FEATURES

**Accurately Detect Rhythm Disturbances with the SJM Confirm Implantable Cardiac Monitor (ICM)**

The SJM Confirm ICM DM2100 is an implantable, patient activated and automatically activated monitoring system that records subcutaneous ECGs and is indicated in the following cases:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

Transient symptoms that may suggest a cardiac arrhythmia could include fainting spells, dizziness, palpitations and shortness of breath.

**Customize and Prioritize Data Storage Options**

The SJM Confirm ICM DM2100 offers simple-to-configure data storage options to enable physicians to prioritize data based on individual patient conditions, ensuring capture of significant events and to reduce the risk that unexpected events are missed. Options include:

- Programmable pre- and post-trigger event storage (auto activation: pre-event storage 10-60 sec; post-event storage 10-60 sec; patient-triggered activation: pre-event storage 60-240 sec; post-event storage 30-60 sec)
- Manual (patient-triggered) and automatic activation for EGM storage
- Additional programmable options (asystole [duration]; bradycardia [rate]; tachycardia [rate, cycle count])
- 48 minutes of stored electrograms

**Receive Vital Information through Extensive Data Reports**

Comprehensive diagnostic data reports provide a quick and accurate summary of heart rate, assisting physicians in their diagnosis and treatment of the patient’s condition. Reports include:

- Episodal diagnostics for auto-trigger events
- Episode duration
- Episode count
- Episode date/time stamp
- Heart rate histogram

**Improve Signal Detection with the Proven SenseAbility® Feature**

The proven St. Jude Medical SenseAbility® feature is designed to allow accurate sensing over a wide range of signals, specifically offering more sensitive QRS detection. The feature also includes detection inhibitors for noise response and activity response.

**Reduce Risk with the Smallest ICM Available**

The small 6.5 cc size of the SJM Confirm ICM DM2100 is designed to reduce the risk of infection during the implant procedure by requiring a smaller incision and a smaller subcutaneous pocket. A small device footprint may also reduce implant time and means less change in body image for patients.

**Simplify the Implantation Procedure with Subcutaneous Electrodes**

The SJM Confirm ICM is intended to be placed using a minimally invasive approach. Subcutaneous electrodes simplify the implant procedure by eliminating the need for a transvenous lead system. Located on opposite sides of the device, the electrodes are designed to provide better episode detection due to consistent contact at the sensor-tissue interface.

**Expand Evaluation Periods with Extended Longevity**

The SJM Confirm ICM is designed to provide up to three years of reliable device monitoring.

**Streamline Follow-Up with the Merlin™ Patient Care System**

The SJM Confirm ICM is compatible with the St. Jude Medical Merlin Patient Care System (PCS). This allows physicians to quickly and easily access patient data and view real-time ECGs.

**Facilitate Data Retrieval with Remote Monitoring**

The system offers transtelephonic monitoring (TTM) capability, enabling timely and accurate data to be transmitted directly from the patient to the physician and streamlining evaluation of the patient’s condition.

**MR Conditional**

The SJM Confirm ICM can be scanned in patients under the following conditions:

- Closed bore, cylindrical magnet
- Static magnetic field strength of 1.5 Tesla (T) only
- Maximum gradient slew rate 200 T/m/s per axis
- Whole body Specific Absorption Rate (SAR) less than or equal to 4.0 W/kg
- The uninterrupted duration of active scanning (when radio frequency (RF) and gradients are on) over the chest during MRI must not exceed 60 minutes
- Confirmation of absence of other contraindicated implantable devices and/or leads, including abandoned leads, lead extenders and lead adaptors

In non-clinical testing, the St. Jude Medical MR Conditional SJM Confirm ICM produced a temperature rise of less than 3°C at a maximum MR system-reported whole body averaged specific absorption rate (SAR) of 3.9 W/kg as displayed on the MR scanner console for 60 minutes of MR scanning in a 1.5T closed bore MR scanner (manufacturer Philips, model Intera 1.5, Software version: 9.5.2).
### Parameters

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
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<tbody>
<tr>
<td>Sampling Rate (Hz)</td>
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<tr>
<td>Dimensions (mm)</td>
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<tr>
<td>Volume (cc)</td>
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<tr>
<td>Weight (g)</td>
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<tr>
<td>Electrode Spacing (mm)</td>
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<tr>
<td>Electrode Minimum Surface Area (mm²)</td>
<td>90</td>
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</tbody>
</table>

### Features

- **Longevity**: 3 years
- **Patient Trigger**: Yes
- **Auto Activation Trigger**: Yes
- **Tachycardia Trigger**: Yes
- **Tachycardia Cycle Count**: Yes
- **Bradycardia Trigger**: Yes
- **Asystole (duration) Trigger**: Yes
- **EGM Storage**: 48 minutes
- **Patient Trigger**: Yes, Programmable
- **Auto Activation**: Yes, Programmable
- **Activity Response**: Inhibit, Monitor, Off
- **Noise Response**: Inhibit

### Diagnostics

- **Episodal Diagnostics**: Yes
- **Heart Rate Histogram**: Yes
- **Mean Heart Rate**: No
- **Remote Monitoring**: Transtelephonic monitoring (TTM)*
- **Patient Activator (PA)**: Battery-powered PA (Model DM2100A)
- **Programming Device**: Merlin Patient Care System

*Connectivity depends upon country and use of a compatible receiver unit. Please contact your St. Jude Medical sales representative for more details.

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**ATRIAL FIBRILLATION**

**CARDIAC RHYTHM MANAGEMENT**

**CARDIOVASCULAR**

**NEUROMODULATION**

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**Brief Summary**: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events, and directions for use.

Not available for sale in the United States. Products referenced within are CE marked.

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Item 100093752 Rev B