Confirm Rx™

Model DM3500
Insertable Cardiac Monitor

User's Manual

St. Jude Medical

Description

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

Table 1. Confirm Rx insertable cardiac monitor

Name	Model Number	Description	MRI Status
Confirm Rx	DM3500	Insertable cardiac monitor	MR Conditional

The St. Jude Medical™ Confirm Rx™ insertable cardiac monitor (ICM) is designed to detect arrhythmias and wirelessly transmit data to the Merlin.net™ Patient Care Network (PCN).

The ICM constitutes the inserted portion of the system. The Merlin™ Patient Care System (PCS) with software version 23.0 (or greater), magnet, myMerlin mobile application (app), and Merlin.net PCN constitute the external portion of the system.

The Merlin PCS and magnet are used to interrogate and program the device in the clinic. Remote transmissions are performed using the app. The app also allows patients to record and send EGMs of symptomatic events to the clinic. All remotely transmitted data is made available on Merlin.net where clinicians can log in, review data, and make a diagnosis.

Indications for Use

The Confirm Rx™ 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. It is also indicated for patients who have been previously diagnosed with atrial fibrillation or who are susceptible to developing atrial fibrillation.

Magnetic Resonance Imaging (MRI)

The Confirm Rx™ ICM is conditionally safe for use in the MRI environment when used according to instructions in the MRI Ready Monitor Systems manual.

Contraindications

There are no known contraindications for the insertion of the Confirm Rx™ ICM. However, the patient's particular medical condition may dictate whether or not a subcutaneous, chronically inserted device can be tolerated.

Warnings and Precautions

Sterilization

- The device and the incision and insertion tools have been sterilized with ethylene oxide prior to shipment. They are intended for single use only and should not be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.
- Do not insert the device if the dot on the ethylene oxide label is purple. Purple indicates that the package has not been sterilized. Return the device to St. Jude Medical.

Package Inspection

- Check the "use-before" date on the package label. Do not insert the device if its "use-before" date has expired.
- 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.

Storage

- Store the device in a clean area. Store the device between -20° and 60°C because temperatures outside this range may damage the device.
- After cold storage, allow the device to reach room temperature before programming or inserting the device because cold temperature may affect initial device function.

Insertion

- Insert the device no deeper than 2 cm to ensure reliable data transmission.

Device Replacement

- Replace the device within one month of receiving a low battery alert, if necessary or desired. Replace the device immediately upon receiving a low battery alert if frequent EGMs are being stored and remotely transmitted.

Explant and Disposal

- Interrogate the device and turn monitoring off before explanting, cleaning or shipping the device to prevent unwanted EGM and episode storage.
- Explant the device upon receiving an EOS alert.
- 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 that 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 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 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
- 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 may permanently damage the device. Avoid it unless the therapy site is not near the device.
- Avoid diathermy, even if the device is programmed off, as it may damage tissue around the device or may permanently damage the device.
- Diagnostic and therapeutic ultrasound treatment is not known to affect the function of the device.
- Transcutaneous Electrical Nerve Stimulation (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 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 inserted device
  - Positioning the groundplate so that the current pathway does not pass near the inserted device, i.e., place the groundplate under the patient's buttocks or legs

Home and Occupational Environments

- High-voltage power transmission lines may generate enough EMI to interfere with device operation if approached too closely.
- 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 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 insertion site.
- Wireless communication devices such as computers that operate on a wireless network, cellular phones, smart phones, tablets, and even cordless telephones may generate enough EMI to interfere with device operation.

- 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. If security personnel perform a search with a handheld wand, the patient should ask that they perform the search quickly, stressing that they should avoid holding the wand over the device for a prolonged

period.

Mobile Devices

- The device has been tested for compatibility with handheld wireless transmitters in accordance with the requirements of ISO 14117:2012. 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 15 cm 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 15 cm 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 insertion procedures and with follow-up evaluation and management of patients with an insertable cardiac monitor (or should refer the patient to such a physician).

Package Contents

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

- One monitor
- One incision tool
- One insertion tool

The outer box contains:

- Literature

Opening the Sterile Package

To open the package:

1. Peel back the outer tray cover, starting with the corner labeled with an arrow.
2. Observing sterile technique, lift up the end of the inner tray that rests in the recess in the outer tray or flip over the outer tray so that the inner tray falls onto the table.
3. Peel off the inner tray cover, starting with the corner labeled with an arrow.
4. Use the recessed areas to facilitate removing the tools from the tray.

Choosing the Insertion Location

The Confirm Rx™ ICM is inserted under the skin in the left pectoral region. Common insertion locations are listed in the table below.

Table 2. Insertion locations

Insertion location	Mapping recommended
4th intercostal space, 45° relative to the sternum, along axis of the heart	No
4th intercostal space, parallel to the sternum	No

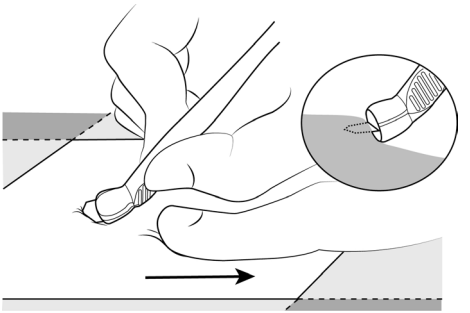
Insertion location	Mapping recommended
Anterolateral, inframammary between the 5th and 6th ribs	Yes

Inserting the Device

To insert the device:

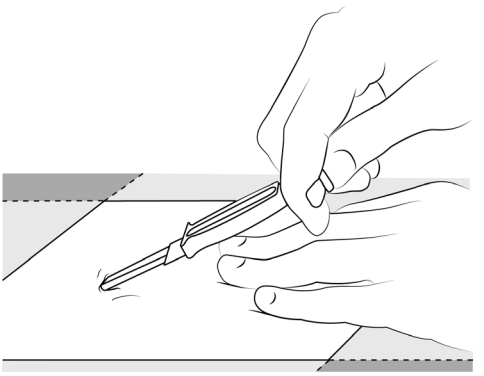
1. Pull back the skin and make an angled cut with the incision tool.

Figure 1. Pull back the skin and make incision



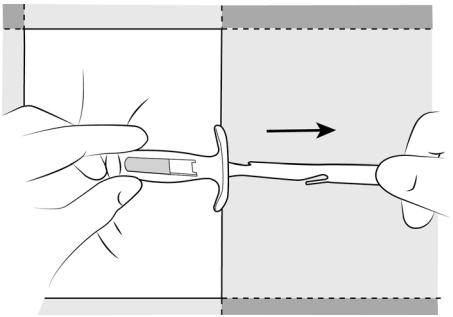
2. Hold the insertion tool as shown in the figure below. Completely insert the introducer under the skin through the incision site.

Figure 2. Insert the introducer



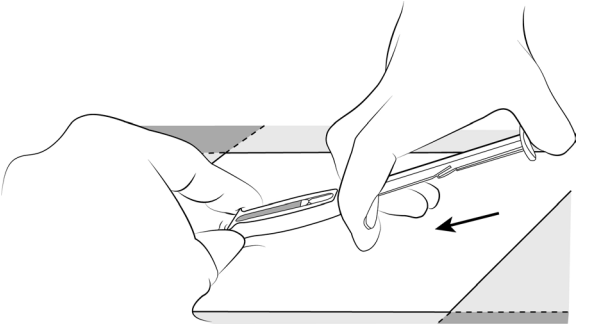
3. Hold the insertion tool firmly at the incision site. Withdraw the plunger until the preloaded device drops into the insertion channel.

Figure 3. Withdraw the plunger



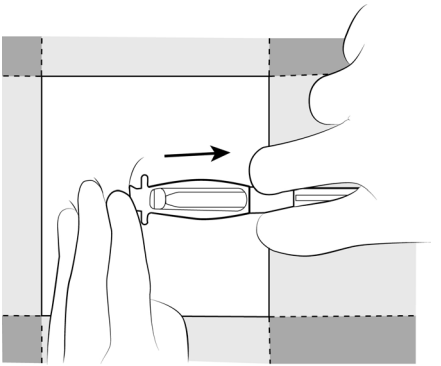
4. Continue to hold the insertion tool firmly at the incision site. Advance the plunger to insert the device.

Figure 4. Advance the plunger



5. Apply pressure to the incision site so that the device does not move, and then remove the insertion tool.

Figure 5. Remove the insertion tool



6. Program the device. Refer to the Merlin™ PCS on-screen help for details.
7. Close the incision site.

Patient Education

St. Jude Medical™ provides a booklet for patients to explain the device and its operation. You can use this to supplement your discussions with the patient and spouse or other interested persons.

Patient Identification Card

A patient identification (ID) card should be provided to all patients with a Confirm Rx™ ICM. The ID card indicates that the patient has an inserted cardiac monitor.

Radiopaque Identification

Each device has an x-ray absorptive marker for non-invasive identification. The two-letter model code is visible on a radiograph.

Table 3. X-ray ID code for Confirm Rx device

Device Model	X-ray ID Model Code
DM3500	CC

Additional Information

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

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radiofrequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/ TV technician for help.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

RTTE Declaration of Conformity

We, St. Jude Medical Implantable Electronic Systems Division, 15900 Valley View Court, Sylmar, California 91342, declare under our sole responsibility that the product:

Confirm Rx™ Insertable Cardiac Monitor Model DM3500

to which this declaration relates is in conformity with the essential requirements and other relevant requirements of the RTTE Directive (1999/5/EC). The product is in conformity with the following standards and/or other normative documents:

Article 3.1a: Health and Safety	Compliance with EN 45502-1/ISO 14708-1. Limitation of exposure to EMF fields: compliant to 1999/519/EC and EN 62479:2010
Article 3.1b: EMC	Compliance with EN 45502-1/ISO 14708-1. Compliance with IEC 60601-1-2, 4th Edition

Article 3.2: Spectrum	Compliance with EN 300 328 v1.9.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the RTTE Directive

Authorized Representative in the European Union: St. Jude Medical Coordination Center BVBA, The Corporate Village, Da Vincilaan 11 Box F1, 1935 Zaventem, Belguim

The conformity assessment procedures referred to in Article 10 and detailed in Annex IV of Directive 1999/5/EC has been followed with the involvement of TÜV SÜD BABT Notified body:

CE
0168

Statement of Compliance with License-Exempt RSS Standard (Canada)

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the

following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Class B Instrument (South Korea)

This instrument is registered as an electromagnetically compatible instrument for home use and may be used at home and all other locations.

Identification Information for Product Registration

This device has a label that contains, among other information, a product identifier in the following format:

Table 4. Registration identification information

Identifier Type	Registration Identifier
FCC registration number	RIASJMRFICMDM3500
Industry Canada (IC) registration number	8745A-DM3500123

Wireless Technology Information

The following table summarizes the technical details of the Bluetooth®[1] low energy (BLE) technology as it is implemented in the device.

Table 5. Bluetooth low energy information

Parameter	Data
Antenna type	Embedded antenna in header
Antenna dimensions	TBD
Modulation	GFSK
Magnetic field strength (at 2 m distance)	34.69 uA/m
Electric field strength (at 2 m distance)	13.07 mV/m
Output power (EIRP*)	1 mW (0 dBm) typical, 10 mW (+10 dBm) maximum
Range	2 m typical
Center frequency	2.44 GHz
Channel	40 channels
Bandwidth	2 MHz per channel
Data flow	Bi-directional

[1] Bluetooth® is a registered trademark of Bluetooth SIG, Inc.

Parameter	Data
Protocol	BLE
*EIRP = Equivalent isotropically radiated power	

Radio Transmitter, Cables, Transducers

The device contains a radio transmitter/receiver with the following parameters.

Radio transmitter parameters:

- Frequency (range): 2.4000 to 2.4835 GHz
- Bandwidth (-15dB): 2.398 to 2.4855 GHz
- Channel: 40 channels using AFH
- Modulation: GFSK
- Radiated output power: 10 mW (+10 dBm) maximum
- Magnetic field strength (at 2 m distance): 34.69 uA/m
- Duty cycle: Variable, but low (<5%)
- Semi-duplex capability

The radio receiver in the device is using the same frequency and bandwidth as the transmitter.

Cables and transducers:

Cables and transducers are not used during normal use of the device nor while programming the device.

Quality of Service for Wireless Technology

Bluetooth® low energy (BLE) wireless technology enables communication between the monitor and the clinician programmer, smart phone, or tablet. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the clinician programmer, smart phone, or tablet is paired with a monitor, the Bluetooth symbol is visible on the clinician programmer, smart phone, or tablet. When the BLE connection is not active, the symbol appears dimmed.

Other requirements include a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully. Each key press may transmit up to 8 data packets, depending on the number of packets

that need to be transmitted (i.e., if there is only one packet to transmit, only one packet will be transmitted).

Wireless Security Measures

The wireless signals are secured through device design that includes the following:

- The monitor encrypts its wireless communication.
- The monitor only communicates with authenticated paired smart phones or tablets.
- The monitor only pairs with one smart phone or tablet.
- The monitor uses a proprietary pairing protocol in addition to the pairing procedure specified in Bluetooth low energy protocols.
- The monitor authenticates the pairing requests using an industry standard cloud-based authentication and authorization protocol.
- The monitor creates a unique key for the paired unit and verifies it at the onset of every communication.

Technical Support

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)

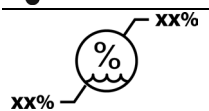
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.

Symbols

The following symbols may be found on the product or product label:

Symbol	Description
	Sterilized using ethylene oxide
	Consult instructions for use
	Follow instructions for use on this website
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	Date of Manufacture
	Manufacturer

Symbol	Description
	Country of manufacture; BE- Belgium, MY- Malaysia, US- United States
	Use by
	Do not reuse
	Serial number
	Temperature limits
	Humidity limitation
	Denotes that the device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device.

Symbol	Description
EC REP	Authorized EC Representative in the European Community
	The device contains a battery and the label is affixed to this device in accordance with European Council Directives 2002/96/EC and 2006/66/EC. These directives call for separate collection and disposal of electrical and electronic equipment and batteries. Sorting such waste and removing it from other forms of waste lessens the contribution of potentially toxic substances into municipal disposal systems and into the larger ecosystem. Return the device to St. Jude Medical at the end of its operating life.
	Australian Communications and Media Authority (ACMA) and New Zealand Radio Spectrum Management (RSM) Regulatory Compliance Mark (RCM)
	This equipment is certified for type certification pursuant of Article 38-24 of the Japan Radio Law
	Korea Certification mark for electrical devices

Symbol	Description
	Reorder number
	Do not use if package is damaged
Made in USA	Made in USA
CE 0168	Affixed in accordance with European Council Directive 90/385/EEC and 2014/53/EU. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.

Cardiac Rhythm Management Division

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Manufacturing Site:
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