

Confirm Rx™ Insertable Cardiac Monitor System

Confirm Rx™ Insertable Cardiac Monitor

Model DM3500

myMerlin™ Mobile Application

Models APP1000, APP1001

PATIENT MANUAL



ST. JUDE MEDICAL

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Important Telephone Numbers

Clinician's office	

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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Introduction

Your clinician has determined that it is beneficial for you to have a monitoring system to help identify the cause of symptoms you experience. Your monitoring system consists of the St. Jude Medical™ Confirm Rx™ insertable cardiac monitor (ICM) device and the myMerlin™ mobile application (app). This manual answers some common questions about your monitoring system and explains how to use the app. Read all of the instructions in this manual before using the app.

What is the myMerlin™ Mobile Application?

The myMerlin mobile application is a software application for your smart phone or tablet. The app uses Bluetooth®¹ low energy (LE) technology to communicate with your device. The app can be used to initiate recording of the heart's electrical activity by your device, read the information about your heart's activity from your device, and send this information to a clinician for remote monitoring.

How does my monitoring system work?

Your monitoring system works in two ways:

- **Automatically.** Your clinician will set your device to monitor and record your heart's electrical activity. The recorded heart activity will be automatically sent to your clinic during the night while you sleep, as required by your clinician.
- **On Command.** When you experience symptoms, you can use the app to tell your device to record your heart's electrical activity. The app will send your symptoms and recorded heart activity to your clinician.

NOTE: Your clinician will identify the symptoms for which you should record your heart's electrical activity. Space is provided at the front of this book for you to write down

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

any special instructions given to you by your clinician.

What is the insertion procedure like?

The insertion typically involves a simple surgical procedure. The doctor numbs the area with local anaesthesia, makes a small incision, and places the device just under the skin in the chest through the small incision.

What is recovery like?

Your clinician may ask you to limit some of your activities because of your symptoms. In general, people who have a device can perform almost all their normal activities. Your clinician will also give you information about caring for your incision and bathing.

What is a follow-up visit like?

You may go to your clinician's office or clinic for follow-up visits. During a follow-up visit, your clinician uses a programmer, a specialized computer, to review information stored in your device. Your clinician can also use the programmer, without surgery, to change how your device is set up. Your clinician uses the information from your device to help identify the cause of your symptoms or asymptomatic cardiac rhythms.

An office visit usually lasts about 30 minutes or less. Your clinician will determine your follow-up visit schedule.

Your clinician may also remotely review the information sent from your device without you having to visit the clinic.

What special precautions do I need to follow?

Your device is not magnetic and has no moving parts. However, you should avoid devices which generate a strong electric or magnetic interference (EMI). EMI could cause inappropriate data storage or prevent data storage. Moving away from the source of EMI or

turning it off will usually allow the device to return to its normal mode of operation.

You should always use caution with the following:

- **Medical procedures.** Although your device should be unaffected by most medical procedures, you should notify your doctor, dentist, physical therapist, chiropractor, or any other health care provider that you have a device.
- **Communication equipment.** Communication equipment such as microwave transmitters or high-power amateur transmitters may generate enough EMI to interfere with the performance of your device if you are too close to the source of EMI.
- **Wireless communication devices.** 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 the performance of your device if you are too close to the source of EMI.
- **Household appliances.** Household appliances such as microwave ovens, electric blankets, and power tools should not damage your device. However, they may interfere with the performance of your device.
- **Industrial equipment.** A variety of industrial equipment may generate enough EMI to interfere with the performance of your 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.
- **Metal detectors and security systems.** Metal detectors found in airports and government buildings, and 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 interfere with the performance of

your device. To minimize the possibility of interference, simply walk through these areas at a normal pace and avoid lingering near or leaning on these systems. If your device triggers an alarm, show your identification card to security personnel.

- **Mobile devices.** The device has been tested for use with smart phones and tablets. Based on the results of the tests, the device should not be affected by the normal operation of smart phones and tablets when used more than 6 in from the device.

To minimize the possibility of interference, do not carry a smart phone in a breast pocket or on a belt within 6 in of the device. Use your smart phone or tablet on the side of your body opposite from the device.

Do not place your smart phone or tablet directly over your inserted device.

What items will I receive?

You will receive product documentation regarding your monitoring system. In addition, you will need to download the myMerlin™ mobile application onto your smart phone or tablet. You can use your own smart phone or tablet if it meets the system requirements of the app. Refer to the Download the myMerlin™ Mobile Application section (page 8) for information.

St. Jude Medical will provide you with a mobile device if necessary. This mobile device allows you to communicate with your device as well as transmit data. The app will be pre-downloaded onto the mobile device for you.

Your Patient Identification Card

A patient identification card will be given to you. This card does the following things:

- Identifies you as having an inserted medical device

- Identifies the device and serial number and location of your device to help determine if you can safely receive an MRI scan
- Helps you pass through security systems like those in airports
- Provides information that allows your physician to be contacted in an emergency

For additional information about your card, contact Technical Support.

When can I begin using the myMerlin™ Mobile Application?

In most cases, you can begin using the app immediately after your device is inserted. Your clinician will give you instructions on when to use the app.

When do I record my heart's electrical activity with the myMerlin™ Mobile Application?

Your clinician will give you specific instructions on when to record your heart's electrical activity with the app.

Using the myMerlin™ Mobile Application

The app has two main functions:

- **Record Symptoms.** Begin data recording in your device when you experience symptoms.
- **Automatic Remote Monitoring.** Your clinician can remotely review the data stored in your device.

NOTE: You can record important telephone numbers and special instructions at the beginning of this book.

To ensure that your app communicates and transmits data

properly:

- Enable Bluetooth® wireless technology on your smart phone or tablet.
- Make sure that you are connected to a cellular or Wi-Fi network. The app transfers data through the use of a cellular or Wi-Fi network. The time it takes for data to transmit depends on the strength of the cellular or Wi-Fi signal.
- Keep your smart phone or tablet at your bedside during your scheduled nightly checks.
- Turn on notifications for the app.

Precautions

- Do not use the app if your smart phone or tablet is damaged.
- Keep your smart phone or tablet charged or have a power supply nearby. Familiarize yourself with your smart phone or tablet's battery life so you can anticipate its recharging needs.
- For regulatory statements regarding your smart phone or tablet, refer to the manufacturer's website.

Download the myMerlin™ Mobile Application

Your clinician will let you know when you can start using the app. You can use the app with smart phones or tablets that meet the following minimum system requirements:

- Android™² OS version 5.0 or greater
- iOS™³ version 10.2 or greater
- Bluetooth® LE wireless technology version 4.0 or greater

The app has been successfully tested with multiple smart phone and tablet configurations such as the following:

- Apple™ iPhone™⁴ 6, iOS 10.2

² Android is a trademark of Google, Incorporated.

³ iOS is a trademark or registered trademark of Cisco in the U. S. and other countries and is used under license.

⁴ Apple and iPhone are trademarks of Apple, Inc.

- Samsung™ Galaxy S™ 5⁵ mobile digital device, Android 5.1.1 software
- Samsung™ Galaxy J3™⁶ mobile digital device, Android 6.0.1 software

Other smart phones and tablets may be compatible with the app. If you are unsure whether your smart phone or tablet is compatible, contact Technical Support.

To download the app:

1. Make sure your smart phone or tablet is connected to a cellular or Wi-Fi network.
2. Use the browser on your smart phone or tablet to navigate to www.sjm.com/heartmonitoring.
3. Tap the myMerlin for Confirm Rx icon.
4. Follow the onscreen prompts to install the app.

If you encounter problems downloading the app, contact Technical Support.

NOTE: To keep your personal information secure:

- Only download and install the official SJM registered application.
- Use your smart phone or tablet's locking capability so that a PIN is required to unlock the mobile device.
- Inform the clinic or SJM in the event that your smart phone or tablet is lost or stolen.

Set up the myMerlin™ Mobile Application

After you download the app, set up the app on your smart phone or tablet. You will need the serial number located on your patient

⁵ Samsung, Galaxy S, and Galaxy J3 are trademarks of Samsung Electronics Co., Ltd.

⁶ Samsung, Galaxy S, and Galaxy J3 are trademarks of Samsung Electronics Co., Ltd.

identification card.

To set up the app:

1. Tap the Set up now button on the myMerlin app Welcome screen.
2. Scroll down the screen to review the Terms and Conditions and Privacy Policy. Select the Agree button.

NOTE: Before you continue with the setup, make sure that Bluetooth® wireless technology is on and that you are connected to a cellular or Wi-Fi network. Keep your smart phone or tablet within 5 ft of you during the setup process.

3. Tap the Continue with Setup button on the Setup screen.
4. Enter your date of birth and the serial number of your Confirm Rx™ ICM and then tap the Next button.
5. Tap the Pair Now button to pair your device with your smart phone or tablet.

NOTE: Pairing with Bluetooth® wireless technology may take several minutes.

6. If prompted, enter the code that is shown on the screen.
7. Tap the Done button to complete the setup.

There may be times when you need to set up the app after the initial setup. The setup steps are the same as those in this section except that an additional activation code is required. Follow the instructions on the screen of your smart phone or tablet to complete the activation code process.

Keep your Smart Phone or Tablet at your Bedside

The app automatically reads the information about your heart's electrical activity from your device and sends it to a database where your clinician can review it. The information is sent during the night while you sleep.

Make sure your smart phone or tablet is sufficiently charged and keep it at your bedside every night.

Record your Symptoms

When you experience symptoms, you can use the app to wirelessly record your heart's electrical activity.

NOTE: Your clinician will tell you whether or not you need to record symptoms. Your app will not have the Record Symptoms button if you do not need to record symptoms.

To record your symptoms:

1. Tap the Record Symptoms button on the bottom of the Home screen.
2. Select the symptoms you are experiencing and then tap the Done button.

The app starts connecting to your device in order to begin recording your heart's electrical activity. The estimated time to completion is displayed in the progress bar.

NOTE: Connecting to your device may take several minutes. Make sure that you keep your smart phone or tablet with you during this time.

Once the recording completes, a notification appears on the screen. The app will automatically send the recorded heart activity information to your clinician.

3. Tap the Done button.

Additional Features

You can use the buttons at the bottom of the Home screen to access information about your monitoring system. Refer to the table below for details.

Table 1. Additional features

Button name	Description
History	Tap this button to view a history of events.
Resources	Tap this button to access learning resources and frequently asked questions (FAQs).
More	Tap this button to view information about your monitoring system as well as contact information.

Troubleshooting

An error message appears on the screen of your smart phone or tablet when there is an issue with your app. Follow the prompts on the screen to resolve the issue. If you are unable to resolve the issue, contact Technical Support.

Glossary

Application (app)

A software application that you download onto your smart phone or tablet.

Clinician

The person that you see at your doctor's office. This may be your doctor, a nurse, a technician, or someone else that works for your doctor.

Device

The inserted part of your monitoring system; records your heart's electrical activity.

Technical Support

If you have trouble using the app or have any questions regarding its use, contact Technical Support.

Monday through Friday (8AM to 8PM Eastern Standard Time)

- 1 877 696 3754 (1 877 MY MERLIN) (toll-free within North America)
- 1 818 493 4258

Monday through Friday (8AM to 5PM Central European Time)

- 46 8 474 4756 (Sweden) (Support in English and Swedish. For additional assistance, contact your clinic.)

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