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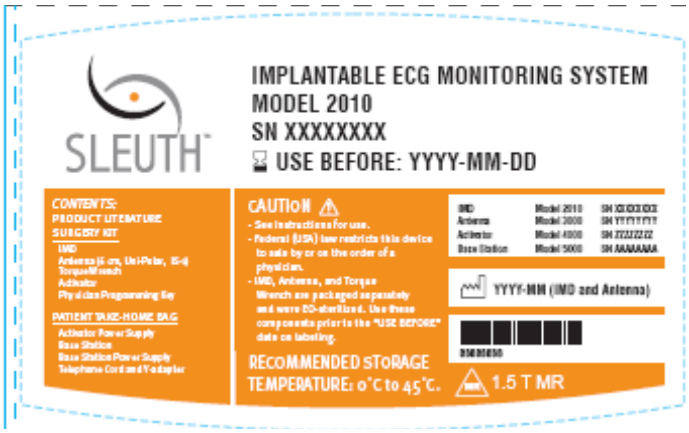
Note: The Activator and Base Station are the property of Transoma Medical and must be returned to either your follow-up doctor or the company following use.

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



FCC ID: UFYTSIM2010
IC:XXXX-TSIM2010

This device complies with Part 15 of the FCC Rules and RSS210 of the Industry Canada Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

The above label information will be located in the instruction manual given to the patient.

Understanding Your Condition

This section provides a brief explanation of common conditions that an implanted electrocardiogram (ECG, also known as an EKG) monitoring system is designed to monitor. Abnormal heart rhythms can be life-threatening if they are not assessed and identified by a trained health care professional. Most arrhythmias fall into one of two main categories:

- ***Bradycardia*** is an abnormally slow or unsteady heart rhythm (usually less than 60 beats per minute) that may be accompanied by symptoms such as fainting, dizziness, lethargy, and shortness of breath.
- ***Tachycardia*** is an excessively fast heart rhythm (usually greater than 100 beats per minute) that may result in fibrillation, where the heart beats so rapidly that it simply "quivers." Fibrillation is the uncoordinated contraction of the heart muscle that results in a lack of synchronization between the atria (upper heart chambers) and the ventricles (lower heart chambers). Tachycardia may be accompanied by symptoms such as fainting, dizziness, feeling the heart beat (palpitations), chest discomfort or pain (angina), and shortness of breath.

Arrhythmias can also occur ***without*** such clear symptoms as those described above. There may be only subtle indicators of an underlying heart condition. Ask your doctor for more information about treatment for abnormal heart rhythms and what you can do to help in the diagnosis of your condition.

Your Implantable ECG Monitoring System

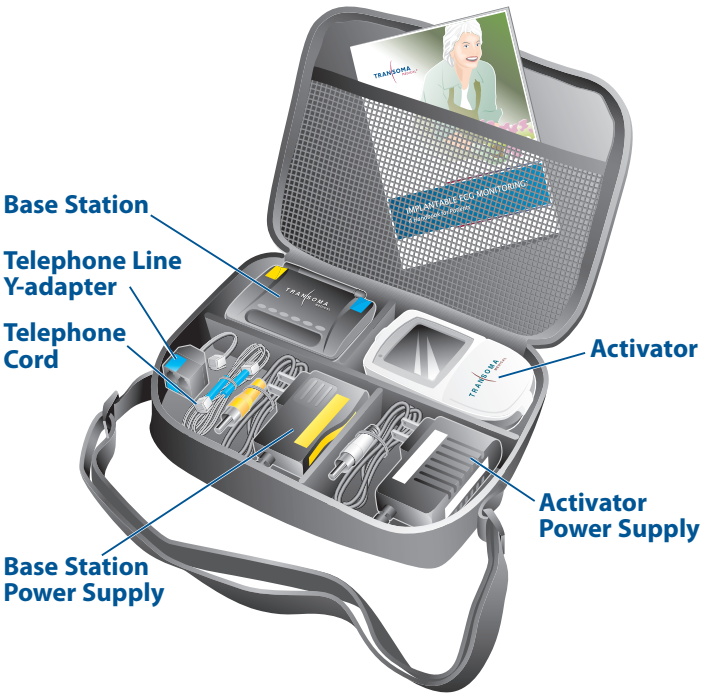
Your doctor has determined that an implanted ECG monitoring system will provide additional information needed to assess and diagnose your condition. The ECG monitoring system is for diagnostic purposes only and does **not** provide treatment of any kind. The implantable monitoring device (IMD) continuously monitors the electrical activities of your heart. The IMD is one component in a system that consists of implanted and external components.

When the IMD sends information to the Activator, the data are securely transmitted from the Activator to the Base Station. The Base Station sends the information over phone lines to a secure database for evaluation by your doctor.

If the Activator is not within range of the Base Station (approximately 30 feet), the information is stored for later transmission.

Patient Take-Home Bag Components

The components of the monitoring system are provided in a Patient Take-Home Bag for you to set up and use at home.



Patient Take-Home Bag

Note: Prior to implant, your doctor or nurse should have discussed the implant procedure, risks and benefits, the need for access to a phone line for connection to the Base Station, system setup, and Activator use and charging requirements.

Note: You must set up the monitoring system components at home for the ECG monitoring system to operate.

Setting Up the Monitoring System at Home

It is vitally important that you set up and activate the external system components, because the monitoring system is not operational until these tasks are complete. To set up the monitoring system, complete the following steps:

1. Set up the Base Station (for example, near a nightstand or other centrally located position) so that it will be within 30 feet of you most of the time when you are at home.
2. Plug the yellow Base Station power supply into the yellow Base Station port and a wall outlet.
3. Plug the telephone line Y-adapter into the telephone wall outlet.
4. Plug the blue telephone cord into the blue Base Station port and the blue Y-adapter port.
5. If desired, use the other Y-adapter port to connect your phone.
6. Plug the white Activator power supply into an AC wall outlet near your nightstand so the Activator can charge while you sleep.

Note: If you experience uncomfortable or painful symptoms, call 9-1-1 or your doctor immediately. The monitoring system should not be used as a replacement for calling 9-1-1 in case of an emergency. If there is no dial tone, hang up the receiver, and then pick it up again. You should hear a dial tone.

The Activator also automatically stores and transmits ECG information (data within criteria that your doctor specifies as well as periodic checks of your heart rhythm) to a secure database to aid your doctor in the diagnosis of your condition.

If you are too far away from the Base Station (such as when you are away from the house), the Activator will store ECG information and automatically transmit it when you return home and are again in range of the Base Station.

When You Press the Activate Button
After you press the ***Activate*** button, the IMD continues to record another two minutes of ECG data. Keep your Activator near you during activation, and you will see a status bar. A communication dish may appear indicating data transfer to the Activator or Base Station. When the "Activation Complete" message appears, the data have either been sent to the secure database or will be sent when your Activator is within range of the Base Station.

Charging the Activator

A battery icon in the upper right corner of the Activator display shows the Activator battery charge status from fully charged to a low battery.

When the Activator battery is low, a message states "Charge Battery" as a reminder. If the Activator battery becomes too low, the display does not come on. During normal use, you should charge the Activator each evening. Use only the Activator power supply included in the Patient Take-Home Bag to charge the Activator.

The light-emitting diode (LED) is amber when the Activator battery is charging and turns green when the battery is fully charged. If the Activator is charged while close to the Base Station, any stored information will be transmitted daily.

Airplane Mode

The Activator is a radio communication device and should be set to Airplane Mode before airplane take-off. Press the button to temporarily disable radio communication and mute sounds. A message appears on the Activator display confirming that the Activator is in Airplane Mode. (This message remains on the display until the Activator returns to normal operation.) To return the Activator to normal operation, press the button again.

Turning Activator Sounds On and Off

The Activator has sounds that you can mute for up to 24 hours at a time. Press the  button to temporarily mute sounds. A message appears on the Activator display confirming that sounds have been muted. To restore sounds, press the  button again.

ECG Events Without Symptoms

Sometimes, your heart rhythm may speed up or slow down even though you do not experience any other symptoms. In this case, one minute of ECG data is automatically stored in the IMD. The data are later uploaded to the Activator, which then transmits the information to a secure database for evaluation by your doctor.

Backlight

The display backlight turns on fully when you open the keypad cover and turns to low when you close the cover or if you press no buttons for a period of time.

Telephone Priority

The Activator attempts to download any data within two minutes of your pressing the green ***Activate*** button. However, if someone picks up the telephone receiver, the Activator does not continue the download, and the phone will be available for emergency use. If there is no dial tone, hang up the receiver, and then pick it up again. You should hear a dial tone. The Activator will retry sending the information until the data have been sent.

Care and Cleaning

Use care when handling the Activator and Base Station. Do not drop, damage, or submerge these components in liquid of any kind. If you need to clean your Activator or Base Station, use a soft, damp cloth. Do not use bleach or harsh detergents to clean these components.

When You Travel

The memory capacity of the Activator allows you to take it (and the Activator power supply) with you when you travel. However, if you are planning to be away from your home (where the Base Station is set up) for more than two weeks, take the entire monitoring system with you.

If traveling by plane, set the Activator to Airplane Mode before take-off. Turn Airplane Mode off when you have exited the plane at your destination.

Your Patient Identification Card

You will receive a patient identification (ID) card before leaving the hospital. (It should be in an outside pocket of the Patient Take-Home Bag.) Always carry your patient ID card so that you can present it to security personnel at airports or other facilities that use metal detectors or antitheft devices. Carry it with you at all times until the implanted components are removed.

Important Monitoring System Tips

Follow these tips to ensure that you and your doctor get the most from your monitoring system:

- ALWAYS take your Activator with you, even if you do not intend to be away from home for long.
- Keep your Activator near you (within approximately ***three feet***) at all times. (For example, do not leave it at home or in your car.)
- Charge your Activator every evening.
- Make sure your Activator is close to the Base Station so that it can transmit stored information daily. (For example, charge the Activator within 30 feet of the Base Station.)
- Understand how to mute sounds (for example, in a movie theater).
- Know how and when to use Airplane Mode.
- Ensure that your spouse, family, or caregiver knows how to operate the Activator in case of an emergency.

Error and Information Messages

The following tables show the error and information messages that the Activator displays. Note the following:

- If the Activator display remains blank for more than 10 seconds, plug the Activator in to recharge it.
- If the display is still blank after you connect the Activator to the Activator power supply, contact Transoma Medical.
- Do not press the ***Activate*** button if the Activator display is blank. Contact Transoma Medical for assistance.

Error Messages

Display Text	Information
Battery Low: Charge battery	Plug the Activator power supply into a wall outlet, and then connect the Activator to the Activator power supply.
Activation Failed: Move closer and retry	(LED flashes amber.) Move the Activator closer to the IMD, and press the ***Activate*** button again.
No Data in 24 Hours: Keep your Activator within reach	(LED flashes amber.) If this message appears, it will be accompanied by an audible alarm that repeats for 10 seconds every hour. The message stays visible until the Activator is moved to within 6.5 feet of the IMD and data are received.
Activator Memory Full: Keep Activator near base for up to 45 min.	(LED flashes amber.) When the Activator memory is full, the Activator attempts to connect and download once every five minutes. Move the Activator within 30 feet of the Base Station, and keep it there for 45 minutes or until the message no longer appears.
Activator Failed: Contact Service Center	Call Transoma Medical for instructions.

Information Messages

Display Text	Information
Muted for up to 24 hours • Sound 	Sounds have been muted (automatically restores audible sounds after 24 hours). Pressing the button again restores sound. (Sound message appears.)
Airplane Mode Radio Disabled 	Sounds and radio communication have been disabled (automatically restores normal operation after 24 hours). This message remains on the display. No activation is possible in this mode. Pressing the button again removes the message and restores normal operation.
Charging…	(LED is amber.) Shows a plug and charging battery, indicating progress; when charging is complete, the LED turns green.
Activation in Progress…	The IMD has received the signal to capture ECG data and is preparing the data for transmission to the Activator.
Communicating…	ECG data are being transmitted either from the IMD to the Activator or from the Activator to the secure database through the Base Station.
Activation Complete	The Activator shows this message after the ECG data have been stored on the IMD.

Frequently Asked Questions

Q Will my device be affected by security gates used at an airport or retail store?

A Do not linger near security gates, because your implantable device may trigger the security system. Display your patient ID card to security personnel to indicate that you have an implantable medical device.

Q Is it okay to accidentally press the Activate button or press it when I have no symptoms?

A Yes. However, you should not press the ***Activate*** button unless you feel symptoms or your doctor has instructed you to do so, because doing so could reduce the battery life of your implanted device.

Q Do I need to contact you if I move, change phone numbers, or change doctors?

A Yes. Please contact Transoma Medical as soon as possible at the telephone number shown on the back cover of this handbook to update your information.

Other Considerations

Dental and Medical Procedures

ALWAYS inform health care personnel treating you that you have an implanted medical device. Some medical procedures may affect the operation of your implanted monitoring system components while they are in use. Other procedures, such as therapeutic radiation, can permanently affect implanted components. For more information, ask your doctor to phone the number on your patient ID card.

MR, X-rays, Fluoroscopy, and External Monitors

The IMD will function normally after but possibly not during magnetic resonance (MR) imaging at 1.5 T, normal diagnostic x-rays, and fluoroscopic procedures. The IMD is known to produce MR-image artifacts (e.g., voids or shadows). Always inform health care personnel treating you that you have an implanted medical device. The IMD and Activator ***will not affect*** and ***are not affected by*** ambulatory ECG monitors or automated blood pressure cuffs.

Operating Temperatures

The Activator is designed to work at temperatures of 32–104°F.

Cellular Phones, Household Appliances, and Tools

 Radio-frequency (RF) transmitter

Although your ECG monitoring system has been tested for compatibility with common household appliances, immunity from interference with cellular telephones, wireless routers, electromagnetic devices, or strong magnetic fields cannot be guaranteed.

To minimize the possibility of interaction between a cellular telephone and your implanted device, keep cellular telephone antennas 6–12 inches away from the implant site.

To further safeguard against any interruption in operation, hold your cellular telephone to the ear opposite the implanted device. Do not carry your cellular telephone in your breast pocket—even when the telephone is off.

Wireless Routers

Position the Base Station so that it is at least 10 feet away from wireless routers.

Implanted IMD with Antenna

Immediately following surgery, you may be aware of your implantable device and have an urge to touch the implant site. Resist manipulating the device—a problem known as Twiddler's Syndrome, in which patients "twiddle," or play with, their implanted device. Twiddler's Syndrome can cause problems such as infection resulting from irritation of the implant pocket or surrounding skin.

At the conclusion of ECG monitoring, your doctor will remove the implanted components in a procedure similar to the original device implant. If your condition is heart related, this procedure may be performed in conjunction with a pacemaker or defibrillator implant procedure.

Patient and Device Registration

The Food and Drug Administration (FDA) requires that manufacturers of certain types of medical devices track those devices from manufacture to the implanting doctor to the patient. Using this information, manufacturers can notify doctors of any relevant device-related information. The information on this form is used only for tracking your system components. It is entirely confidential.

For More Information

The best place to find more information about ECG monitoring and your condition is with your doctor. He or she will be able to answer many of your questions. You can also contact Transoma Medical at the address shown on the back cover of this handbook.

Notes

Notes

Compliance Statement

The IMD satisfies the requirements specified in FCC Part 15, Subpart C Article 15.249 for intentional radiators. The FCC identifier for the IMD is FCC ID UFYTSIM2010.

The Activator with the connected Activator power supply and the Base Station satisfy the requirements specified in Radio Disturbance Characteristics of Industrial, Scientific, and Medical (ISM) Radio Frequency Equipment (CISPR) 11 for Group 1, Class B unintentional radiators as well as Federal Communication Commission (FCC) Part 15, Subpart B Article 15.109 for unintentional radiators. The Activator with the connected Activator power supply also satisfies the requirements specified in FCC Part 15, Subpart C Article 15.209 and Article 15.247 for intentional radiators. The FCC identifier for the Model 4000 Activator is FCC ID UFYTSAV4000.

The Base Station, the Activator, and the Activator power supply satisfy the requirements of IEC 60601-1 and IEC 60601-1-2.

Instructions for Use Summary

Indications

The Sleuth™ system is an implantable, patient- and automatically-activated monitoring system that records subcutaneous ECG and is indicated for:

- Patients with clinical syndromes or situations at increased risk of cardiac arrhythmias
- Patients who experience transient symptoms that may suggest a cardiac arrhythmia

Contraindications

There are no known contraindications to the implantable monitoring device (IMD) or subcutaneous Antenna (Antenna). However, contraindications may exist to the implantation of any subcutaneous, chronically implanted device. Therefore, the individual patient's medical condition must be considered.

Precautions

To avoid damage to their implanted IMD, patients should avoid diathermy, unipolar electrocautery, therapeutic ultrasound, and therapeutic and ionizing radiation. The IMD will function normally **after** but possibly not **during** diagnostic ultrasound, bipolar electrocautery, electromagnetic interference (EMI), external defibrillation, internal defibrillation, lithotripsy, magnetic resonance (MR) imaging, and x-ray. Following any of these procedures, verify proper IMD function. Refer to the Instructions for Use manual for precautions, implant procedures, programming information, and product specifications.

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

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