SJM Confirm™
Model DM2100
Implantable Cardiac Monitor
Model DM2102
Implantable Cardiac Monitor with AF Detection

USER'S MANUAL
Proposition 65, a State of California voter initiative, requires the following notice:

WARNING: This product and its packaging have been sterilized with ethylene oxide. This packaging may expose you to ethylene oxide, a chemical known to the state of California to cause cancer or birth defects or other reproductive harm.

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Device Description

This manual describes the following St. Jude Medical™ devices:

Table 1. SJM Confirm implantable cardiac monitor description

<table>
<thead>
<tr>
<th>Name</th>
<th>Model #</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SJM Confirm</td>
<td>DM2100</td>
<td>Implantable cardiac monitor</td>
</tr>
<tr>
<td>SJM Confirm</td>
<td>DM2102</td>
<td>Implantable cardiac monitor with AF detection</td>
</tr>
</tbody>
</table>

The St. Jude Medical™ SJM Confirm implantable cardiac monitor (ICM) is designed to monitor and store ECG data and to communicate with the St. Jude Medical Merlin™ Patient Care System (PCS) and the St. Jude Medical™ SJM Confirm external patient activator (PA).

The ICM constitutes the implantable portion of the monitoring system. The Merlin PCS with software version 6.8 (or greater), a telemetry wand, and the PA, constitute the external portion of the monitoring system.

Indications and Usage

The SJM Confirm™ ICM is indicated for the monitoring and diagnostic evaluation of patients who
experience unexplained symptoms such as: dizziness, palpitations, chest pain, syncope, and shortness of breath, as well as patients who are at risk for other cardiac arrhythmias. The SJM Confirm ICM, Model DM2102, is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

**Contraindications**

There are no known contraindications for the implantation of the SJM Confirm™ ICM. However, the patient’s particular medical condition may dictate whether or not a subcutaneous, chronically implanted device can be tolerated.

**Warnings and Precautions**

Device Usage. For single use only.

Resuscitation Availability. Do not perform device testing unless an external defibrillator and medical personnel skilled in cardiopulmonary resuscitation (CPR) are readily available.

**Sterilization, Storage and Handling**

Resterilization. Do not resterilize and re-implant an explanted device.

Use before date. Do not implant the device after the "use before" date because the battery may have reduced longevity.
If package is damaged. Do not use the device if the packaging is wet, punctured, opened or damaged because the integrity of the sterile packaging may be compromised. Return the device to St. Jude Medical.

Device storage. Store the device in a clean area. Store the device between -10° and 55°C because temperatures outside this range may damage the device.

Temperature Equilibration. After cold storage, allow the device to reach room temperature before programming or implanting the device because cold temperature may affect initial device function.

Implantation and Device Programming

Remove or replace the device when the battery voltage reaches 3.30 V.

Implant the device no deeper than 4 cm to ensure reliable data transmission.

Program the device parameters as specified in the Merlin™ PCS on-screen help.

Device Explant and Disposal

Interrogate the device to acquire stored EGMs and episode data. Turn monitoring off before explanting, cleaning or shipping the device to prevent unwanted EGM and episode storage.

Return all explanted devices to St. Jude Medical.

Never incinerate the device because of the potential for explosion. Explant the device before cremation.
Environmental and Medical Therapy Hazards

Instruct patients to avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause device malfunction or damage, resulting in inappropriate episode storage or inhibition of episode storage. Moving away from the source or turning it off will usually allow the device to return to its normal mode of operation.

Hospital and Medical Environments

Electrosurgical cautery. Electrosurgical cautery could induce arrhythmias and/or fibrillation, or may cause device malfunction or damage. If electrocautery is necessary, keep the current path and groundplate as far away from the device as possible.

External defibrillation. External defibrillation may damage the device. Minimize current flowing through the device by following these precautions when using external defibrillation on a patient with a device:

- Position defibrillation paddles as far from the device as possible (minimum of 13 cm)
- Use the lowest clinically appropriate energy output
- Confirm the device function following any external defibrillation

High radiation sources. Do not direct high radiation sources such as cobalt 60 or gamma radiation at the device. If a patient requires radiation therapy in the vicinity of the device, place lead shielding over the device to prevent radiation damage and confirm its function after treatment.

Lithotripsy. Lithotripsy may permanently damage the device. Avoid it unless the therapy site is not near
the device.

Diathermy. Avoid diathermy, even if the device is programmed off, as it may damage tissue around the device or may permanently damage the device.

Ultrasound therapy. Diagnostic and therapeutic ultrasound treatment is not known to affect the function of the device.

Transcutaneous Electrical Nerve Stimulation (TENS). TENS may interfere with device function. To reduce interference, place the TENS electrodes close to one another and as far from the device as possible. Monitor cardiac activity during TENS use.

Radiofrequency (RF) ablation. RF ablation in a patient with a device may cause device malfunction or damage. Minimize RF ablation risks by:

- Disabling monitoring
- Avoiding direct contact between the ablation catheter and the implanted device
- Positioning the groundplate so that the current pathway does not pass near the implanted device, i.e., place the groundplate under the patient’s buttocks or legs

Having external defibrillation equipment available

**Home and Occupational Environments**

High-voltage power transmission lines. High-voltage power transmission lines may generate enough EMI to interfere with device operation if approached too closely.
Communication equipment. Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with device operation if approached too closely.

Home appliances. Home appliances in good working order and properly grounded do not usually produce enough EMI to interfere with device operation. There are reports of device disturbances caused by electric hand tools or electric razors used directly over the device implant site.

Wireless communication devices. Wireless communication devices such as wireless networks, handheld personal computers (PDA), and even cordless telephones may generate enough EMI to interfere with device operation.

Industrial equipment. A variety of industrial equipment produce EMI of sufficient field strength and modulation characteristics to interfere with proper operation of the device. These include, but are not limited to: arc welders; induction furnaces; very large or defective electric motors; and internal combustion engines with poorly shielded ignition systems.

Electronic Article Surveillance (EAS)
Advise patients that the Electronic Article Surveillance/Anti-theft (EAS) systems such as those at the point of sale and entrances/exits of stores, libraries, banks, etc., emit signals that may interact with the device. It is very unlikely that these systems will interact with their device significantly. However, to minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems.
**Metal Detectors**
Advise patients that metal detector security systems such as those found in airports and government buildings emit signals that may interact with their device. It is very unlikely that these systems will interact with their device significantly. To minimize the possibility of interaction, advise patients to simply walk through these areas at a normal pace and avoid lingering. Even so, the device contains metal that may set off the airport security system alarm. If the alarm does sound, the patient should present security personnel with their patient identification card.

**Cellular Phones**
The device has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of AAMI PC69. This testing covered the operating frequencies (450 MHz - 3 GHz) and pulsed modulation techniques of all of the digital cellular phone technologies in worldwide use today. Based on the results of this testing, the device should not be affected by the normal operation of cellular phones when used more than 6 inches from the device.
To minimize the possibility of interaction, advise patients not to carry a cellular phone in a breast pocket or on a belt within 6 inches of the device, and to use a cellular phone on the side of their body opposite from the device.

**Potential Adverse Events**
Possible adverse events (in alphabetical order) associated with the device, include, but are not limited
to the following:
- Allergic reaction
- Bleeding
- Chronic nerve damage
- Erosion
- Excessive fibrotic tissue growth
- Extrusion
- Formation of hematomas or cysts
- Infection
- Keloid formation

Clinician Use Information

Physician Training
Physicians should be familiar with sterile device implant procedure and with follow-up evaluation and management of patients with an implantable cardiac monitor (or should refer the patient to such a physician).
Directions for Use
Device operating characteristics should be verified at the time of implantation and recorded in the patient file. Complete the Patient Registration Form and return it to St. Jude Medical as it provides necessary information for warranty purposes and patient tracking.
Copies of this user’s manual can be obtained by contacting your St. Jude Medical representative.

Maintaining Device Effectiveness

Sterilization
The device has been sterilized with ethylene oxide prior to shipment. This device is for single use only and is not intended to be resterilized.
If the sterile package has been compromised, contact St. Jude Medical.

Device storage
Do not implant the device when:
- It has been dropped on a hard surface because this could have damaged device components.
- The sterility indicator within the inner package is purple, because it might not have been sterilized.
- Its storage package has been pierced or altered, because this could have rendered it non-sterile.
- It has been stored or transported outside the environmental temperature limits.
Storage and transportation limits: -10° to 55°C.
An electrical reset condition may occur at temperatures below -10°C. After cold storage, allow the device to reach room temperature before programming or implanting the device because cold temperature may affect initial device function.

- Its "use before" date has expired, because this can adversely affect device longevity or device sterility.

**Radiopaque Identification**

Each device has an x-ray absorptive marker for non-invasive identification. The marker consists of the St. Jude Medical logo (SJM) and model code.

<table>
<thead>
<tr>
<th>Device Model</th>
<th>X-ray ID Model Code</th>
</tr>
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<tbody>
<tr>
<td>DM2100, DM2102</td>
<td>AM</td>
</tr>
</tbody>
</table>

**Package Contents**

The device is supplied in a sterile tray for introduction into the operating field. The tray contains:

- One monitor
The outer box contains:
- One external patient activator
- Literature

**MRI Procedure**

It is important to read the information in this section before conducting an MRI scan on a patient with an implanted St. Jude Medical™ MR Conditional SJM Confirm™ implantable cardiac monitor (ICM). Contact Technical Support (page 25) if you have any questions.

An MR Conditional SJM Confirm ICM is conditionally safe for use in the MRI environment when used according to the instructions in this section.

The MR Conditional symbol appears on package labels for devices that have demonstrated to pose no known hazards in a specified MR environment with specified conditions for use.
Figure 1. MR Conditional symbol

Warnings and Precautions

MR Conditions for Use
Testing has demonstrated that the St. Jude Medical™ MR Conditional SJM Confirm™ ICM is conditionally safe for use in the MRI environment when used according to the instructions in this manual.

The MR Conditional 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 of 200 T/m/s per axis
- Whole body Specific Absorption Rate (SAR) less than or equal to 2.0 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).

**MR Conditional Contraindications**

- Patients with abandoned cardiac hardware including leads, lead extenders, or lead adaptors are contraindicated for an MRI scan.
- Patients with non-MR Conditional implantable devices are contraindicated for an MRI scan.
- Patients with a St. Jude Medical™ SJM Confirm™ ICM that has been implanted for less than 6 weeks are contraindicated for an MRI scan. The 6 week post-implant waiting period allows time for the implant pocket and wound to heal which minimizes the effects of "tugging" on the device caused by magnetic fields.
- Patients with a St. Jude Medical SJM Confirm ICM must not be on his or her side within the MRI
bore. This position is contraindicated for an MRI scan.

- Use of local transmit-only coils or local transmit and receive coils placed directly over the device has not been studied and such use is contraindicated

**Potential Adverse Event**

The St. Jude Medical™ MR Conditional SJM Confirm™ ICM has been designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- Device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- Damage to the functionality or mechanical integrity of the device resulting in the inability to communicate with the device
- Movement or vibration of the device
- Induction of currents or voltages resulting in pectoral nerve stimulation
- Tugging (force, vibration or torque)
- Electrical stress on components or sensing circuitry or event detection and the potential for recording false signals, incorrect rate detection or corruption of data
Monitoring System and Patient Considerations

Implanted Hardware
Verify that the SJM Confirm™ ICM is labeled as MR Conditional. Only St. Jude Medical™ MR Conditional SJM Confirm ICMs have been tested. Patients can be considered safe for an MRI scan only if the implanted system consists of a St. Jude Medical MR Conditional device. Do not authorize a scan or perform a scan on patients with previously implanted (active or abandoned) cardiac hardware which may include medical devices, leads, lead extenders, or lead adaptors. Doing so may increase the risk of myocardial tissue damage due to heating and other MR RF field-related hazards. The interaction with other implantable devices has not been evaluated. Patients can be considered safe for an MRI scan only if no other implantable medical devices, leads, lead extenders, or lead adaptors are present.

Potential Interactions
The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. The St. Jude Medical™ MR Conditional SJM Confirm™ ICM has been designed to reduce these effects so that the mechanical stress on the implanted system and tissue interface is minimized. Patients may feel a mild tugging or vibration sensation at the site of the device implant while in or near the MRI scanner.
Device Management Physician and Clinician Instructions

To safely perform an MRI scan on a patient with a St. Jude Medical™ MR Conditional SJM Confirm™ ICM system:

1. Review and verify the MRI Conditions for Use (page 12).
2. Review the MR Conditional Contraindications (page 13).
3. Review the MRI Scan Considerations (page 20).
4. Review the Pre-MRI Procedure Requirements (page 17).
5. Patient receives the MRI Scan.
6. Review the Post-MRI Procedure (page 19).

MRI Equipment Requirements

The MRI equipment requirements listed here must be satisfied during all MRI scans performed on patients with a St. Jude Medical™ MR Conditional SJM Confirm™ ICM. If you are unsure of the capabilities of your MRI machine, contact the MRI manufacturer.

The safety and reliability of a St. Jude Medical MR Conditional SJM Confirm ICM has been evaluated in vitro using MRI equipment that has the following operating characteristics:

- Hydrogen proton magnetic resonance imaging equipment with a static magnetic field of 1.5T.
- RF excitation frequency that is approximately 64 MHz in a 1.5T static magnetic field
- Closed bore, cylindrical magnet systems
- A gradient field with a maximum peak rate of change of magnetic field (dB/dt) of 125 T/s per axis

The SJM Confirm ICM has been evaluated in vitro using test equipment with a gradient field time rate of change of 125 T/s. The maximum gradient magnetic field (dB/dt) that the gradient system will produce during a scan may not be reported via the MRI console or MRI equipment specifications. Therefore, the above MRI equipment requirement that restricts scans to whole body gradient systems with a gradient slew rate specification of 200 T/m/s or less is an alternative means of ensuring that the gradient system cannot produce gradient magnetic field levels that could potentially harm the patient. Using a whole body gradient system that exceeds the gradient slew rate specification of 200 T/m/s, or any type of special purpose gradient system, is allowed only if the maximum gradient magnetic field (dB/dt) the device is exposed to can be verified to be 125 T/s or less.

Pre-MRI Procedure Requirements

Prior to the MRI procedure:
- Check that the prior data from the monitoring device has been saved and retrieved before the MRI scan.
- Check that the SJM Confirm™ patient activator is not in the MRI room.
- Check that the patient is not on his or her side within the MRI bore
- Check that the patient has no other cardiac devices, leads or abandoned leads
- Check that the device has been implanted for more than 6 weeks

MRI Procedure Requirements

Verify that the MR Conditions for Use are met:

- Closed bore, cylindrical magnet
- A static magnetic field strength of 1.5 Tesla
- An RF excitation frequency in the range of 63.75 ± 0.5 MHz
- A gradient field with a maximum peak rate of change of magnetic field (dB/dt) of 125 T/s (<= 200 T/m/s) per axis
- RF and gradient field exposure over the chest during MRI does not exceed 60 min

CAUTION

Check that the programmer is not in the MRI room. Do not bring the SJM Patient Activator model DM2100A or the Merlin™ Patient Care System (PCS) Model 3650 into the MRI environment (MR scanner magnet room), as defined by the American College of Radiology. They are MR Unsafe.
Post-MRI Procedure
After the MRI procedure is complete:
 Check that programmed parameters of the device using the programmer
 Clear the data collected during the MRI procedure because the MRI procedure might temporarily have affected the event detection and recording of the device

Electromagnetic Fields Generated by MRI Systems
An MRI system produces three (3) types of electromagnetic fields that may interact with implanted devices. All three (3) of these fields are necessary to produce an MRI image.

Static Magnetic Field - This is a steady state, not-varying magnetic field that is normally always on, even when no scan is in progress. The spatial gradient (dB/dz) of the static magnetic field is at its maximum near the entrance to the bore of the MRI equipment.

Gradient Magnetic Fields - These low-frequency, pulsed magnetic fields are present only during a scan. MRI equipment uses three (3) orthogonal gradient magnetic fields to form the image. These gradient magnetic fields vary linearly within the bore.

RF Field - this is a pulsed RF field that is present only during a scan. The RF field can be produced by a variety of transmission RF coils, such as a whole body transmit coil or an extremity coil (for example, a transmit head coil).
Patient Identification (ID) Card
A device ID card should be provided to all patients with a St. Jude Medical™ SJM Confirm™ ICM. The ID card indicates that the patient has an implanted cardiac monitor.

Radiology and MRI Technologists Instructions
To safely perform an MRI scan on a patient with the St. Jude Medical™ MR Conditional SJM Confirm™ ICM system:
1. Review and verify the MR Conditions for Use (page 12).
2. Review the MR Conditional Contraindications (page 13).
3. Review the MRI Procedure Requirements (page 18).
4. Review the MRI Scan Considerations (page 20).
5. Perform the MRI Scan.

MRI Scan Considerations
Implanted Hardware
Verify that the SJM Confirm™ ICM is labeled as MR Conditional. Only St. Jude Medical™ MR Conditional SJM Confirm™ ICMs have been tested. Patients can be considered safe for an MRI scan only if the implanted system consists of a St. Jude Medical MR Conditional device.
Do not authorize a scan or perform a scan on patients with previously implanted (active or abandoned) cardiac hardware which may include medical devices, leads, lead extenders, or lead adaptors. Doing so may increase the risk of myocardial tissue damage due to heating and other MR RF field-related hazards. The interaction with other implantable devices has not been evaluated. Patients can be considered safe for an MRI scan only if no other implantable medical devices, leads, lead extenders, or lead adaptors are present.

**Patient Monitoring**
Proper patient monitoring must be provided during the MRI scan. Verbal communication with the patient during the MRI scan is recommended.

**Patient Rescue**
Keep an external defibrillator available during the MRI scan.

**Image Quality**
St. Jude Medical™ MR Conditional SJM Confirm™ ICMs have demonstrated minimal image distortion for areas surrounding the implanted monitoring device. Significant image distortion can result from the presence of the monitoring device within the field of view. Image artifacts and distortion resulting from the presence of the monitoring device within the field of view must be considered when selecting the
field of view and imaging parameters. These factors must also be considered when interpreting the MRI images.

The worst-case percent image artifacts of the SJM Confirm ICM extends for approximately 6 cm (2.4 inches) around the device when imaged using the Gradient-Echo sequence in a 1.5T closed bore MR scanner (Model: Avanto, Manufacturer: Siemens, Software: Numaris/4, Version: Synco MR B17 DHHS). The image artifacts of the SJM Confirm ICM placed on the grid and imaged in a 1.5T closed bore MRI scanner\(^1\) are shown in the following figures.

Table 3. Effect of the SJM Confirm ICM on Image Quality of the MRI

<table>
<thead>
<tr>
<th>B0 (T)</th>
<th>Scan Sequence</th>
<th>Imaging Plane</th>
<th>Flip Angle (°)</th>
<th>Percent Artifact(^2)</th>
<th>Artifact Length(^3) (cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5</td>
<td>Spin-Echo</td>
<td>Coronal</td>
<td>90</td>
<td>3.69</td>
<td>13</td>
</tr>
<tr>
<td>1.5</td>
<td>Gradient-Echo</td>
<td>Coronal</td>
<td>30</td>
<td>9.31</td>
<td>13.5</td>
</tr>
</tbody>
</table>

\(^1\) Siemens Avanto 1.5T MRI scanner with Numaris/4 software version Syngo MR B17 DHHS.
\(^3\) Longest linear dimension of the artifact observed in the image with the largest percent artifact.
Figure 2. Worst-case artifacts in a coronal image of the SJM Confirm ICM acquired in a 1.5T MR scanner using a Spin-Echo sequence.\footnote{Each square in the grid is 1 inch x 1 inch.}
Figure 3. Worst-case artifacts in a coronal image of the SJM Confirm ICM acquired in a 1.5T MR scanner using a Gradient Echo sequence.\textsuperscript{5}

\textsuperscript{5} Each square in the grid is 1 inch x 1 inch.
Potential Interactions
The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. The St. Jude Medical™ MR Conditional SJM Confirm™ ICM has been designed to reduce these effects so that the mechanical stress on the implanted system and tissue interface is minimized. Patients may feel a mild tugging or vibration sensation at the site of the device implant while in or near the MRI scanner.

MR Conditional ICM Device Location
The St. Jude Medical™ MR Conditional SJM Confirm™ ICM is usually implanted under the skin in the right or left pectoral region.

Additional Information
For additional information on this device, see the Merlin™ PCS on-screen help.

Technical Support
St. Jude Medical Cardiac Rhythm Management Division maintains 24-hour phone lines for technical questions and product support:
- 1 818 362 6822 or
- 1 800 722 3774 (toll-free within North America)
- +46 8 474 4147
For additional assistance, call your local St. Jude Medical representative.
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