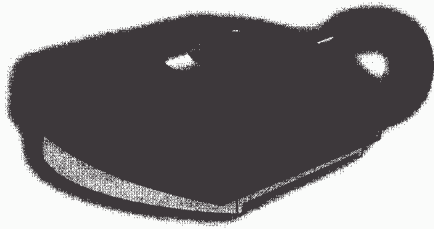


 Ventritex®



USER'S MANUAL

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**Housecall™ Transtelephonic
Follow-up System**
Model TR-3000
Transmitter

December, 1998



CAUTION: Federal (U.S.A) law restricts this device to sale by or on the order of a physician with appropriate training.



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Introduction

Your doctor has given you a Transmitter that is part of the Ventritex™ Housecall™ System. This booklet describes this system and explains how to set up and use the Transmitter.

What is the Ventritex Housecall System?

When you received your Ventritex™ defibrillator, 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. He or she may also want to check it when you report that you have experienced an arrhythmia or have received a shock from the defibrillator. Usually, you would have to return to the doctor's office for these follow-up sessions. With your doctor's permission, however, the Housecall System allows you to conduct routine follow-up sessions remotely. You stay home while a trained person—the monitor—reads the data stored in your defibrillator.

The Housecall System consists of two components: the Transmitter that you take home with you and the Receiver located in the monitor's office. The Transmitter is shown in Figure 1. A description of the parts of the Transmitter follows the illustration.

The Receiver is located in the monitor's office. During a follow-up session, it sends instructions over the phone line to the Transmitter. The Transmitter then reads the data from your defibrillator and sends it to the Receiver. Your doctor can look at this data to help judge the performance of your defibrillator.

Your defibrillator continues to work normally while the Transmitter reads the data.

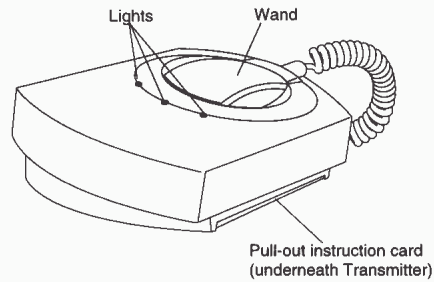


Figure 1. The Housecall Transmitter

During a follow-up session, you hold the *wand* over your defibrillator to transmit data to the Receiver.

The *power button* is located under the wand. When you lift the wand, the Transmitter turns itself on. When you replace the wand, the Transmitter turns itself off.

The *lights* let you know what is happening. Be sure to pay attention to the lights throughout the procedure.

The pull-out *instruction card* underneath the Transmitter provides a quick reminder of how to use the Transmitter.

What Does the Housecall System Do?

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

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

- Any electrograms (EGMs) the defibrillator has recorded
- An electrogram of your current condition

How Does the Transmitter Affect Your Phone?

The Transmitter plugs into your phone line and uses the telephone network to transmit data to the Receiver. As far as your phone is concerned, this is just like any other phone call. The cost of the phone call is the same as a normal phone call. When the Transmitter is not being used, it is off and the phone works normally.

During most of the session, you will be able to speak to the monitor using the telephone. However, when the Transmitter is sending data to the Receiver, the telephone is disabled. If you need to speak to the monitor while the Transmitter is sending data, pick up the phone and place the Transmitter wand in its cradle.

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

If you have Call Waiting and someone calls while data is being sent, Call Waiting will interrupt communication. To prevent this, disable Call Waiting 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, it is all right if someone else speaks to the monitor on an extension phone. However, when you begin to send data, that person should hang up. Only the phone connected to the Transmitter should be off the hook.

Replacing the wand in the cradle automatically turns off the Transmitter. If you forget to place the wand in the cradle, the Transmitter will turn itself off after 60 minutes. Leaving the

Transmitter on does not affect your phone. 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 phone plug adapter as described on page 6 in case you need to plug the Transmitter into a 4-pin 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 electrocution:

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

WARNING—To reduce the risk of burns, electrocution, fire, or injury to persons:

1. Supervision is necessary when the Transmitter is used by, on, or near children.

2. Use the Transmitter only for its intended use as described in this manual. Do not use attachments not recommended by St. Jude Medical Cardiac Rhythm Management Division (CRMD).
3. Never operate the Transmitter if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or if it has been dropped into water. Tell the monitor about the problem and return the Transmitter to St. Jude Medical CRMD for service or replacement.
4. Keep the cord away from heated surfaces.
5. Never drop or insert any object into any opening.
6. 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 phone with the Transmitter. Most cordless phones will also work. However, we recommend that you do not use a digital spread-spectrum cordless phone. These phones may cause the Transmitter to malfunction. The phone must have a standard (RJ-11 modular) plug that fits the jack on the back of the Transmitter. Your wall phone jack must also accept a standard plug. If you have the older, 4-pin plugs and jacks, you can use an adapter that will allow you to use the Transmitter. (See Figure 2 for examples of the plugs and adapters.) 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, call the telephone company for help.

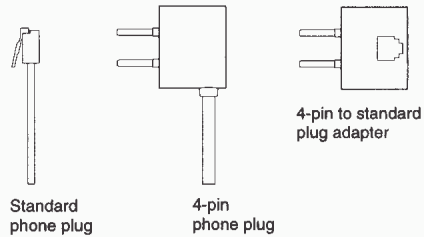


Figure 2. Phone plugs and adapter

Follow these instructions for setting up the Transmitter. For diagrams of the telephone-Transmitter connections, see pages 8 and 9.

Please keep the original shipping box in case you need to return the Transmitter for service.

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

We recommend that you choose a convenient spot near a telephone jack, an electrical outlet, and a chair. You will be asked to hold the wand steady over your defibrillator for several minutes at a time. This will be easier if you are seated comfortably. Make sure that the wand reaches the chair and that you are able to see the lights.

Once you have set the Transmitter up, leave it in place. Do not unplug and put it away between uses.

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

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

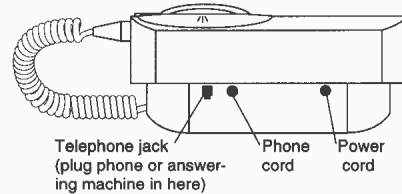


Figure 3. The back panel of the Transmitter

3. Plug the Transmitter's phone cord into the wall telephone jack.

4. Plug the transformer end of the power cord into the wall electrical outlet.

The Transmitter tests itself to make sure that everything is working. During the self-test, each of the lights blink one after the other. If the Transmitter passes the self-test, 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 and the Transmitter beeps. Unplug the Transmitter from the electrical outlet and plug it in again. If it still does not pass the self-test, tell the monitor.

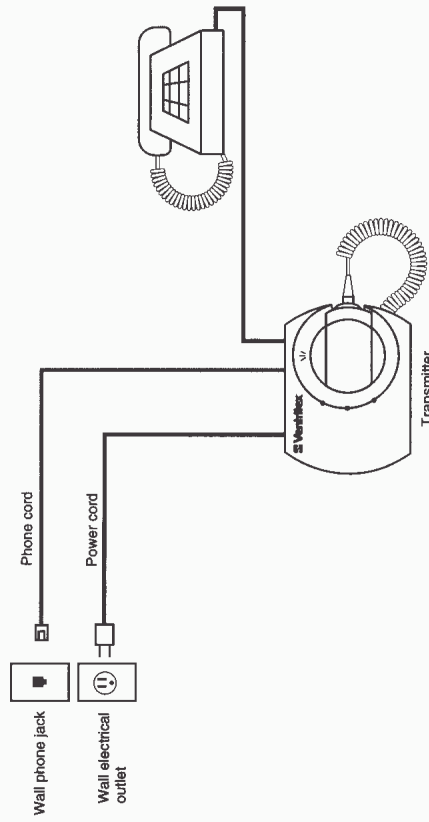


Figure 4. Telephone-Transmitter connections without an answering machine

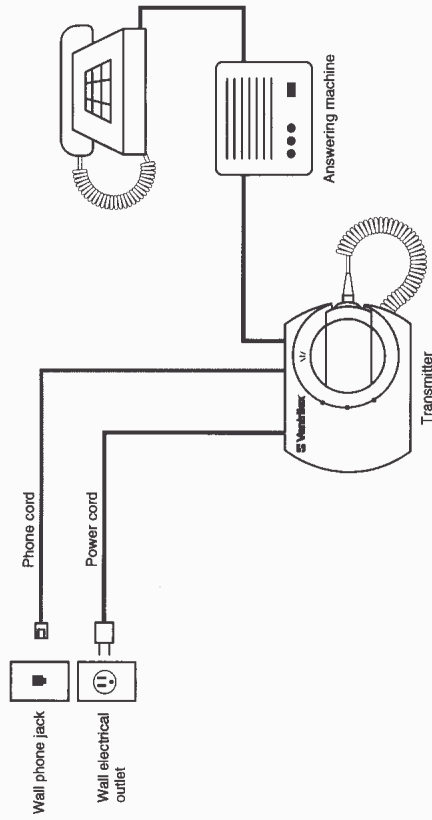


Figure 5. Telephone-Transmitter connections with an answering machine

Using the Transmitter

The instructions in this chapter describe how to use the Transmitter. The monitor may give you additional instructions. There is also a slide-out quick-reference card under the base of the Transmitter.

Before you start, make sure you are seated comfortably. You may be asked to hold the wand steady over your defibrillator for several minutes.

1. To begin the session, make contact with the monitor by phone.

You can call the monitor or the monitor can call you.

2. Lift the wand to turn the Transmitter on.

Lifting the wand turns the Transmitter on. Replacing the wand turns the Transmitter off. When you first lift the wand, the Power light goes on. If the Transmitter detects an internal problem, all of the lights will blink. Figure 6 shows the position of the lights.

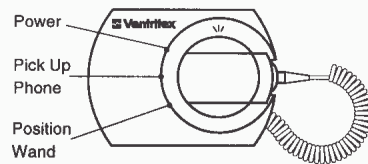


Figure 6. The Transmitter's lights

3. When the Position Wand light blinks, place the wand over your defibrillator and hold it steady. DO NOT HANG UP THE PHONE. Watch the Position Wand light on the Transmitter.

When the wand is in the correct position, the Position Wand light stops blinking and remains on.

If the wand is in the wrong spot, the Position Wand light continues to blink . Move the wand slowly until the light stops blinking, then hold the wand steady.

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 defibrillator, place the wand against your skin.

If it takes more than 45 seconds to find the right spot for the wand, the Transmitter sounds a long beep and the Position Wand light goes off. The monitor will tell you what to do next.

When the wand is in the right position, the data collection can begin. The Position Wand light stops blinking and stays on. The Transmitter stops beeping.

The monitor will tell you when data collection begins. The Transmitter beeps while it collects the data. You will not be able to speak to the monitor during collection.

If the wand moves out of position during data collection, communication stops. The Position Wand light blinks and the Transmitter beeps. Move the wand slowly until the light stops blinking. Hold the wand steady. If it takes more than 20 seconds to find the right spot for the wand or if the transmission is interrupted, the Pick Up Phone light blinks and the Transmitter makes a ringing sound. Pick up the phone and follow the monitor's instructions.

Collecting data usually takes less than a minute. Sometimes, though, the monitor may want to retrieve electrograms (EGMs) stored in the defibrillator. This may take two to three minutes.

NOTE: If communication is disrupted, the data collection must start again. This means that data collection will take longer than expected.

4. When the Pick Up Phone light blinks, pick up the phone and talk to the monitor.

The Transmitter rings three times to alert you to pick up the phone.

The monitor may want to collect more data. Follow his or her instructions. The monitor will let you know when the follow-up is finished.

5. When the follow up session is finished, hang up the phone. Place the wand in its cradle to shut off the Transmitter.

Troubleshooting

This section lists some 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, tell the monitor.

No lights go on when you pick up the wand.

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

Action: Make sure that the power cord is plugged in. Place the wand back in the cradle and pick it up again.

All of the lights blink continuously.

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

Action: Unplug the Transmitter from the electrical outlet and plug it in again. If all of the lights still blink continuously, tell the monitor.

The Position Wand light is blinking.

Explanation: The wand is in the wrong position. It can not read the data from your defibrillator.

Action: Move the wand until the Position Wand light stops blinking. Please hold the wand steady. If you are wearing heavy clothing, place the wand against your skin. Pressing down gently to decrease the distance between the wand and the defibrillator may also help.

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 set the Transmitter up farther away from them.

Make sure that the wand is at least six inches from the body of the Transmitter.

If you can't find the right position, the Pick Up Phone light blinks. Pick up the phone and follow the monitor's instructions.

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, tell the monitor. He or she will call St. Jude Medical CRMD and arrange for us to send you a replacement Transmitter.

Glossary

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

Defibrillator—also known as a pulse generator or an ICD (implantable cardioverter-defibrillator).

Electrogram (EGM)—often called electrocardiogram, EKG or ECG, it 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 defibrillator as well as the reports of any events that may have occurred since the last check-up.

Instruction Card—a card stored underneath the front of the Transmitter that pulls out to provide a quick reminder of how to use the Transmitter.

Monitor—the trained technician who operates the Receiver and conducts the follow-up procedure.

Receiver—the part of the Housecall System located in the monitor's office. The Receiver sends instructions to the Transmitter and receives the data that the Transmitter reads from your defibrillator.

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

Wand—the part of the Transmitter that you hold over your defibrillator.

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 (R.E.N.) for this equipment. If requested, provide this information to your telephone company.

The R.E.N. 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 R.E.N.'s of all devices should not exceed five (5). To be certain of the number of devices you can connect to your line, as determined by the R.E.N., you should call your local telephone company to determine the maximum R.E.N. 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 St. Jude Medical Cardiac Rhythm Management Division (CRMD) in the U.S.A. at 800-546-1213 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.

There are no repairs that can be made by the customer to the Transmitter.

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 Transmitter not approved by St. Jude Medical CRMD could void your right to operate the Housecall 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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Limited 90 Day Warranty for the Housecall Transmitter

St. Jude Medical Cardiac Rhythm Management Division (CRMD) warrants that for a period of 90 days following delivery to the original purchaser, the Housecall 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 CRMD, usage not in accordance with product instructions, failure to perform required preventive maintenance, abuse, and misuse.

During the 90 day warranty period, St. Jude Medical CRMD will repair or replace a malfunctioning Transmitter if it is returned to St. Jude Medical CRMD. To qualify for such repair or replacement, St. Jude Medical CRMD must be notified within 30 days of the malfunction and, if so directed by St. Jude Medical CRMD, the purchaser must return the Transmitter for repair or replacement. If warranty service is required, St. Jude Medical CRMD will issue a Return Material Authorization Number. You must ship the product back to St. Jude Medical CRMD in their 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 CRMD will ship the repaired or replacement Transmitter to you, freight prepaid.

If St. Jude Medical CRMD 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 CRMD 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 CRMD 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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