

4-9-08 Draft

# User's Manual

**Merlin™@home**

Transmitter Model EX1150

## CAUTION

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

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## Introduction

Your doctor has given you the Merlin™@home transmitter that is part of the St. Jude Medical® Merlin@home Remote Monitoring System. This manual describes this system and explains how to set up and use the transmitter.

## What does the Merlin™@home transmitter do?

The Merlin™@home transmitter conducts your Merlin@home session. During your Merlin@home session, the transmitter reads the data from your defibrillator and sends it to a server where your clinic can view it. This data includes:

- The type and serial number of your defibrillator
- The settings for your defibrillator
- What has happened since your last follow-up session
- Your defibrillator's battery status

Your transmitter can also conduct a device check, which checks your defibrillator's battery status.

Your defibrillator continues to work normally while the transmitter reads the data. Your doctor can use this data to help check the status of your defibrillator.

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### Note

Only your clinic, and "Technical Service" (page 6) if requested by your doctor, can view the confidential data you send during your Merlin@home session.

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## How does the Merlin™@home transmitter affect your telephone?

The Merlin™@home transmitter plugs into your telephone line (see "Setting up the transmitter" on page 3) and uses the telephone network to send data to the server, where your clinic can view the data. As far as your telephone is concerned, this is like any other telephone call to a toll-free number within the United States.

Before your Merlin™@home session starts, you must hang up all phones. If someone calls during your session, he or she receives a busy signal.

When the transmitter is not reading or sending data, it is idle. Leaving the transmitter connected to your telephone does not affect your telephone's normal operation. You can still make and receive calls.

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### Note

At any time during your Merlin@home session, you can interrupt your session to use the telephone.

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## Can you use the transmitter while traveling?

Check with your doctor before traveling with the Merlin™@home transmitter. If he or she agrees that it is all right, carefully repackage the transmitter in its carrying case. You may want to purchase an RJ-11 telephone plug adapter in case you need to plug the transmitter into an older telephone wall jack.

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### **Note**

You can use the transmitter in the United States only.

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## Important Safeguards

Always follow basic safety precautions when using electrical products, especially when children are present. These include:

- Read all instructions before using.
- Keep these instructions.

## **WARNING**

- For emergencies, call 911.
- Do not spill any liquid on the transmitter. If you spill any liquid, unplug the transmitter and wipe the liquid off right away. Do not plug the transmitter in until it is completely dry.

### To reduce the risk of shock:

- Do not use the transmitter while bathing.
- Do not place or store the transmitter where it can fall or be pulled into a tub or sink.
- Do not place or drop the transmitter into water or other liquid.
- Do not reach for a transmitter that has fallen into water. Unplug it immediately.

### To reduce the risk of burns, shock, fire, or injury to persons:

- Supervision is necessary when the transmitter is used by, on, or near children.
- Use the transmitter only for its intended use as described in this manual. Do not use attachments not recommended by St. Jude Medical.
- Never operate the transmitter if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water. Contact "Technical Service" (page 6) for service or replacement instructions.
- Keep the cord away from heated surfaces.
- Do not operate the transmitter on heated surfaces.
- Do not use outdoors or operate where aerosol (spray) products are being used. Do not operate in an oxygen-rich environment (for example, in an oxygen tent or oxygen chamber).
- Do not use the transmitter near flammable substances.

## **Setting up the transmitter**

To use the Merlin™@home transmitter, your telephone must use touch-tone dialing. You can use either a push-button or rotary telephone. The telephone must have a standard (RJ-11) plug. Your telephone wall jack must also accept a standard plug. If you have an older plug or jack, you can purchase an RJ-11 adapter that allows you to use the transmitter.

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**Note**

- If your telephone is wired into the wall, you cannot use the transmitter unless you install standard telephone wall jacks. To do this, contact the telephone company for help.
  - If DSL shares your telephone line, contact your DSL service provider for a filter to prevent any possible interference. Plug the filter into the telephone wall jack and plug the phone line splitter into the filter. For more information on how to use the filter, contact your DSL service provider.
  - If you do not place your transmitter on your night stand, contact your clinic for a recommendation.
  - Keep the original shipping box in case you need to return the transmitter for service.
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**CAUTION**

The transmitter can only be used with direct analog telephone lines. It is not compatible with, and may be damaged by, any other type of phone line.

For instructions on how to set up the transmitter, see the Merlin@home Transmitter Start-Up Guide.

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**Note**

- Choose a convenient and comfortable spot near a telephone wall jack and electrical outlet. A night stand is a good choice, so a scheduled follow-up can occur while you sleep. The transmitter should be within 10 feet of your normal sleeping position.
  - Place the transmitter on a sturdy, flat, hard surface. The transmitter must be flat on the surface at all times.
  - Move other electronic items away from the transmitter.
  - Make sure that you are able to see the transmitter's icons and lights.
  - Make sure the front of the transmitter faces you when you sleep.
  - Once you have the transmitter set up, leave it in place. Do not unplug it or put it away between uses.
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## Merlin™@home sessions and device checks

There are two types of Merlin™@home sessions and device checks:

- Scheduled
- Unscheduled



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**Note**

Do not press the Start button while the Merlin@home transmitter is reading or sending your data.

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## Scheduled session and device check

Scheduled sessions and device checks occur automatically. Your schedule is defined by your clinician. Most often the data transfer occurs sometime during the night while you sleep. After setting up your Merlin@home transmitter, you don't need to do anything for a scheduled session or a device check to occur.

## Unscheduled session and device check

Conduct an unscheduled session if your clinician instructs you to do so, when you set up the transmitter, or you are not feeling well. For instructions on how to conduct an unscheduled session, see the Merlin@home Transmitter Start-Up Guide.

You can conduct an unscheduled device check to check your defibrillator's battery status. Conduct an unscheduled device check the same way you conduct an unscheduled session, except after you press the Start button and hear a beep, continue to press the Start button for 3 to 4 seconds until you hear a second beep.

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**Note**

- Before you conduct an unscheduled session or device check, call your clinic to tell them that you are going to send your data.
  - Do not sit closer than 8 inches from the transmitter.
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## Transmitter errors

Errors may result from variations in telephone equipment, data transmission time, or the quality of the telephone connection. For information on transmitter errors and how to respond to them, see the Merlin™@home Transmitter Start-Up Guide.

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**Note**

When all icons or lights are off, the transmitter may not be functioning. Call "Technical Service" (page 6).

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## Caring for the transmitter

If necessary, you can clean the outside of the Merlin™@home transmitter with a cloth dampened with water. Do not clean the transmitter while a session is in progress. The transmitter is classified as IPX0 because it is not waterproof. Do not immerse the transmitter in any liquid.

The transmitter does not contain any user-serviceable parts. Do not open the case. If there is a problem with the transmitter, contact "Technical Service" (page 6) for a replacement.

## Glossary

*Clinic* — The place that views your data after the Merlin™@home transmitter sends your data to the server.

*Data* — The information stored in your defibrillator. The information includes your defibrillator's type and serial number, settings, and battery status.

*Defibrillator* — Also known as an *ICD* (implantable cardioverter-defibrillator) or *CRT-D* (cardiac resynchronization therapy defibrillator); uses electrical impulses to treat life-threatening ventricular tachyarrhythmias.

*Merlin@home session* — A remote monitoring session in which your data is sent to the server, where the clinic can view your data.

*Server* — The place where your data from the Merlin™@home session is sent.

*Transmitter* — The part of the Merlin@home Remote Monitoring System that reads the data in your defibrillator and sends it to the server.

## Technical Service










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

- by phone for Merlin™@home issues, 1 877 696 3754 (1 877 MY MERLIN)
- 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

Definitions of globally recognized hardware, applied part, and packaging symbols required by regulatory authorities are described below.

Symbol	Description
	Manufacturer
	Authorized Representative in the European Community
	Refer to the instruction manual.
	Direct current. Equipment is suitable for alternating current only; identifies relevant terminals.
	To identify the terminals to which a telephone adapter is to be connected.
	Non-ionizing electromagnetic radiation. Indicates elevated, potentially dangerous levels of non-ionizing radiation.
	Class II equipment. Meets safety requirements specified for Class II equipment according to IEC 60601-1.
	Affixed to this device in accordance with European Council Directive 90/385/EEC and 1999/5/EC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.
	Return the Merlin™@home transmitter to St. Jude Medical at the end of its operating life. The crossed-out trash can symbol marked on the Merlin@home transmitter indicates that St. Jude Medical complies with the European Union's Waste Electrical and Electronic Equipment (WEEE) directive. That directive calls for separate collection and disposal of hazardous waste from electrical and electronic equipment. 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.

**Table 1. Symbols**

# Technical Information

The Merlin™@home transmitter is Class II medical equipment and complies with IEC60601-1:2005 and UL60601-1:2003 and CAN/CSAC22.2 No. 60601.1-M90.

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## Note

- There are no user-serviceable parts in the Merlin@home transmitter. No calibration is required. Do not modify the Merlin@home transmitter.
  - When used under normal operating circumstances, this equipment generates no pollution.
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Input/Output	Rating
Transmitter input	100-240 VAC, 50-60 Hz
Power consumption	0.1 A

**Table 2. Electrical rating**

Parameter	Condition
Minimum Temperature	-68°F (-20°C)
Maximum Temperature	158°F (70°C)
Maximum Humidity	90%

**Table 3. Storage conditions**

Parameter	Condition
Minimum Temperature	50°F (10°C)
Maximum Temperature	104°F (40°C)
Maximum Humidity	75%

**Table 4. Operating Conditions**

## Telephone accessories

Telephone accessories included with the transmitter are:

- Telephone cable
- Phone line splitter

An optional telephone accessory is the Model EX 1151 USB cellular adapter.

## Electromagnetic Compatibility

The Merlin™@home transmitter requires special precautions with regard to electromagnetic compatibility (EMC) and should be used in accordance with the information provided in this manual.

The Merlin@home transmitter complies with the requirements of the international EMC standard IEC 60601-1-2:2001 when used with the cables listed in "Telephone accessories" (page 9).

The Merlin@home transmitter is intended for use in the electromagnetic environment specified in Tables 5 through 8. The user should ensure that it is used in such an environment.

**WARNING**

**The Merlin@home transmitter complies with the limits for medical devices contained in IEC/EN 60601-1-2:2001. However, the Merlin@home transmitter may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to mitigate this effect by reorienting or relocating the receiving device or shielding the location.**


Test	Compliance	Electromagnetic Environment – Guidance
RF Emission CISPR 11	Group 1	The Merlin™@home transmitter must emit electromagnetic energy in order to perform their intended function. Nearby electronic equipment may be affected.
RF Emission CISPR 11	Class B	The Merlin@home transmitter is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

**Table 5. Guidance and manufacturer's declaration – electromagnetic emissions**

Test	IEC 60601 Test Level (Actual Level) <sup>1</sup>	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact (±6 kV contact)  ±8 kV air (±8 kV air)	None
Electrical fast transient/burst IEC 61000-4-4	±1 kV for input/output lines (±1 kV for input/output lines)	None
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	3 A/m (3 A/m)	None

**Table 6. Guidance and manufacturer's declaration – electromagnetic immunity**

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

Test	IEC 60601 Test Level <sup>1</sup>	Immunity Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Merlin@home transmitter, including cables, than the recommended separation distance.</p> <p><b>Recommended separation distance:</b></p> <p><b><math>d = 1.2\sqrt{P}</math></b></p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	<p><b><math>d = 1.2\sqrt{P}</math></b> (80 MHz to 800 MHz)</p> <p><b><math>d = 2.3\sqrt{P}</math></b> (800 MHz to 2.5 GHz)</p> <p>where <b>P</b> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <b>d</b> is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>2</sup>, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

**Table 7. Guidance and manufacturer's declaration – electromagnetic immunity (conducted RF and 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 Merlin@home transmitter is used exceeds the applicable RF compliance level above, the Merlin@home transmitter should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Merlin@home transmitter.

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## Note

The Merlin@home transmitter is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the Merlin@home transmitter can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Merlin@home transmitter as recommended below in Table 8, according to the maximum output power of the communications equipment. For transmitters rated at a maximum output power not listed in Table 8, the recommended separation distance (**d**) in meters can be estimated using the equation applicable to the frequency of the transmitter, where **P** is the maximum output power rating of the transmitter in watts (**W**) according to the transmitter manufacturer.

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Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m) <sup>1</sup>		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz <sup>2</sup> $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1.0	1.2	1.2	2.3
10.0	3.8	3.8	7.3
100.0	12	12	23

**Table 8. Recommended separation distances between portable and mobile communications equipment and the Merlin@home transmitter and St. Jude Medical RF device**

1. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
2. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.



## Radio Frequency Information

MICS band: 402-405 MHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 301 839-2
- USA: FCC 47 CFR Part 95.601-95.673 Subpart E, 95.1201-95.1219 Subpart I

2.45 GHz. The effective radiated power is below the limits as specified in:

- Europe: EN ETSI 300 328
- USA: FCC 47 CFR Part 15.249

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### Note

Maintain a reasonable distance between other electronic equipment and the Merlin™@home transmitter.

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### WARNING

**This transmitter is authorized by rule under the Medical Implant Communications Service (part 95 of the FCC Rules) and must not cause harmful interference to stations operating in the 400.150 - 406.000 MHz band in the Meteorological Aids (that is, transmitters and receivers used to communicate weather data), the Meteorological Satellite, or the Earth Exploration Satellite Services and must accept interference that may be caused by such aids, including interference that may cause undesired operation. This transmitter shall be used only in accordance with the FCC Rules governing the Medical Implant Communications Service. Analog and digital voice communications are prohibited. Although this transmitter has been approved by the Federal Communications Commission, there is no guarantee that it will not receive interference or that any particular transmission from this transmitter will be free from interference.**

## FCC Information

This equipment complies with Part 68 of the FCC rules and the requirements adopted by the ACTA. On the exterior of this equipment is a label that contains, among other information, a product identifier in the format:

**Antenna: US: RIASJMRFANT**

**Modem: US: 3A4M508BSM2-T-W**

If requested, this number must be provided to the telephone company.

Identifier	Description
FCC Registration Number (antenna)	US: RIASJMRFANT
FCC Registration Number (modem)	US: 3A4M508BSM2-T-W
Ringer Equivalence Number (REN)	0.8B
USOC Jack Type	RJ11 (US)

**Table 9. FCC identification information**

A FCC compliant telephone cord and modular plug is provided with this equipment. This equipment is designed to be connected to the telephone network or premises wiring using a compatible modular jack that is Part 68 compliant. See installation instructions for details.

The REN is used to determine the quantity of devices that may be connected to the telephone line. Excessive RENs on the telephone line may result in the devices not ringing in response to an incoming call. Typically, the sum of RENs should not exceed five (5.0). To be certain of the number of devices that may be connected to a line (as determined by the total RENs) contact the local telephone company.

If the Merlin™@home transmitter causes harm to the telephone network, the telephone company will notify you in advance that temporary discontinuance of service may be required. But if advance notice isn't practical, the telephone company will notify the customer as soon as possible. Also, you will be advised of your right to file a complaint with the FCC if you believe it is necessary.

The telephone company may make changes to it's facilities, equipment, operations or procedures that could affect the operation of the equipment. If this happens the telephone company will provide advance notice so you can make the necessary modifications to maintain uninterrupted service.

If you have trouble with the Merlin@home transmitter, for repair or warranty information, contact Technical Service.

If the equipment is causing harm to the telephone network, the telephone company may request that you disconnect the equipment until the problem is resolved.

Connection to party line service is subject to state tariffs. (Contact the state public utility commission, public service commission or corporation commission for information.)

**CAUTION**

Per FCC Rules, changes or modifications of the Merlin@home transmitter not approved by St. Jude Medical could void your right to operate the Merlin@home transmitter.

## **Note**

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 radio frequency 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: (1) Reorient or relocate the receiving antenna. (2) Increase the separation between the equipment and transmitter. (3) Connect the equipment into an outlet on a circuit different from that to which the transmitter is connected. (4) Consult the dealer or an experienced radio/TV technician for help.

This device may not interfere with stations operating in the 400.150-406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

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## Warranty

St. Jude Medical warrants that for a period of one year following delivery to the original purchaser, the Merlin™@home Transmitter will be free from defects in materials and workmanship.

This warranty does not cover damage due to external causes, including but not limited to accident, electrical power problems, servicing not authorized by St. Jude Medical, usage not in accordance with product instructions, failure to perform required preventive maintenance, abuse, and misuse.

During the one year warranty period, St. Jude Medical will repair or replace a malfunctioning transmitter if it is returned to St. Jude Medical. To qualify for such repair or replacement, St. Jude Medical must be notified within 30 days of the malfunction and, if so directed by St. Jude Medical, the purchaser must return the transmitter for repair or replacement to:

### **St. Jude Medical**

#### **Cardiac Rhythm Management Division**

**15900 Valley View Court**

**Sylmar, CA 91342**

If warranty service is required, St. Jude Medical will issue a Return Material Authorization Number. You must ship the product back to St. Jude Medical in the original packaging or equivalent, prepay shipping charges, and you must insure the shipment or accept the risk of loss or damage during shipment.

St. Jude Medical will ship the repaired or replacement transmitter to you, freight prepaid.

If St. Jude Medical repairs or replaces your transmitter, the warranty term will be for the remainder of the original term or 60 days, whichever is longer.

THIS WARRANTY REPRESENTS THE ENTIRE OBLIGATION OF ST. JUDE MEDICAL AND IS MADE IN LIEU OF ANY OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ST. JUDE MEDICAL WILL NOT BE LIABLE FOR ANY DAMAGES, WHETHER DIRECT, CONSEQUENTIAL, OR INCIDENTAL, CAUSED BY DEFECTS, FAILURES, OR MALFUNCTIONS OF ITS PRODUCTS, WHETHER SUCH A CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

Some states do not allow the exclusion of incidental or consequential damages, so the preceding limitation or exclusion may not apply. Some states do not allow limitations on how long an implied warranty lasts, so the preceding limitation may not apply.

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