF Response</td>
<td>Off, Passive; Atrial Pace8</td>
</tr>
<tr>
<td>PMT Options</td>
<td>Off; Passive, Atrial Pace8</td>
</tr>
<tr>
<td>PMT Detection Rate (ms)</td>
<td>Off; 100–400 in steps of 5</td>
</tr>
</tbody>
</table>

### AF Management

- **Magnet Response**: Off; Battery Test
- **Magnet Response**: Off; Passive, Automatic, Automatic
- **AF Suppression**: Off; On, Off, On
- **AF Suppression**: Off; Passive, Automatic, Automatic
- **Magnet Response**: Off; Battery Test
- **AF Suppression**: Off, On, Off, On
- **Magnet Response**: Off; Battery Test

### Other

- **Magnet Response**: Off; Battery Test

### Stored Electrogams

- **AF Suppression**: Off, On
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