

## SJM Confirm™

### Implantable Cardiac Monitor – Model DM2102

#### Product Highlights

- Accurately detects atrial fibrillation (AF) and rhythm disturbances
- Implantable, patient-activated and automatically activated monitoring system that records subcutaneous ECGs and is indicated in the following cases:
  - Patients who have been previously diagnosed with AF or who are susceptible to developing AF
  - Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
  - Patients who experience transient symptoms that may suggest a cardiac arrhythmia
- Offers simple-to-configure data storage options to enable physicians to prioritise data based on individual patient conditions, ensuring capture of significant events and to reduce the risk that unexpected events are missed
- Comprehensive diagnostic data reports from the provide a quick and accurate summary of heart rate, assisting physicians in their diagnosis and treatment of the patient's condition
- The small 6.5 cc size of the SJM Confirm ICM DM2102 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
- 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



#### Ordering Information

Contents: Implantable Cardiac Monitor

Model Number	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)
DM2102	56,3 x 18,5 x 8	12	6,5 (± 0,5)

#### Separately Available Accessories

Contents: SJM Confirm External Patient Activator device

Model Number	Description
DM2100A	External Patient Activator Model DM2100A

**Indications:** 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.

**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

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

## SJM Confirm™

## Implantable Cardiac Monitor – Model DM2102

## Product Specifications

PHYSICAL SPECIFICATIONS	
<b>Model</b>	<b>DM2102</b>
Sampling Rate (Hz)	128
Dimensions (mm)	56,3 x 18,5 x 8
Volume (cc)	6,5
Weight (g)	12
Electrode Spacing (mm)	39
Electrode Minimum Surface Area (mm <sup>2</sup> )	30

  

PARAMETER	SETTINGS
<b>Features</b>	
Longevity	3 years
Patient Trigger	Yes
Auto Activation Trigger	Yes
Atrial Fibrillation Trigger	Yes
Programmable AF episode duration	>30 sec, >1 min, 2 min, >5 min, >10 min
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
<b>Diagnostics</b>	
Episodal Diagnostics	Yes
Heart Rate Histogram	Yes
Mean Heart Rate	No
Remote Monitoring	Transtelephonic monitoring (TTM)*
Patient Activator (PA)	Battery-powered PA (Model DM2100A)

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

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. ©2011 St. Jude Medical, Inc. All rights reserved.

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