

Merlin@home™

Transmitter

Model EX1100, EX1100W

# USER'S MANUAL



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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 information from your implanted device (device) and sends it to a server where your clinic can view it. This information includes:

- The type and serial number of your device
- The settings for your device
- What has happened since your last follow-up session
- Battery status of your device

Your transmitter can perform a status check on your device.

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

Depending on the transmitter provided by your doctor (either EX1100 or EX1100W) your Merlin@home transmitter works with the following:

- Model EX1100
  - telephone (landline)
  - cellular adapter
  - wireless broadband kit
- Model EX1100W
  - cellular adapter
  - wireless broadband kit

### NOTES:

- The Merlin@home transmitter model EX1100W is not available in all geographies.
- Only your clinic, and Technical Support (page 6) if requested by your doctor, can view the confidential information you send during your Merlin@home session.
- Normal use of the transmitter has little impact on the battery usage of your device. Conduct your sessions according to the schedule provided by your clinic.

## Using your Merlin@home™ Transmitter with your Telephone

### Note

The following information is applicable if you are using a telephone line to connect the transmitter. If you are using the cellular or wireless broadband adapters to connect the transmitter, a telephone line is not needed.

The Merlin@home™ transmitter plugs into your telephone line, see Setting Up the Transmitter (page 3), and uses the telephone network to send information to the server, where your clinic can

view the information. Before your Merlin@home session starts, you must hang up all phones. If someone calls during your session, you receive a Can't Send Information message. For more information, see the Merlin@home Transmitter Quick Start Guide provided with your transmitter. When the transmitter is not reading or sending information, it is idle. Leaving the transmitter connected to your telephone line does not affect your telephone's normal operation. You can still make and receive calls.

#### **Note**

At any time during your Merlin@home session, you can interrupt your session to use the telephone. If you do not hear a dial tone when you pick up your telephone handset, hang up and pick up your telephone handset again. If your Merlin@home session is interrupted, the transmitter may display a Can't Send Information message. If so, press the Start button and the transmitter will attempt to send your information at a later time.

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

#### **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 connector into the filter. For more information on how to use the filter, contact your DSL service provider.

#### **CAUTION**

**The transmitter is designed for use with direct analog telephone lines. It may be damaged by any other type of phone line. See Technical Support (page 6).**

## **Using your Merlin@home™ Transmitter with a Cellular Adapter**

The Merlin@home™ transmitter model EX1100 and the Merlin@home™ transmitter model EX1100W can be used with the cellular adapter provided with your transmitter. For more information, see the Set Up Guide and Quick Start Guide provided with your transmitter.

## **Using your Merlin@home™ Transmitter with a Wireless Broadband Kit**

The Merlin@home™ transmitter model EX1100 and the Merlin@home™ transmitter model EX1100W can be used with a wireless broadband kit. For more information, see the Set Up Guide provided with your transmitter.

## **Can You Use the Transmitter While Traveling?**

The Merlin@home™ transmitter works within your country, but it might not work outside your country. Check with your doctor before traveling with the transmitter. If he or she agrees that it is

all right, carefully repackage the transmitter in its original packaging. If you are using a telephone with your Merlin@home transmitter, 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.

## 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**

- This transmitter is not a replacement for appropriate medical attention in case of an emergency
- 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 Support (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

For instructions on how to set up the transmitter, see the Merlin@home Transmitter Set Up Guide provided with your transmitter.

### **Note**

- Place the transmitter on a sturdy, flat, hard surface. The transmitter must be flat on the surface at all times.
- The Merlin@home transmitter is not magnetic and has no moving parts. However, you should avoid devices which generate a strong electric or magnetic

interference (EMI). EMI could interfere with the performance of the transmitter. Moving the source of EMI away from the transmitter or turning the source of EMI off will usually allow the transmitter to return to its normal mode of operation. Sources of EMI may include communication equipment, wireless communication devices, household appliances, and industrial equipment.

- Do not press the Reset button on the back of the transmitter unless requested to do so by Technical Support (page 6) or your clinic.
- Use only St. Jude Medical supplied accessories in the USB port. Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3.1Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the technical service department.
- Sometimes issues with your phone, cellular adapter, or internet service provider may prevent your transmitter from sending your information. Contact Technical Support (page 6) or your clinic. Your transmitter might require servicing. Keep the original shipping box in case you need to return the transmitter for service.
- The transmitter is configured for either single patient or multiple patient use. For multiple patient use, the transmitter retrieves full follow up data. or retrieves data for display only in the Heart Failure Management application on the Merlin.net™ PCN.
- Leave your transmitter plugged into the wall electrical outlet, unless otherwise indicated by your clinic.

## Merlin@home™ Session

Conduct a Merlin@home™ session according to the schedule set by your clinic. For instructions on how to set up and use the transmitter, see the Merlin@home Transmitter Set Up Guide and Quick Start Guide provided with your transmitter.

## Device Check

Conduct a device check only if your clinician instructs you to do so. To conduct a device check:

1. Place the wand, green side towards you, over your device.

Do one of the following:

- If only the green light is lit, go to Step 2.
  - If the "Stars" icon is lit, go to Step 3.
2. Press the Start button. The "Stars" icon lights up.
  3. Press the Start button for 3 to 4 seconds until you hear two beeps.

The "Read" icon flashes when the transmitter searches for your device. It will stop flashing but



remains lit while the transmitter reads the device and the progress lights will move left to right.

4. The "Tower" icon lights up when the transmitter has read your device. You can remove your wand.
5. The "Stars" icon lights up when your device check is complete. The "Stars" icon will turn off after a short time.

## Shut Down

To power down the Merlin@home™ transmitter, unplug the power supply from the wall electrical outlet. If using a telephone, you may leave the phone cord from the transmitter plugged into the wall or disconnect it. It should not affect your telephone.

## Transmitter Reset

Reset your transmitter only if Technical Support (page 6) instructs you to do so.

## Transmitter Messages

Errors may result from variations in telephone equipment, information transmission time, or the quality of the telephone connection. If the transmitter is plugged in and the green power light does not come on, contact Technical Support (page 6). For more information on transmitter errors and messages and how to respond to them, see the Merlin@home™ Transmitter Quick Start Guide provided with your transmitter.

### Note

Occasionally the software in your Merlin@home transmitter is automatically updated. If any action is required on your part, you will be notified.

## Software Updates and Your Transmitter

It is important to keep your transmitter powered on and the connectivity accessory plugged in so that the transmitter can receive occasional automatic software updates. If transmitter connectivity is not maintained, your transmitter's software may not be updated to the current version and your transmitter may no longer be able to transmit or receive information.

## 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.

Preventative maintenance, including periodic safety checks, is not required for this device. If there is a problem with the transmitter, contact Technical Support (page 6) for a replacement.

### WARNING

**The transmitter does not contain any user-serviceable parts. This product complies with medical product regulatory standards. In order to maintain that compliance, do not open the case.**

## Glossary

**Clinic** — The place that views your information after the Merlin@home™ transmitter sends your

information to the server.

**Information** — The information stored in your device. The information includes your device type and serial number, settings, and battery status.

**Device** — Your implanted device, also known as an ICD (implantable cardioverter-defibrillator), CRT-D (cardiac resynchronization therapy defibrillator), pacemaker, or CRT-P (cardiac resynchronization therapy pacemaker).

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

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

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

## Technical Support

For Merlin@home™ transmitter issues:

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.)

## Indications




The Merlin@home™ transmitter is indicated for use by patients with supported St. Jude Medical implants (implanted devices), and clinicians.








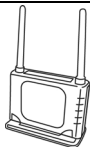








## Contraindications
















The Merlin@home™ transmitter is contraindicated for use with any implanted medical device other than supported St. Jude Medical implants (implanted devices).






## Symbols

Table 1. The following symbols may be found on the product or product label:

Symbol	Description
	Transmitter
	Contents
	Model EX1100, EX1100W Merlin@home transmitters

Symbol	Description
	Phone cord and splitter (phone connector)
	Merlin@home inductive wand
	Product literature
	Consult instructions for use
	Follow instructions for use on this website
	USB wireless adapter
	USB wireless adapter's clip and USB cable
	Wireless access point
	Wireless access point's ethernet cable
	Wireless access point's power supply
	Manufacturer
	Manufacturing facility
	Authorized Representative in the European Community
	Australian Sponsor
	Follow the instructions for use
	Direct current

Symbol	Description
	To identify the terminals to which a telephone adapter is to be connected
	Interference may occur in the vicinity of this equipment
	Transmitter works with a wireless broadband kit
	Transmitter works with a cellular adapter
	Transmitter does not work with a landline telephone
	Date of Manufacture
	Class II equipment. Meets safety requirements specified for Class II equipment according to IEC 60601-1.
	To identify a combined input/output connector or mode
	Type BF applied part
	Serial number
	Part number
	For prescription use only
	Temperature limitations
	Humidity limitations
	TÜV Listed, US and Canada. Conforms to UL60601-1. Certified to CAN/CSA C22.2 No.601.1-M90

Symbol	Description
	<p>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.</p> <p>The full text of the European Union RE directive 2014/53/EU declaration of conformity is available at the following internet address: <a href="http://www.sjmglobal.com/euconformity">www.sjmglobal.com/euconformity</a>.</p> <p>This product operates between 9 and 200 kHz with an H-field strength of less than 25 dBµA/m at 10 m.</p>
	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
	<p>Affixed to this device in accordance with European Council Directives 2002/96/EC.</p> <p>These directives call for separate collection and disposal of 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.</p> <p>Return the device to St. Jude Medical at the end of its operating life.</p>
<b>IP21</b>	Ingress Protection Rating. "2" indicates the Merlin@home enclosure is protected against a solid object > 12.5 mm. "1" indicates the enclosure is protected against vertically falling drops of water.
<b>Made in Malaysia</b>	Made in Malaysia

## Technical Information

The Merlin@home™ transmitter is Class II medical equipment and complies with IEC60601-1:2012 and UL60601-1:2012 and CAN/CSA-C22.2 No. 601.1-M90. The Merlin@home transmitter is a Canadian ICES-003 Class B digital apparatus. Operation is subject to the following two conditions: 1) This device may not cause interference, and 2) This device must accept any interference that may cause undesired operation of the device.

### 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.

Table 2. Electrical ratings

Input/Output	Rating
Transmitter input	100-240 VAC, 50-60 Hz
Power consumption (maximum)	350 - 150 mA
Power consumption (standby)	3 VA

Table 3. Storage conditions

Parameter	Condition
Minimum Temperature	-4°F (-20°C)
Maximum Temperature	158°F (70°C)
Maximum Humidity	90%
Minimum Atmospheric Pressure (hPa)	500
Maximum Atmospheric Pressure (hPa)	1060

Table 4. Operating conditions

Parameter	Condition
Minimum Temperature	50°F (10°C)
Maximum Temperature	104°F (40°C)
Maximum Humidity	75%
Minimum Atmospheric Pressure (hPa)	700
Maximum Atmospheric Pressure (hPa)	1060

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 70°C (158°F).

## Transmitter Accessories

Telephone accessories included with the transmitter are (model EX1100 only):

- Telephone cable
- Phone connector

Optional transmitter accessories are:

- Model EX1151 Wireless USB Adapter series
- Model EX1170 Wireless Broadband<sup>1</sup> Kit series<sup>2</sup>

<sup>1</sup> St. Jude Medical is the distributor of products included in the Model EX1170 Wireless Broadband Kit series. The products are CE marked by their respective manufacturers.

<sup>2</sup> You can use an equivalent access point instead of the wireless access point provided in the Model EX1170 Wireless Broadband Kit series. For more information, see Technical Support.

## Note

As with all wireless communications, there is a very small chance that transmitted information might be intercepted. For added security, your transmissions to the secure server are encrypted.

## 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 when used with the cables listed in Transmitter Accessories (page 10).

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.**

**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.**

Table 5. Guidance and manufacturer's declaration - electromagnetic emissions

Test	Compliance	Electromagnetic Environment - Guidance
RF Emission CISPR 11	Group 1	The Merlin@home™ transmitter must emit electromagnetic energy in order to perform its 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 A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) <sup>3</sup>	Electromagnetic Environment - Guidance
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<sup>3</sup> Figures in parentheses are the immunity compliance levels for each test.

Table 6. Guidance and manufacturer's declaration - electromagnetic immunity

Test	IEC 60601 Test Level (Actual Level) <sup>3</sup>	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact (±8 kV contact)  ±15 kV air (±15 kV air)	None
Electrical fast transient/burst IEC 61000-4-4	±2 kV for input/output lines (±2 kV for input/output lines)	None
Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8	30 A/m (30 A/m)	None


Table 7. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level <sup>4</sup>	Immunity Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Merlin@home transmitter, including cables, than the recommended

<sup>4</sup> At 80 MHz and 800 MHz, the higher frequency range applies.



Table 7. Guidance and manufacturer's declaration - electromagnetic immunity (conducted RF and radiated RF)

Test	IEC 60601 Test Level <sup>4</sup>	Immunity Compliance Level	Electromagnetic Environment - Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 Vrms	<p>separation distance.</p> <p><b>Recommended separation distance:</b></p> <p><b>d = 1.2 √P</b></p> <p><b>d = 1.2 √P</b> (80 MHz to 800 MHz)</p> <p><b>d = 2.3 √P</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*, 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></div>

\*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.

**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.

Table 8. Recommended separation distances between portable and mobile communications equipment and the Merlin@home transmitter

Rated maximum output power of transmitter (W)	Recommended separation distance according to frequency of transmitter (m) <sup>5</sup>		
	150 kHz to 80 MHz <b>d = 1.2 √P</b>	80 MHz to 800 MHz <sup>6</sup> <b>d = 1.2 √P</b>	800 MHz to 2.5 GHz <b>d = 2.3 √P</b>
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

## Inductive Telemetry Wand

- RF Transmission – Carrier frequency below 100 kHz (inductive telemetry). The effective radiated power is below the limits as specified in EN 302 195.
- RF Reception – Below 100 kHz (inductive telemetry).

### Note

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

<sup>5</sup> These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

<sup>6</sup> At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.





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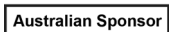
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