SJM Confirm™

Implantable Cardiac Monitor
Model DM2102

FEATURES

Accurately Detect Atrial Fibrillation (AF) and Rhythm Disturbances with the SJM Confirm Implantable Cardiac Monitor (ICM)

The SJM Confirm ICM DM2102 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
- Patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing AF

Customize and Prioritize Data Storage Options

The SJM Confirm ICM DM2102 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 AF Episode Duration- >30 sec, >1 min, >2 min, >5 min, >10 min
- 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:

- AF burden up to 18 months
- Episodal diagnostics for auto-trigger events
- Episode duration
- Episode count
- Episode date/time stamp
- Heart rate histogram

Improve Signal Detection with the Proven Sense*Ability*® Feature

The proven St. Jude Medical Sense*Ability*® 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 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.

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).

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

SJM Confirm Implantable Cardiac Monitor

MODEL DM2102

SPECIFICATIONS

PARAMETERS	Description
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^2)	30

FEATURES

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 ▪ Pre-Trigger, 60-240 sec ▪ Post-Trigger, 30-60 sec
Auto Activation	Yes, Programmable ▪ Pre-Trigger, 10-60 sec ▪ Post-Trigger, 10-60 sec
Activity Response	Inhibit, Monitor, Off
Noise Response	Inhibit

DIAGNOSTICS

Episodal Diagnostics	Yes
Heart Rate Histogram	Yes
Mean Heart Rate	Yes
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.*

ATRIAL FIBRILLATION CARDIAC RHYTHM MANAGEMENT CARDIOVASCULAR NEUROMODULATION

Global Headquarters
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

Atrial Fibrillation Division
One St. Jude Medical Drive
St. Paul, Minnesota 55117
USA
+1 651 756 2000
+1 651 756 3301 Fax

St. Jude Medical Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11
+32 2 772 83 84 Fax

St. Jude Medical Brasil Ltda.
Rua Itapeva, 538
5º ao 8º andar
01332-000 – São Paulo – SP
Brazil
+55 11 5080 5400
+55 11 5080 5423 Fax

St. Jude Medical (Hong Kong) Limited
Suite 1608, 16/F Exchange Tower
33 Wang Chiu Road
Kowloon Bay, Kowloon
Hong Kong SAR
+852 2996 7688
+852 2956 0622 Fax

SJMprofessional.com

ST. JUDE MEDICAL™
MORE CONTROL. LESS RISK.

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.

Item 100053753 Rev B

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 014607 0141 Rev. 02

Manufacturer:
St. Jude Medical
Cardiac Rhythm Management Division
15900 Valley View Court
Sylmar CA 91342
USA

EC-Representative:
St. Jude Medical Coordination Center BVBA
The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem,
BELGIUM

Product: **Impl. Monitoring and Recording Systems**

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with AIMDD Annex 2 (4). This design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex 2 certificate is mandatory. See also notes overleaf.

Report no.: 713132655

Valid from: 2019-02-05
Valid until: 2023-09-24

Date, 2019-02-05

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-200.14.03

TÜV SÜD Product Service

EC Certificate

EC Design-Examination Certificate
Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD), Annex 2 (4)
(Other devices than custom made or intended for clinical investigation)

No. I7 014607 0141 Rev. 02

Model(s): **see below**

Facility(ies): St. Jude Medical Cardiac Rhythm Management Division
15900 Valley View Court, Sylmar CA 91342, USA

Parameters: ./.

Design Facility(ies): St. Jude Medical Cardiac Rhythm Management Division,
15900 Valley View Court, Sylmar, CA 91342, USA

Product: **Implantable Monitoring and Recording Systems**

Test Report No.: 71339189 / 713002296

The following product is designed/manufactured in the facility(ies)

- St. Jude Medical, CRMD, 15900 Valley View Court, Sylmar, CA 91342, USA (Design/Manufacturing)

Model:	**Model no.:**	**Variant:**
SJM CONFIRM™ External Patient Activator	DM2100A	
SJM CONFIRM™ Implantable Cardiac Monitor	DM2102	MR Conditional

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV®

SJM Declaration of Conformity
Impl. Monitoring and Recording Systems

St. Jude Medical (SJM) hereby declares that the following SJM facilities and products conform to the applicable provisions of Annex 2 of the European Union's Active Implantable Medical Devices Directive, AIMDD, 90/385/EEC. All supporting documentation is retained under the premises of SJM. We declare no application has been lodged with any other notified body for the same products. This declaration is issued under the sole responsibility of the manufacturer. This declaration supersedes any declaration issued previously for the same product(s).

Manufacturer Address:	*St. Jude Medical Cardiac Rhythm Management Division* *15900 Valley View Court* *Sylmar, CA 91342, USA*
European Representative:	St. Jude Medical Coordination Center BVBA The Corporate Village Da Vincilaan 11 Box F1 1935 Zaventem, Belgium
Product Type:	Impl. Monitoring and Recording Systems
Product Name(s):	*See attachment*
Model Number(s):	*See attachment*
Classification:	AIMD
GMDN Code(s):	*See attachment*
Original CE Mark Date:	*See attachment*
Certificate No. and expiration date:	EC Certification No: I7 014607 0141 Rev. 02 Expiration Date: 2023-09-24 FQA Certificate No: I1 014607 0211 Rev. 01 Expiration Date: 2024-05-26 EN ISO 13485:2016 Certificate No: Q5 014607 0231 Rev. 00 Expiration Date: 2022-03-31

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22 APR 2020

Issue Date

SJM Declaration of Conformity
Impl. Monitoring and Recording Systems

Applicable Quality System Standards:	Fulfills the requirements of Annex 2 of the European Union's Active Medical Devices Directive, AIMDD, 90/385/EEC/corresponding national legislation Fulfills applicable requirements including CE marking and the Essential Requirements of AIMDD, 90/385/EEC/corresponding national legislation
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstelle Ridlerstraße 65, 80339, Münich, Germany
Notified Body Number:	0123
Manufacturing Facilities:	St. Jude Medical Cardiac Rhythm Management Division 15900 Valley View Court Sylmar, CA 91342, USA

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22 APR 2020

Issue Date

SJM Declaration of Conformity
Impl. Monitoring and Recording Systems
ATTACHMENT TO DECLARATION OF CONFORMITY

The following product(s) is/are approved under EC-certificate number **I7 014607 0141 Rev. 02:**

Product Name	Model Number	Variant	GMDN Code	Date of First CE Marking
SJM CONFIRM™ Implantable Cardiac Monitor	DM2102	MR Conditional	47804	2008-09-25
SJM CONFIRM™ External Patient Activator	DM2100A	N/A	47805	2008-09-25

Signature:

Kathy Berg

Kathy Berg
Sr. Manager Regulatory Affairs

22 APR 2020
Issue Date