

Heartrak *ECAT*²

EXTERNAL CARDIAC
AMBULATORY TELEMETRY



Patient Handbook



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INTRODUCING HEARTRAK ECAT^{®2} MONITORING SYSTEM

Cardiac arrhythmias are abnormal heart rhythms such as fast, slow, or irregular heartbeat. Symptoms that may lead a physician to suspect arrhythmia include fainting or nearly fainting, palpitations, and fatigue among others. The Heartrak ECAT² monitor provides continuous cardiac monitoring over an extended period of time in an effort to capture and record sporadic cardiac asymptomatic or symptomatic arrhythmias. Your physician will review the recorded data and will consider it along with other factors to determine a diagnosis and best treatment. Asymptomatic arrhythmias are arrhythmias that occur without any symptoms. Arrhythmias do not necessarily indicate an underlying cardiac disorder.

THE HEARTRAK ECAT² MONITORING SYSTEM is the Heartrak ECAT² Monitor and Heartrak[®] Communicator equipment included in the Patient Kit plus Monitoring Service. The monitor records ECG data and sends data to the Communicator, which sends data to Monitoring Center.

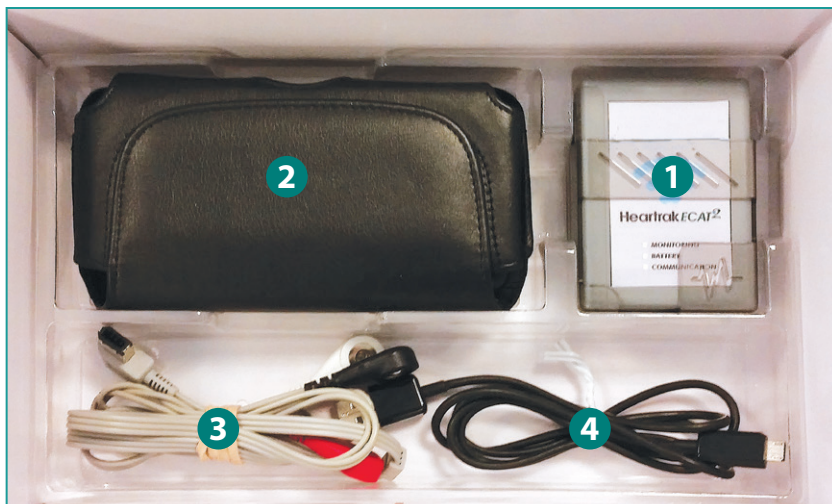
**Heartrak ECAT² is not an emergency response system.
If symptoms cause you concern, call your physician.
In an emergency, use a landline or cellular telephone
to call 911 and/or local emergency services.**

PATIENT RESPONSIBILITIES

- The Heartrak ECAT² monitoring system has been prescribed to you by your physician to aid in the potential diagnosis of arrhythmia. **You must wear the monitor both day and night for the length of time that your physician prescribed for your monitoring study.** You may participate in your normal activities while wearing the monitor unless those activities will place the monitor, Communicator, or lead wires in areas that are wet, damp, extremely hot, or dusty. For example, to avoid damaging the equipment, you must take the monitor, lead wires, and Communicator off and place them in another room before entering the bathroom to take a bath or shower.
- If you are not able to wear the monitor for more than 4 hours, call Monitoring Center and tell them when you will take the monitor off and when you will put it back on.
- Contact Monitoring Center at any time if you need help using the equipment or you think it is not functioning properly.
- If you plan air travel during your monitoring study, ask your airlines what the airport security and airline regulations are for packing and/or wearing electrode patches and using the monitor and Communicator, which are electronic devices. According to FAA guidelines for portable electronic devices, you will need to turn off and stow Heartrak ECAT² monitor and Communicator during the flight.
- Take good care of the equipment that the Monitoring Center has loaned you. At the end of your study, you must return equipment and unused materials to the Monitoring Center. *You will be billed for the replacement cost of any equipment that is either damaged or not returned.*

1. CHECK CONTENTS OF PATIENT KIT

STEP 1: Make certain that you have all of the items shown below.
Call Monitoring Center if any items are missing.



1. Monitor and Belt-Clip Holster
2. Communicator and Case
3. Lead Wires
4. Communicator Charger
5. Disposable Batteries for Monitor *(not shown)*
6. Electrode Patches *(not shown)*
7. Patient Handbook and Communicator Features sheet *(not shown)*
8. Pre-paid, Return Envelope will be included if you are to mail the equipment and all unused materials back to the Monitoring Center *(not shown)*

STEP 2: Save the container and pre-paid return envelope, if one was provided, to return equipment and all unused materials to Monitoring Center. See return instructions on page 17.

2. INSERT MONITOR'S BATTERY

- STEP 1:** Remove the monitor from the belt-clip holster as follows:
- A) Hold the bottom of the belt-clip holster with one hand.
 - B) Hold the top of the monitor with your other hand, and then pull the monitor out of the belt-clip holster.



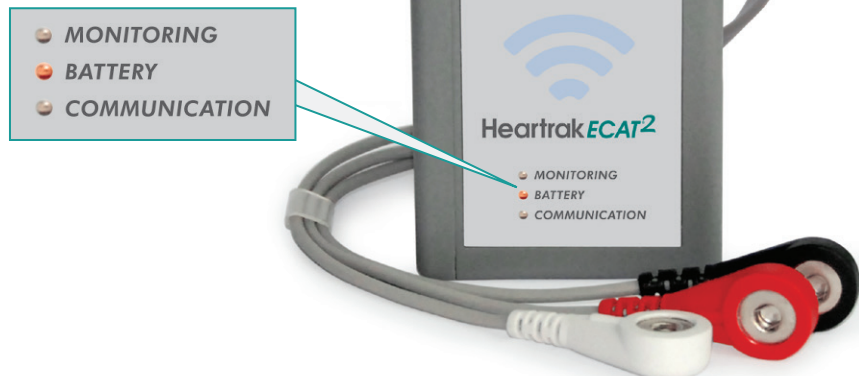
- STEP 2:** Locate the battery cover on the left side of the monitor. Hold the bottom of the monitor in one hand, with the other hand hold the top of the monitor, and with your thumb push down and toward the bottom of the monitor to slide the battery cover off. See illustration below of battery correctly placed in monitor.



- STEP 3:** Insert an "AA" battery, included in the Patient Kit, into the battery compartment following the polarity instructions ("+" on the battery to "+" on the wall of the battery compartment and "-" on the battery to "-" on the wall of the battery compartment; that is, flat end of battery against the spring). Position and then slide the battery cover shut.

When the monitor emits 1 beep every 15 seconds and the RED Battery status light begins to blink, change the monitor's battery. You can expect to replace the battery every 2 days.

Blinking RED Battery light indicates low battery.



Please dispose of all used batteries properly.

3. USING THE COMMUNICATOR

The Communicator sends ECG data to Monitoring Center. The Communicator also displays system status messages and is used for communication with Monitoring Center. **See the Communicator Features sheet for information on how to use the Communicator.**

STEP 1: The Communicator's battery should be fully charged when you receive it, if not, please recharge it.

STEP 2: Turn on Communicator.

STEP 3: Do not turn the Communicator OFF during the entire monitoring period. In order to conserve power, the Communicator screen display light turns off. You may illuminate the screen by pressing any key on the Communicator.

STEP 4: For best performance, keep the monitor and Communicator within 10 feet of each other at all times. You can attach the monitor and Communicator to the waistband of your clothing during the day. At night attach the monitor to the waistband of your clothing and charge the Communicator nearby.

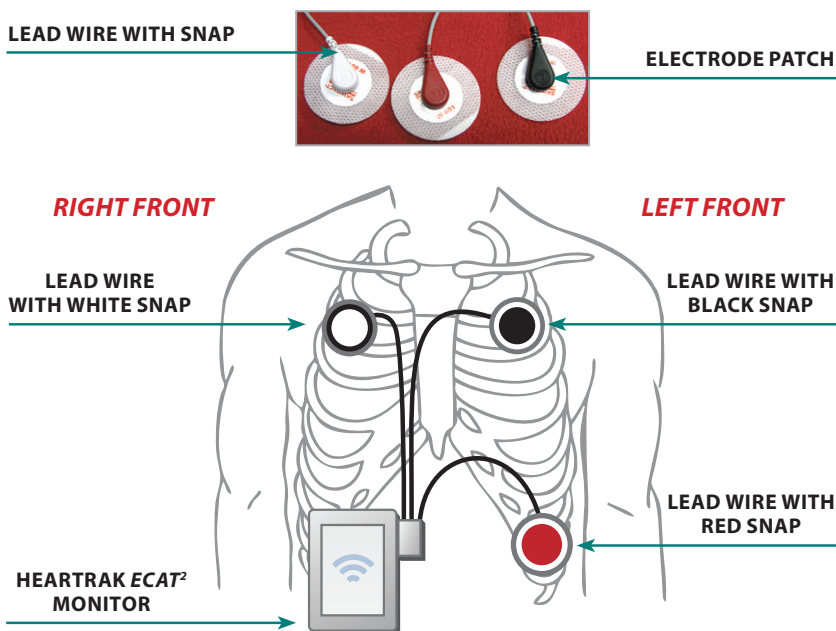
STEP 5: Charge the Communicator's battery each night in a location within 10 feet of where you will be sleeping. Insert the Communicator's charger connector into the Communicator. See Communicator Features sheet for the location of the charger slot. Insert the charger's power plug into a wall power outlet.

4. ATTACH ELECTRODE PATCHES TO YOUR BODY

STEP 1: If necessary, shave hair from the areas on the chest where the electrode patches are to be placed.

STEP 2: At each location where you plan to place an electrode, clean your skin with water or rubbing alcohol and let your skin dry thoroughly.

STEP 3: Snap one electrode patch onto each lead wire.



STEP 4: Lead wire with **WHITE SNAP** — remove backing from the electrode patch and place on the upper-right portion of your chest, 2 to 3 inches below the collarbone.

STEP 5: Lead wire with **RED SNAP** — remove backing from the electrode patch and place below your left breast, over your lower ribcage.

STEP 6: Lead wire with **BLACK SNAP** — remove backing from the electrode patch and place it on the upper-left portion of your chest, 2 to 3 inches below the collarbone.

CAUTION: Remove Communicator, monitor, and lead wires and place them in another room before you enter the bathroom to take a bath or shower.

STEP 7: Change electrode patches every other day or any time they become loose. Removing an electrode patch is like removing a bandage. You can keep electrode patches on when you shower or take a bath and rub water and soap on the area around electrodes. Then while pressing down with one finger to hold the skin near the patch taut, slowly, carefully pull back portions of the electrode patch and remove it.



STEP 8: Be sure to let your skin dry thoroughly before you reapply electrodes. To protect your skin, avoid reapplying the electrode patch to the exact, same spot on consecutive days. You can place electrode patches about 2 inches in any direction from the location where you placed the electrode patch before.

STEP 9: Tangled lead wires can become disconnected easily. Place the electrodes on your chest, get dressed, and then reach under your clothing to neatly arrange the wires from the electrodes to the place where you will attach the monitor to the waistband of your clothing.

5. CONNECT MONITOR AND BEGIN MONITORING

Blinking GREEN Monitoring light confirms monitor is actively monitoring.



STEP 1: Position the lead wire connector as illustrated above and then gently insert the connector into the monitor. *The monitor will emit one short beep.*

STEP 2: Attach monitor to the waistband of your clothing.

STEP 3: To be certain that monitoring has begun, look at the front of the monitor. If the GREEN Monitoring light is blinking, the monitor is actively monitoring.

6. CONFIRM ACTIVE CONNECTION BETWEEN MONITOR AND COMMUNICATOR

STEP 1: Press any key on the Communicator to illuminate screen.

- A) If a GREEN check mark ✓ displays, there is an active connection between Communicator and monitor and you are ready to follow instructions in Section 7.



- B) If a RED ✗ displays, there is NO active connection between Communicator and monitor.



To correct:

1. Move monitor within 10 feet of Communicator.
2. Make certain battery is NOT low in monitor.
3. Make certain battery is charged in Communicator.

If there is still NO active connection, call Monitoring Center for assistance.

- C) If “**Activation Pending**” displays, use a landline or cellular phone to call Monitoring Center and ask them to activate your Communicator.



7. PRESS RECORD BUTTON, THEN SELECT SYMPTOM AND ACTIVITY LEVEL

STEP 1: When you experience a symptom, briefly press and then release the RECORD button on the top of the monitor. The monitor will emit a short, 1-second beep to signify that a recording has begun and will emit two short beeps when the recording has ended. The GREEN Monitoring light will be on and non-blinking.



Within a minute or two, the GREEN Monitoring light will begin to blink and the Communicator will display a list of symptoms.

STEP 2: Symptoms

See Communicator Features sheet that describes how to select symptom(s) and activity level.

A) Select **Baseline** for the baseline recording you will make at the request of a Monitoring Center technician at the beginning of your study. Activity level should be **None** for the baseline recording.

B) When you experience a symptom or symptoms and press the RECORD button, use Communicator to select one or more symptoms that are applicable: **Shortness of breath, Dizziness/Lightheaded, Palpitations/Skipped beats, Chest pain, Rapid heart beat, Fluttering.**

C) Select Accidental if you pressed the RECORD I button by mistake.

STEP 3: Activity Level

Select the one activity level: **None, Light, Medium, or Heavy/Exercising** that best describes the level of your activity when you experienced the symptom or symptoms that prompted you to press the RECORD button.

Note: The Communicator will display the symptom(s) and activity level screens for about 2½ minutes. If you cannot submit your selections within 2½ minutes, call the Monitoring Center and tell them your symptom(s) and activity level.

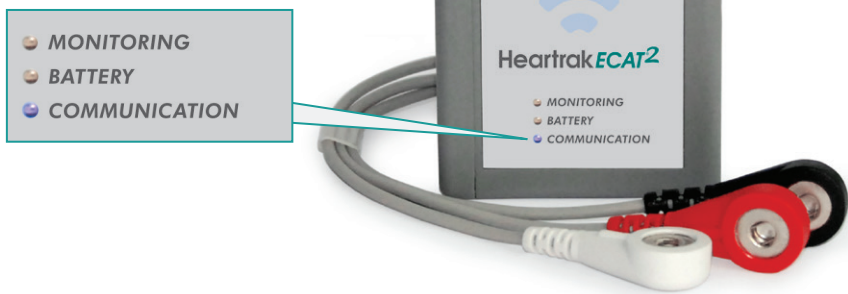
8. MONITOR RECORDS ECG DATA AUTOMATICALLY

If the monitor begins recording automatically and the monitor is within 10 feet of the Communicator, the monitor will send ECG data to Communicator and then Communicator will send ECG data to Monitoring Center.

9. SENDING ECG DATA TO MONITORING CENTER

BLUE Communication light on the monitor:

- 1) *Slowly blinking, confirms monitor has ECG data to send to the Communicator;*
- 2) *Rapidly blinking, confirms monitor is actively sending data to the Communicator.*



After an ECG recording is made, the monitor's slowly blinking BLUE Communication light will indicate that the monitor has ECG data to send to the Communicator.

When the monitor's BLUE Communication light begins blinking rapidly, it is actively sending ECG data to the Communicator. When there is active connection between the monitor and the Communicator, the Communicator receives data from the monitor and sends data to the Monitoring Center.

10. RETURN EQUIPMENT AND UNUSED MATERIALS TO MONITORING CENTER

At the conclusion of your cardiac monitoring period, the Communicator screen will display, "MONITORING COMPLETE. PLEASE RETURN EQUIPMENT." Follow your Monitoring Center's instructions to return equipment and all unused materials. ***You will be billed for the replacement cost of any equipment that is either damaged or not returned.***

STEP 1: Turn off the monitor by disconnecting the lead wire connector and removing the battery. Turn off the Communicator. Unplug the Communicator charger.

STEP 2: Place the monitor and belt-clip holster, lead wires, unused batteries, Communicator, Communicator charger, Communicator case, Patient Handbook, Communicator Features sheet, and unopened electrodes package in the container that Monitoring Center provided.



STEP 3: Follow the instructions to return equipment.

IF MONITORING CENTER HAS INSTRUCTED YOU TO RETURN EQUIPMENT AND ALL UNUSED MATERIALS BY MAIL, TAKE THE FOLLOWING STEPS:

STEP 4: Place equipment and all unused materials into the container provided by Monitoring Center and then into the pre-paid, return mailing envelope that was provided. Close the envelope and use the envelope's self-adhesive strip to seal it.



Thank you for your participation in our cardiac monitoring service.

Wireless Communication

To greatly facilitate recording and transmission of ECG data, Heartrak ECAT² communicates wirelessly. The RF (Radio Frequency) module embedded in Heartrak ECAT² meets Bluetooth v 2.0 standards and is FCC approved. Universal Medical, Inc. designed, built, and tested Heartrak ECAT² in compliance with the following standards: ANSI/AAMI EC38:1998, IEC 60601-1- 2:2007 Medical Electrical Equipment Part 1-2 General Requirements for Basic Safety and Essential Performance, IEC 60601-1:2005 Medical Electrical Equipment Part 1: General requirements for basic safety. IEC 60601-1- 11:2010 Medical electrical equipment – Part 12-11: General requirements for basic safety and essential performance collateral standard: requirements for medical electrical equipment and medical electrical systems used in home healthcare environment. IEC 60601-2- 47:2012 Medical Electrical Equipment Safety including essential performance of ambulatory electrocardiographic systems and Code of Federal Regulations, Chapter 21, Part 898 (Performance Standard for Electrode Lead Wires and Patient Cables). Warnings: IEC 60601-1- 2:2014 - Use of Heartrak ECAT² device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Portable RF communications equipment should be used no closer than 30 cm (12 inches) to any part of the Heartrak ECAT² device. Otherwise, degradation of the performance of this equipment could result. FDA Guidance for RF devices - Other equipment could interfere with the equipment or system, even if the other equipment complies with CISPR emission requirements.

Heartrak^{ECAT2}

External Cardiac Ambulatory Telemetry



Patient Handbook

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