

 ST. JUDE MEDICAL



Housecall Plus™
Remote Follow-Up System
Transmitter Model 3180-T

USER'S MANUAL

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Draft (8/27/03)



Housecall PlusTM Remote Follow-Up System

Transmitter Model 3180-T

User's Manual

CAUTION

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

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INTRODUCTION

Your doctor has given you a Transmitter that is part of the St. Jude Medical® Housecall Plus™ Remote Follow-Up System. This booklet describes this system and explains how to set up and use the Transmitter.

What is the Housecall Plus™ System?

When you received your implanted device, your doctor programmed it to suit your individual medical condition. Every so often, your doctor checks it to make sure that everything is still as it should be and to see what has happened since your last follow-up. If you have a defibrillator, your doctor may also want to check it when you report that you have experienced an arrhythmia or have received a shock. Usually you would have to return to the doctor's office or follow-up center for these follow-up sessions, but with your doctor's permission, the Housecall Plus™ Transmitter allows you to conduct routine follow-up sessions remotely. You stay at home while a clinician trained in follow-up reads the data stored in your device over the telephone line.

The Housecall Plus System consists of two components: the Transmitter that you take home with you and the Receiver located in the clinician's office or follow-up center. The Transmitter is shown in Figure 1-1. A description of the Transmitter follows the illustration.

During a follow-up session, the Receiver sends instructions over the telephone line to the Transmitter. The Transmitter then reads the data from your device and sends it to the Receiver. (Your device continues to work normally while the Transmitter reads the data.) Your doctor can use this data to help judge the performance of your device.

During your follow-up session, the **wand** rests over your device and transmits data to the Receiver. You'll also wear **wrist straps**, which read and send additional information about your heart, such as your heart rate.

Opening the *Transmitter Lid* turns the Transmitter on and interrupts normal phone functioning. When you close the lid, the Transmitter turns itself off and returns your telephone to normal function. Closing the lid disconnects the Transmitter (even when the wand or wrist strap wires are outside of the Transmitter).

Lights and beeping sounds let you know what is happening during the follow-up session, so it's important to pay attention to the lights and the beeps throughout the session. For more information on what the lights and beeps mean, see Table 1-1 on page 1-10.

A *speakerphone* has been built into the Transmitter, allowing you to speak with your clinician without using your telephone handset.

The *volume control* allows you to adjust the speakerphone volume.

The *instructions* inside the Transmitter lid provide a quick reminder of how to use the Transmitter.

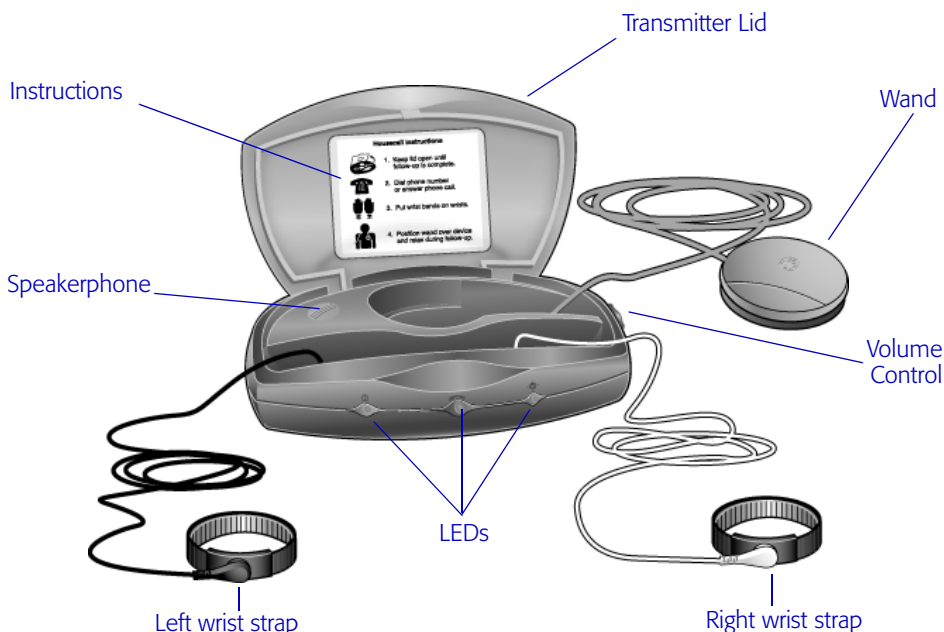


Figure 1-1. The Housecall Plus Transmitter

What Does the Housecall Plus™ Transmitter Do?

During a follow-up session, the Transmitter collects and sends the data stored in your device to the Receiver. This data includes:

- The type and serial number of your device
- The settings for your device
- What has happened since your last follow-up session
- Any electrograms (EGMs) the device has recorded
- An electrogram of your current heart rate and rhythm
- A surface ECG
- Your device's battery status.

How Does the Transmitter Affect Your Telephone?

The Transmitter plugs into your telephone line (see *Setting Up the Transmitter* on page 1-4) and uses the telephone network to transmit data to the Receiver at the clinician's office or follow-up center. As far as your telephone is concerned, this is just like any other telephone call. When the Transmitter is not being used, it is off and the telephone works normally.

You can speak to the clinician using either your telephone handset or the speakerphone that is built inside the Transmitter. However, when the Transmitter is sending data to the Receiver, the speakerphone is disabled. If you need to speak to the clinician while the Transmitter is sending data, use your telephone handset. After you have finished speaking with the clinician, hang up the handset to continue follow-up.

Note In an emergency, you can speak with the clinician. You may hear some noises for several seconds, but after that, the phone line should clear up and you'll be able to hear the clinician.

If someone calls during the follow-up session they will receive a busy signal, just as they would during any other telephone call.

Note If you have Call Waiting and someone calls while data is being sent, Call Waiting will interrupt communication. To prevent this, Call Waiting should be disabled during your follow-up session. For information on how to do that, consult the information on Call Waiting provided by the telephone company.

Before you start transmitting data, someone else may speak to the clinician on an extension telephone. However, ***you must hang up all phones before you begin to transmit data.***

Closing the lid on the Transmitter automatically turns off the Transmitter. If you forget to close the lid on the Transmitter, the Transmitter turns itself off after one hour. Leaving the Transmitter connected to your telephone does not affect your telephone's normal operation. You can still make and receive calls.

Can You Use the Transmitter While Traveling?

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 box. You may want to carry a telephone plug adapter in case you need to plug the Transmitter into an older telephone jack.

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 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.**
- **WARNING! 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. (Refer to *Troubleshooting* on page 1-11 if you suspect that the Transmitter has been damaged.) Contact your clinician for service or replacement instructions.**
 - **Keep the cord away from heated surfaces.**
 - **Do not operate the Transmitter on heated surfaces.**
 - **Never drop or insert any object into any opening.**
 - **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).**
- **KEEP THESE INSTRUCTIONS.**

SETTING UP THE TRANSMITTER

You can use either a push-button or rotary telephone with the Transmitter. The telephone must have a standard (RJ-11 modular) plug that fits the jack on the back of the Transmitter. Your wall telephone jack must also accept a standard plug. If you have an older plug or jack, you can use an adapter that will allow you to use the Transmitter.

Note If your telephone is wired into the wall, you will not be able to use the Transmitter unless you install standard jacks. If you want to do so, contact the telephone company for help.

Note The Transmitter is not compatible with digital phone lines or local PBX telephone systems.

Note Keep the original shipping box in case you need to return the Transmitter for service.

Follow these instructions for setting up the Transmitter. (For diagrams of the telephone-Transmitter connections, see Figure 1-2 and Figure 1-3.)

1. Place the Transmitter on a sturdy, flat surface.

We recommend that you choose a convenient and comfortable spot near a telephone jack and electrical outlet. The wand must rest on your device for several minutes at a time. This will be easier if you are sitting or lying down comfortably. Make sure that the wand reaches you and that you are able to see the lights on the Transmitter.

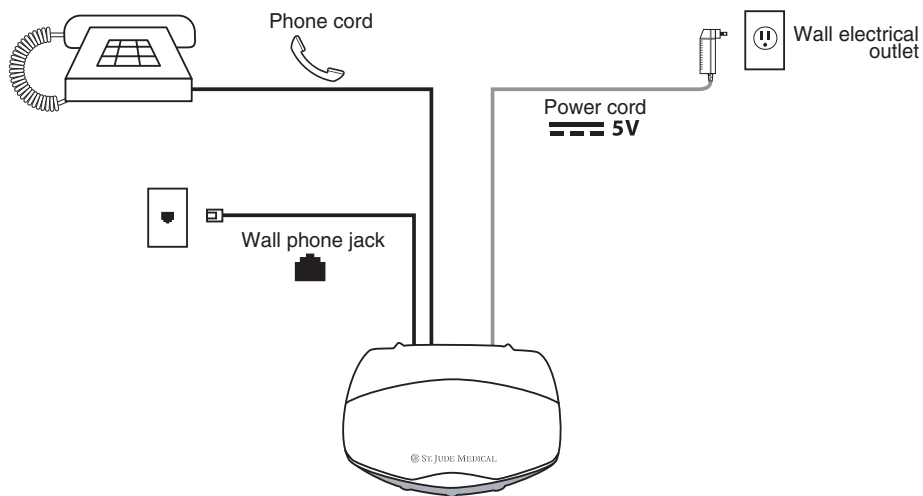


Figure 1-2. Telephone-Transmitter connections without an answering machine

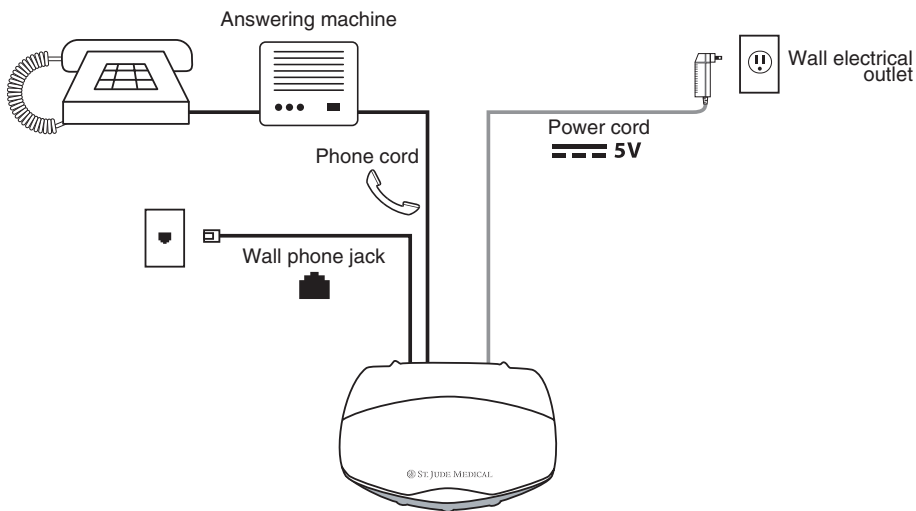


Figure 1-3. Telephone-Transmitter connections with an answering machine

2. Plug your telephone into the jack on the back of the Transmitter (📞).

If you have a telephone answering machine, plug its telephone cord into the telephone jack on the back of the Transmitter. Plug the telephone into the answering machine. The answering machine will operate normally.

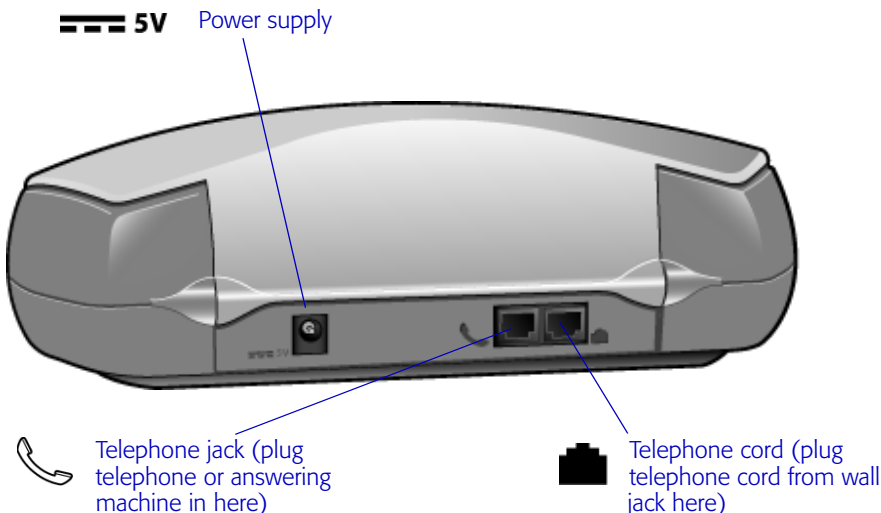


Figure 1-4. The back panel of the Transmitter

3. **Plug the Transmitter's telephone cord into the back of the Transmitter () and then into the wall telephone jack.**
4. **Plug the power supply into the back of the Transmitter ( 5V) and then into the wall electrical outlet.**

The Transmitter tests itself to make sure that everything is working. During this self-test, each of the lights blink one after the other. If the Transmitter passes the self-test, it beeps once and the lights stop blinking and remain off. The Transmitter is now ready to use.

If the Transmitter does not pass the self-test, all of the lights blink at the same time and you will hear a series of double beeps. Unplug the Transmitter from the electrical outlet and plug it in again. If it still does not pass the self-test, contact your clinician. The telephone number is listed on the inside of the Transmitter lid.

5. **Once you have the Transmitter set up, leave it in place. It is not necessary to unplug it or put it away between uses. Simply tuck the wrist straps and wand into their holders and close the lid.**

THE HOUSECALL PLUS™ REMOTE FOLLOW-UP SESSION

The instructions in this section describe how to use the Transmitter during a typical follow-up session. The clinician may give you additional instructions. There is also a quick-reference label inside the Transmitter lid.

Before You Start the Session

1. **Read your follow-up center's follow-up routine before you begin the session. If you have any questions, contact your clinician.**
2. **You will be asked to rest the wand on your device for several minutes. Make sure that during the session you will be able to lie down or sit comfortably and remain still throughout the session.**
3. **The Transmitter communicates with you through a series of flashing lights and beeping sounds. Review Figure 1-5 on page 1-5, which shows the position of the lights on the front of the Transmitter, and Table 1-1 on page 1-10, which describes what the lights and beeps mean and how to respond to them.**
4. **Contact your clinician.**

You can call the clinician or the clinician can call you. *Be sure to keep the Transmitter lid closed until after you make contact with your clinician.*

Once contact has been made with your clinician, open the Transmitter lid, hang up your telephone hand set, and speak to the clinician through the speakerphone.

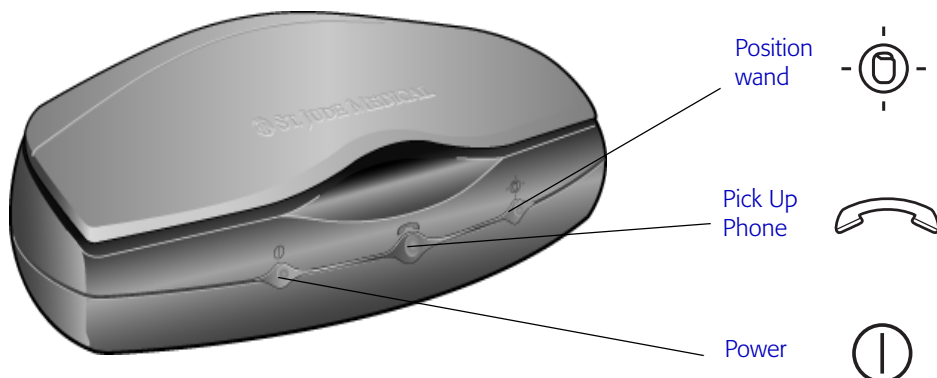


Figure 1-5. The Transmitter's lights

Using the Transmitter

1. **After contacting your clinician, open the lid to turn the Transmitter on.**

Opening the lid turns the Transmitter on. Closing the lid turns the Transmitter off. When you first open the lid, the Power light goes on. If the Transmitter detects an internal problem, all of the lights will blink at the same time and you will hear a series of double beeps. (See *Troubleshooting* on page 1-11.)

2. **When the clinician instructs you to position the wand, position the wand over your device until you see the Position Wand light stop blinking and remain on and you will hear three beeps.**

If the Transmitter lid is open and you are speaking on the phone with the clinician, you won't hear any other sounds

If the Transmitter lid is closed, you will hear one beep every 10 seconds during the interrogation.

3. **The solid light means the wand is positioned correctly. Remove your hand and allow the wand to rest on your device. (The wand has a textured surface that will help to hold it in place.)**

You can position the wand by laying on your back and resting the wand on your device or by sitting up, draping the wand around your neck and resting it on your device, as shown in Figure 1-6.

The wand will work through a thin shirt. If your clothing is thick or if you have trouble getting the wand to communicate with the device, place the wand against your skin.



Figure 1-6. Positioning the wand (seated)

4. Remove the wrist straps from their cradle and put them on your wrists.

The strap with the white cord goes on your right wrist and the strap with the black cord goes on your left wrist. The wrist straps must rest securely on your wrist, so if the wrist straps feel too loose, push them up slightly on your arm until they are secure.

5. The clinician will tell you when data collection begins. Relax while the Transmitter collects the data from your device. Continue to watch and listen to the Transmitter for instructions from the clinician.

You will hear low beeping sounds every 10 seconds coming from the Transmitter throughout the session. Table 1-1 on page 1-10 describes what these lights and beeps mean and how to respond to them.

You cannot use the speakerphone at the same time the data is being collected, so if you need to speak to the clinician while the Transmitter is sending data, use your telephone handset.

Note When you pick up your telephone handset to speak with the clinician, you may hear some noises for several seconds. After that, the phone line should clear up and you'll be able to hear the clinician.

The time required to collect data can vary, depending on the amount of data that is stored in the device memory. This may take several minutes. If communication is disrupted, data collection must start again. This means that data collection may take longer than expected.

6. If the Pick Up Phone light blinks and the Transmitter rings three times, it means the clinician wants to speak with you. You can speak with him or her using either your telephone handset or through the speaker-

phone in the Transmitter. Hang up the phone after you are done speaking with the clinician.

The Transmitter alerts you when the clinician needs to speak with you. He or she may want to collect more data or give you additional instructions. The clinician will let you know when the follow-up session is finished.

7. **When the follow-up session is finished, hang up the telephone and store the wand and wrist straps inside the Transmitter. Close the lid to turn off the Transmitter.**

Lights		Sound	What It Means	What To Do
All lights OFF		No sound	If the Transmitter's lid is closed, the Transmitter is not powered on. If the Transmitter's lid is open, it is in standby mode.	If not in use, this is OK. Otherwise, (1) check the power source and cables for correct installation and (2) make sure the lid is open.
Power Pick Up Phone Position Wand	OFF OFF OFF	No sound	Transmitter power is on and ready.	Wait for clinician's instructions.
Power Pick Up Phone Position Wand	ON OFF BLINKING	Continuous series of three beeps	Transmitter is trying to locate the device. The wand is not in the correct position or has moved out of the correct position.	Move wand over your device. When the Transmitter locates the device, the Position Wand light will remain on and you'll hear three slow beeps.
Power Pick Up Phone Position Wand	ON OFF ON	No sound	The Transmitter has located your device and wand is in the correct position.	Wait for clinician's instructions.
		Continuous beep at 10 second intervals	Transmitter has located your device and is retrieving data.	Follow-up is in progress and clinician will contact you when it is completed.

Table 1-1. Transmitter's lights and sounds

Lights		Sound	What It Means	What To Do
Power Pick Up Phone Position Wand	ON BLINKING ON or OFF	Transmitter rings three times	Clinician wants to speak with you.	Use the speakerphone or your telephone handset to listen to the clinician's instructions.
All lights BLINKING		Continuous series of double beeps	Transmitter did not pass the self-test or some other type of error occurred while in session.	Unplug the Transmitter's power cord and plug it in again. If the self-test does not pass or an error occurs again, contact your clinician.

Table 1-1. Transmitter's lights and sounds

TROUBLESHOOTING

This section lists some of the problems you may encounter when using the Transmitter and how to solve them. If you have tried these suggestions and the Transmitter still does not work, contact your clinician. The telephone number is listed on the inside of the Transmitter lid.

- No lights go on when you open the lid.**

Cause: No power is reaching the Transmitter or it is not turned on.

To correct the problem: Open up the lid and make sure that the power cord is plugged in to both the wall outlet and the back of the Transmitter. Close the Transmitter lid and open it again.
- All of the lights blink continuously and you hear a series of double beeps.**

Cause: The Transmitter has failed the self-test of its software and circuits.

To correct the problem: Unplug the Transmitter from the electrical outlet and plug it in again. If all of the lights still blink continuously, contact your clinician.
- The Position Wand light is blinking and you hear a continuous series of three beeps.**

Cause (1): The wand is out of position. It cannot read the data from your device.

To correct the problem: Move the wand over the device until the Position Wand light stops blinking. Remove your hand and allow the wand to rest on your device. If you are wearing heavy clothing, place the wand against your skin.

Make sure that there are no sources of electrical interference in the area (for example, television sets, computer monitors, fluorescent lights, etc.). If there are, turn them off or move the Transmitter and wand farther away from them.

Cause (2): The telephone connection has been interrupted.

To correct the problem: Close the Transmitter lid. The clinician will then call you back and instruct you on what to do next. When you see the Pick Up Phone light blink and you hear the Transmitter ring three times, you need to speak with your clinician. Use either your telephone handset or the Transmitter's speakerphone to listen to your clinician's instructions. It's important to follow all of the instructions your clinician gives you.

CARING FOR THE TRANSMITTER

If necessary, you can clean the outside of the Transmitter with a damp cloth and a mild detergent. *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 your clinician. He or she will send you a replacement Transmitter.

GLOSSARY

Clinician — The highly trained individual who operates the Receiver and conducts the follow-up session.

Data — The information stored in your device. The information includes the type and serial number of your device, the settings for your device, an account of what has happened with the device since your last follow-up session, and any electrograms (EGMs) the device has recorded.

Defibrillator — A type of device, also known as an *ICD* (implantable cardio-verter-defibrillator), that uses electrical impulses to treat life-threatening ventricular tachyarrhythmias.

Device — Also known as a pulse generator. There are two types of devices, a defibrillator (or ICD) or a pacemaker.

Electrogram (EGM) — Often called an *electrocardiogram*, *EKG*, or *ECG*. An electrogram is a record of the electrical currents produced by the heart.

Follow-up session — A check-up during which your doctor looks at the settings of your device as well as the reports of any events that may have occurred since the last check-up.

Instruction label — A label on the inside of the Transmitter lid that provides a quick reminder of how to use the Transmitter.

Pacemaker — A type of device that uses electrical impulses to control heart rate.

Pulse Generator— Also known as a device. There are two types of pulse generators, a defibrillator (or ICD) or a pacemaker.

Receiver — The part of the Housecall Plus™ System located in the clinician's office or follow-up center. The Receiver sends instructions to the Transmitter and receives the data that the Transmitter reads from your device.

Speakerphone — The speakerphone built into the Transmitter is a combination microphone and speaker device that allows you to speak with your clinician without using your telephone handset.

Transmitter — The part of the Housecall Plus System that reads the data in your device and sends it to the Receiver.

Wand — The part of the Transmitter that rests on your device and reads the data that is sent to the Receiver.

Wrist straps—The wrist straps contain electrodes that measure your heart activity. This data is then sent through the Transmitter to your clinician and is recorded as part of your follow-up session.

TECHNICAL SUPPORT

If you have any trouble using the Transmitter or have any questions regarding its use or maintenance, contact your clinician.

FCC INFORMATION

This equipment complies with Part 68 of FCC rules. On the bottom of this equipment is a label that contains, among other information, the FCC registration number and Ringer Equivalence Number (REN) for this equipment. If requested, provide this information to your telephone company.

The REN is useful in determining the number of devices you can connect to your telephone line and still have all those devices ring when your number is called. In most, but not all areas, the sum of the RENs of all devices should not exceed five. To be certain of the number of devices you can connect to your line, as determined by the REN, you should contact your local telephone company to determine the maximum REN for your calling area.

If your Transmitter causes harm to the telephone network, the telephone company may discontinue your service temporarily. If possible, they will notify you in advance.

If advance notice isn't practical, you will be notified as soon as possible. You will be advised of your right to file a complaint with the FCC.

Your telephone company may make changes in its facilities, equipment operations, or procedures that could effect the proper operation of your equipment. If they do, you will be given advance notice so as to give you an opportunity to maintain uninterrupted service.

If you experience trouble with your Transmitter, please contact your clinician for repair/warranty information. The telephone company may ask you to disconnect this equipment from the network until the problem has been corrected or you are sure that the equipment is not malfunctioning.

The Transmitter does not contain any user-serviceable parts.

This equipment may not be used on coin service provided by the telephone company. Connection to party lines is subject to state tariffs. (Contact your state public utility commission or corporation commission for information.)

Caution *Per FCC Rules, changes or modifications of the Housecall Plus™ Transmitter not approved by St. Jude Medical could void your right to operate the Housecall Plus 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.

WARRANTY

St. Jude Medical warrants that for a period of three years following delivery to the original purchaser, the Housecall Plus™ 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 three 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. 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.

ADDITIONAL TECHNICAL INFORMATION

Electrical Rating

Input/Output	Rating
Transmitter Input	5V  , 1 Amp
Power Supply Input	100 - 240 V~, 50 - 60 Hz, 400 MA
Power Supply Output	5V  , 2.4 Amp

Table 2. Electrical Ratings

Storage Conditions

Property	Storage
Minimum Temperature	-4° F (-20° C)
Maximum Temperature	+131° F (+55° C)
Maximum Humidity	90%

Table 1-1. Storage conditions

Symbols

Definitions of globally recognized hardware and packaging symbols required regulatory authorities are described below.

Symbol	Description
	Attention, consult accompanying documents.
	Class II equipment. Meets safety requirements specified for Class II equipment according to IEC 60536.
	Defibrillation-proof type CF applied part. Complies with IEC 60601-1.
	Direct current. Equipment is suitable for alternating current only; identifies relevant terminals.
	Non-ionizing electromagnetic radiation. Indicates elevated, potentially dangerous levels of non-ionizing radiation.

Table 1-2. Symbols



15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

SE-175 84 JÄRFÄLLA
Sweden
+46 8 474 4000

701 E. Evelyn Avenue
Sunnyvale, CA 94086 USA
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