# SJM Confirm™
Model DM2100A

External Patient Activator

# User's Manual

St. Jude Medical

## Important Telephone Numbers

| | |
|---|---|
| Clinician's office | |
| To send data | |
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Special Instructions

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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™ SJM Confirm™ implantable cardiac monitor and the St. Jude Medical SJM Confirm external patient activator. This booklet answers some common questions about your monitoring system and explains how to use the SJM Confirm external patient activator (PA).

## What is the SJM Confirm PA?

The PA is an external handheld device, similar to a handheld computer. The PA uses radio waves to communicate with your implanted device. The PA initiates recording of the heart's electrical activity by your implanted device, reads stored data from your implanted device, and sends stored data to a clinician.

## How does my monitoring system work?

Your monitoring systems works in two ways:

- **Automatically**. Your clinician will set your device to monitor and record your heart's electrical activity.
- **On Command**. When you experience symptoms, you can use the PA to tell your device to record your heart's electrical activity. Your clinician will identify the symptoms for which you will record your heart's electrical activity. You can record this information at the beginning of this book.

## What is the implant procedure like?

The implant 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 upper 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 will 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 symptoms you experience.

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

## What do I do after I record my heart's electrical activity with the PA?

Your clinician will give you specific instructions on what to do after you record your heart's electrical activity with the PA.

## Why do I need an identification card?

You will be given an identification card with information about your device and the PA. Put the card in your wallet or carry it with you at all times. Show your card if you are ever in an emergency, are admitted to a hospital, see a new doctor, or need to prove that you have a device.

## When can I begin using the PA?

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

## What special precautions do I need to follow?

Your device and the PA are not magnetic and have 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 or the PA 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.
- **Hospital and Medical equipment.** A variety of standard hospital and medical equipment may generate enough EMI to interfere with the performance of the activator. These include, but are not limited to: blood pressure monitors, ECG equipment, external defibrillation equipment, and x-ray machines.

- **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 or the PA 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, handheld personal computers (PDA), cellular phones, and even cordless telephones may generate enough EMI to interfere with the performance of your device or the PA 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 or the PA. However, they may interfere with the performance of your device or the PA.
- **Office equipment.** A variety of standard office equipment may generate enough EMI to interfere with the performance of the activator. These include, but are not limited to: desktop or laptop computers, fax machines, and phone systems.
- **Industrial equipment**. A variety of industrial equipment may generate enough EMI to interfere with the performance of your device or the PA. 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 or the PA. 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.

- **Cellular phones**. The device has been tested for use with cellular phones. Based on the results of the tests, 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 interference, do not carry a cellular phone in a breast pocket or on a belt within 15 cm of the device. Use a cellular phone on the side of your body opposite from the device.

# Important Safeguards

Basic safety precautions should always be followed when using electrical products, especially when children are present. These include the following:

- READ ALL INSTRUCTIONS BEFORE USING.
- DANGER! To reduce the risk of shock:
  - Do not use the PA while bathing.
  - Do not place or store the PA where it can fall or be pulled into a tub or sink.
  - Do not place or drop the PA into water or other liquid.
- WARNING! To reduce the risk of burns, shock, fire, or injury to persons:
  - Supervision is necessary when the PA is used by, on, or near children.
  - Use the PA only for its intended use as described in this manual.

- Never operate the PA if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water or other liquid. Contact Technical Support (page 11) for service or replacement instructions.
- Never drop or insert any object into any opening of the PA.
- Do not use the PA near flammable substances.

- To reduce the risk of damage to the PA:
  - Do not transport or store the PA in a location where the temperature could reach higher than 55ºC or lower than -20ºC.
- KEEP THESE INSTRUCTIONS.

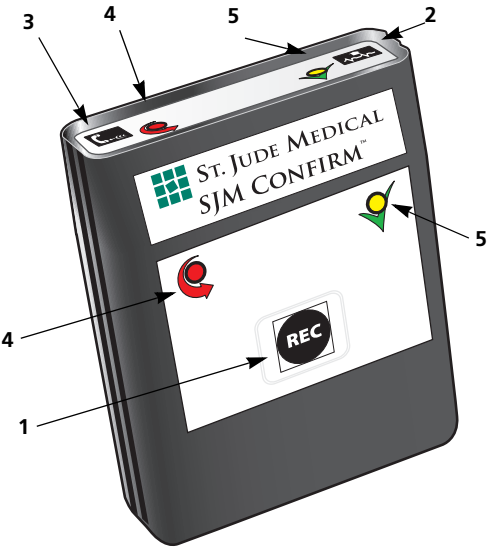
# Using The PA

You will use the PA to do a variety of things. Your clinician will tell you when to do the following:

- **Record Data**. Begin data recording in your implanted device.
- **Read Data**. Read the data stored in your device and transfer the data to the PA.
- **Send Data**. Send the data stored in the PA using your telephone line.
- **Clear Data**. Remove all stored data from the PA.

**Note**

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




1 Record button
2 Read button
3 Send button
4 Red lights
5 Yellow lights

**Figure 1. Patient Activator - front and top**


6 PA speaker

**Figure 2. Patient Activator - back**

# Battery Status

The PA is designed to record data on command once a week, read data from your implanted device once a month, and send data once a month. Under these conditions you can expect the PA battery to last about 3 years. Sending data more than once a month will drain the battery sooner.

# Caring for the PA

The PA is designed to be used as indicated; however, it is an electronic device and susceptible to many environmental stresses. Take care to avoid damaging the PA.

If necessary, you can clean the outside of the PA with a cloth dampened with water. The PA is classified as IP22 and protected against dripping water when placed inside the carrying pouch. The PA should be placed inside the carrying pouch during normal use. Do not immerse the PA in any liquid.

There is no shut down procedure for the PA. The battery is not intended to be removed while in use.

The PA does not contain any user-serviceable parts. Do not open the case. Preventive maintenance, including periodic safety checks, is not required for this device. Do not modify the PA. If there is a problem with the PA, contact Technical Support (page 11).

# Glossary

- **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. This may also be the person you call to send data.
- **Device** — The implanted part of your monitoring system; records your heart's electrical activity.
- **Patient activator (PA)** — The external handheld equipment that you use to record, read, and send data from your device.

# Technical Support

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

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)
- +61 2 9936 1200 (Australia)
- manuals.sjm.com

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

# Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://manuals.sjm.com.

| | |
|---|---|
|   | Record Data button |
|  | Read Data button |
|  | Send Data button |
|  | Telephone handset symbol |
|  | Clinic telephone number |

| | |
|---|---|
|  | Done action |
|  | Retry action |
|   | Do not use in MRI scan room |
| CE 0123 | European conformity, affixed according to the relevant provisions of AIMD directive 90/385/EEC and RE directive 2014/53/EU Annex II. Hereby, St. Jude Medical declares that this device complies with the essential requirements and other relevant provisions of these directives.<br><br>The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: www.sjmglobal.com/euconformity.<br><br>This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m. |
|  | Manufacturing facility |

| | |
|---|---|
|  | Product literature |
| Australian Sponsor | Australian Sponsor |
|  | Affixed to this device in accordance with European Council Directive 2002/96/EC. See Disposal on page 22. |
| ℞ ONLY | Prescription only |
|   | Follow instructions for use on this website |
| Made in USA | Made in USA |
| IP22 | Ingress Protection Rating. The first "2" indicates the device enclosure is protected against a solid object > 12.5 mm. The second "2" indicates the enclosure is protected against dripping water up to 15° from vertical. |

# Technical Information

**Note**

- There are no user-serviceable parts in the PA. No calibration is required. Do not modify the PA.
- When used under normal operating conditions, this equipment generates no pollution.

| | |
|---|---|
| PA Model Number | DM2100A |
| Dimensions (cm) | 7.1 x 5.6 x 1.8 |
| Case material | High-impact plastic |
| Power source | 1 cell; 3.6 V (nominal); Chemistry: Lithium Thionyl Chloride |
| Battery longevity | 3 years |
| Audible output level | 60 dB (minimum) at 10.0 cm |
| Classification with respect to electric shock | Internally powered |

| | |
|---|---|
| Protection from electric shock (IEC 60601-1) | Type BF |
| Protection against ingress of liquids | Ordinary equipment |
| Mode of operation | Continuous |

## Accessories

There are no accessories for the PA.

## Electromagnetic Compatibility

The PA requires special precaution with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The PA is intended for use in the electromagnetic environment specified in Tables 1, 2, and 3. The user should ensure that it is used in such an environment.

**WARNING**

**The PA is intended for in-home use. It complies with the limits for medical devices contained in IEC/EN 60601-1-2.**

**However, the PA may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to evaluate this effect by reorienting or relocating the PA or shielding the location.**

| Test | Compliance |
|---|---|
| | **Electromagnetic Environment – Guidance** |
| RF Emission CISPR 11 | Group 1 |
| | The PA must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF Emission CISPR 11 | Class B |
| | The PA is suitable for use in all establishments, including domestic establishments. |

**Table 1. Guidance and manufacturer's declaration – electromagnetic emissions**

| Test | IEC 60601 Test Level (Actual Level)[1] |
|---|---|
| | **Electromagnetic Environment – Guidance** |
| Electrostatic Discharge (ESD)<br>IEC 61000-4-2 | ±8 kV contact (±8 kV contact)<br><br>±15 kV air (±15 kV air) |
| | None |
| Power Frequency (50/60 Hz) Magnetic Field<br>IEC 61000-4-8 | 30 A/m (30 A/m) |
| | None |

**Table 2. Guidance and manufacturer's declaration – electromagnetic immunity**

1. Figures in parentheses are the immunity compliance levels for each test.

| Test | IEC 60601 Test Level[1] | Immunity Compliance Level |
|---|---|---|
| **Electromagnetic Environment – Guidance** | | |
| Radiated RF IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.7 GHz | 10 V/m |

**Table 3. Guidance and manufacturer's declaration – electromagnetic immunity (radiated RF)**

| Test | IEC 60601 Test Level[1] | Immunity Compliance Level |
|---|---|---|
| **Electromagnetic Environment – Guidance** | | |
| Portable and mobile RF communications equipment should be used no closer to the PA, including cables, than the recommended separation distance.<br>**Recommended separation distance:**<br>$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$<br>**(80 MHz to 800 MHz):**<br>$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$<br>**(800 MHz to 2.7 GHz):**<br>$d = \left[\frac{7}{E_1}\right]\sqrt{P}$<br>where **P** is the maximum output power rating of the PA in watts (W) according to the PA manufacturer and **d** is the recommended separation distance in meters (m).<br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[2], should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:  | | |

**Table 3. Guidance and manufacturer's declaration – electromagnetic immunity (radiated RF)**

1. At 80 MHz and 800 MHz, the higher frequency range applies.

2. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength of the location in which the PA is used exceeds the applicable RF compliance level above, the PA should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the PA.

## RF Operating Frequencies

Nearby equipment emitting strong magnetic fields can interfere with the PA inductive communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics of the PA is as follows:

- Inductive Telemetry
  - RF Transmission – Carrier frequency centered at 60 kHz (inductive telemetry). The effective radiated power is below the limits as specified in EN 302 195.
  - RF Reception – Centered at 60 kHZ (inductive telemetry).

**Note**

Maintain a reasonable distance between other electronic equipment and the PA.

## Storage and Operating Conditions

| Property | Storage | Operating |
|---|---|---|
| Minimum Temperature °C/°F | -20/-4 | 0/32 |
| Maximum Temperature °C/°F | 55/131 | 50/122 |
| Minimum Humidity (% non-condensing) | 5 | 10 |
| Maximum Humidity (% non-condensing) | 95 | 95 |
| Atmospheric Pressure Range (kPa) | 51-107 | 70-107 |

**Table 4. Storage and operating conditions**

The device may take up to two hours to reach an operating temperature of 20°C (68°F) from the minimum storage temperature of -20°C (-4°F). The device may take up to two hours to reach an operating temperature of 20°C (68°F) from the maximum storage temperature of 55°C (131°F).

## Disposal

Return the PA to St. Jude Medical at the end of its operating life or dispose of the PA according to your local regulations. Contact your local St. Jude Medical representative for information on disposal.

## FCC Information

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.

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## O



## P



## S



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