ACT I and ACT III
Patient User Guide

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SUP362, ACT Patient User Guide, Rev C, DCR 11-023

ACT I and ACT III Patient User Guide

This user guide includes information and instructions about the ACT (Continuous ECG Monitor and Arrhythmia Detector) monitoring system. Please read it carefully before you begin testing.

If you have any questions regarding the ACT monitoring system please contact LifeWatch at 1-800-517-6330.

	Federal Law (USA) restricts this device to sale by or on the order of a practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.

	**CAUTION:** This manual should always accompany the unit. All personnel utilizing the ACT system must have read and be familiar with the contents of this manual. **First time use** – You must call LifeWatch to receive instructions on how to proceed for the first time use. The first time the ACT monitoring system is activated and is attached to you, it will display screens that are not seen in regular use. These screens are calibration procedures the ACT monitoring system needs to perform to adjust its operation for first time use. Please read the “First Time Activation” section, for more details.

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1. Introduction

Intended Use

ACT I – CG 6108

Sensor   Cell Phone Monitor

The ACT I Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors a one lead ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data trans telephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

ACT III – CG 6108-3L

Sensor   Cell Phone Monitor

The ACT III Continuous ECG Monitor and Arrhythmia Detector is intended for use by patients who experience transient symptoms that may suggest cardiac arrhythmia. The device continuously monitors patient ECG, automatically generates an alarm triggered by an arrhythmia detection algorithm, or generates an alarm manually triggered by the patient, and transmits the recorded data trans

telephonically to a monitoring center. The monitoring center provides the ECG data to the medical practitioner for evaluation.

The ACT monitoring system is intended to be prescribed for patients who have demonstrated a need for cardiac monitoring and are at low risk of developing life-threatening arrhythmias. Conditions where the system should **not** be used include patients likely to experience primary Ventricular Fibrillation or Ventricular Tachycardia and patients who have other co-morbid cardiovascular conditions where an arrhythmia could be potentially life threatening.

The ACT monitoring system is intended to be used in conjunction with a monitoring service that reviews the recorded transmissions and provides that information to the physician for his/her final diagnostic interpretation. The monitoring system is not intended for use as an emergency response system for patients who may experience life-threatening arrhythmias.

The following list represents patient populations for whom use of the ACT monitoring system is most appropriate. This list should be used in conjunction with Medicare and other payor medical necessity guidelines:

- Patients with dizziness or lightheadedness
- Patients with palpitations
- Patients with syncope of unknown etiology
- Patients who require monitoring for non-life-threatening arrhythmias, such as Atrial Fibrillation, Supra-ventricular Arrhythmias, evaluation of various Bradyarrhythmias. This includes post-operative monitoring for these rhythms.
- Patients recovering from coronary artery bypass graft (CABG) surgery who require monitoring for arrhythmias
- Patients requiring monitoring for arrhythmias-including co-morbid conditions such as hyperthyroidism or chronic lung disease
- Patients with obstructive sleep apnea to evaluate possible

nocturnal arrhythmias

- Patients requiring arrhythmia evaluation for etiology of stroke or transient cerebral ischemia, possibly secondary to Atrial Fibrillation

To use the ACT monitoring system, the user or primary care provider must be able to perform all of the following:

- Understand the principle of operation and system messages described in this manual
- Place the sensor and electrodes on the chest
- Operate a handheld device (cell phone monitor)
- Operate simple push-buttons

The ACT monitoring system is safe for use by patients wearing an oxygen mask for breathing.

The ACT monitoring system is not water resistant and must not get wet. Do not use or store the ACT monitoring system where liquids of any nature may come into contact with it. Raindrops, water spray, juice, coffee, steam, perspiration, perfume, deodorant, etc. may also affect the performance of the monitoring system and cause a possible malfunction. While bathing or showering, the system should be placed in a dry environment, outside of the bathroom. The electrode patches may be worn in the shower or bath as long as they are disconnected from the sensor.

The function of the ACT monitoring system is dependent on cellular phone service and Bluetooth technology. Limitations in data transmission may occur if there is limited cellular service in the area. A landline modem can be provided for locations with limited cellular service coverage and/or if interference with the wireless Bluetooth connection is experienced.

You may occasionally experience a delay in the ability to send recorded events due to unexpected cellular limitations. If this occurs, contact LifeWatch as soon as possible. Any technical difficulties should be reported as quickly as possible so as to resolve the issue with minimal service interruption.

As with all standard cell phones, charge the cell phone monitor whenever possible, and at least every night. The battery in the sensor should be changed as instructed by the low battery messages. The performance of the Cell Phone Monitor and Sensor, including data recording and transmission, may be adversely impacted if not adequately charged.

Important Symbols

A number of symbols are used throughout this manual in order to draw attention to safety items and other important information.

The following symbols are used:

	**Warning** Symbol indicates a potentially hazardous situation, which, if not avoided, could result in death or serious injury to the user.
	**Caution** Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.
	**Notes** Symbol indicates important general information for using the system successfully.

Warnings and Cautions

The following section contains a complete list of the major warnings and cautions relevant to the ACT monitoring system. These warnings and cautions are also repeated, as appropriate, in sections of this manual. Your prescribing physician is responsible for reading and understanding all warnings and cautions prior to prescribing the ACT monitoring system.

Warning 	• The ACT monitoring system is intended to be used in conjunction with a monitoring service that reviews the recorded transmissions and provides that information to the physician for his/her final diagnostic interpretation. • The ACT monitoring system is not intended for use as an emergency medical response system and should not be used by patients at risk for serious or life-threatening cardiac arrhythmias, such as ventricular tachycardia and ventricular fibrillation. Refer to the Physician Manual Specification for the types of arrhythmias detected by the ACT monitoring system. • The ACT monitoring system is not intended for use in the diagnosis of myocardial infarction or for chest pain monitoring. • Due to the risk of ignition or fire, the ACT monitoring system is not intended for use in a hyperbaric chamber, within an oxygen tent or in the presence of flammable anesthetics / medical gases.

Warning 	• To prevent fire or shock hazard, do not expose the ACT monitoring system to moisture, liquids or condensation. • To prevent an allergic reaction, do not use the ACT monitoring system or accessories if you have a known allergy to nickel or other metals. • The ACT monitoring system is not defibrillation-proof. Exposure to defibrillation may damage the ACT monitoring system, or the ACT monitoring system may interfere with the operation of the defibrillator. The ACT monitoring systems MUST be removed prior to defibrillation as it contains metals that could cause the defibrillator to arc. • Use of conductive, connected devices and patient lead wires/electrodes like the ACT monitoring system in MRI procedures may result in serious burns. • If you should come into possession of your ECG recording do not take any actions of a medical nature based on your understanding UNLESS you are a medical professional.

Warning 	• The ACT monitoring system is not intended for use on persons with an Implantable Cardioverter Defibrillator (ICD). **Use with Implanted Conventional Pacemakers - (not including ICDs)** If you have an implanted pacemaker, the manufacturer may recommend certain precautions when using a cellular phone. Since the ACT cell phone monitor is also a cellular phone, you should take the same precautions when carrying and using the cell phone monitor. In general, most manufacturers recommend the following: • Keep a distance of at least six inches (15 cm) between the cell phone monitor and a pacemaker. • Carry the cell phone monitor on the opposite side of the body from the pacemaker. • Don't carry a cell phone in a breast pocket or on a belt if that would place the phone within six inches (15 cm) of the pacemaker. • Refer to the manufacturer's information for guidance regarding the pacemaker and interference issues.

Caution 	• The ACT monitoring system is intended to be worn during normal daily activities. If vigorous physical activity or exercise is part of your normal daily activity, the associated perspiration and lead wire movement can loosen the electrodes. Contact LifeWatch to obtain special electrodes for these situations. • Disposable electrodes must be changed according to instructions provided in this manual to assure optimal recording quality and limited skin irritation. • The ACT monitoring system generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. • The ACT monitoring system employs Bluetooth and cellular technology. The location of the ACT monitoring system and the associated environment, including cellular phone coverage in the particular area, may cause transmission interruption or delay. • Do not open or attempt to repair the sensor. Only authorized service personnel may repair the system components. • Over-the-counter batteries should never be used as they can seriously damage the sensor. Only use the specialized batteries included in the kit. If more batteries are needed, contact LifeWatch.

Caution 	• To avoid damage to the system, the system and accessories should be kept away from extreme heat including placement of the ACT monitoring system on the dashboard of a car or near a heater. • The system should not be subjected to severe impact or bending force. Exposure to these types of stresses can damage the system components. • Charge the cell phone monitor every night (irrespective of indicator status), making sure that it is within 10 feet (3 meter) of the sensor. In addition, charge the cell phone monitor whenever possible during the day. • The cell phone monitor energy consumption may be high during the first few days of monitoring (up to 72 hours). Keep the cell phone monitor charged at all times. • Return the used and unused sensor batteries to LifeWatch for proper disposal. Do not discard the batteries in or near a fire. • If the sensor battery is replaced when the sensor is out of Bluetooth range from the cell phone monitor, the sensor will not be able to connect with the cell phone monitor and will not be able to record until it reconnects with the cell phone monitor.

Caution 	• If the sensor (ACT I firmware version 0.1g and ACT III firmware version 1.0.4) is not connected to the cell phone monitor (via Bluetooth) for more than 2 hours (ACT I) or 6 hours (ACT III) and the sensor's battery is replaced, the sensor (on reconnection) will start with new data and not download the data stored, thus overriding the data stored when it was not connected. • Electrode disconnection might cause a faulty ECG analysis and/or false events due to noise created by the electrode disconnection. • The impedance test (occurring every two minutes) overrides ECG recording, which means the ECG will lack 1 second (ACT I) or 0.5 second (ACT III) of recording every two minutes. • Do not turn the cell phone monitor sound off or reduce the volume so that it is inaudible. • After exiting the ACT (monitor) application, it will take up to 3 minutes for all the processes to end. This means you must wait 3 minutes before starting the ACT (monitor) application again. • Take the charged cell phone monitor with you and wear the sensor at all times (except when showering or bathing) during the monitoring period.

Caution 	• A Bluetooth disconnection between the cell phone monitor and the sensor might occur due to electromagnetic interference. In this case the sensor will search for the cell phone monitor device every 3 minutes. • If the cell phone monitor Bluetooth communication is not active for 60 minutes, the ACT (monitor) application will automatically restart the Bluetooth communication. • Always change the sensor battery when connected (Bluetooth) to the cell phone monitor, a low sensor battery message indicates there are up to three hours before the battery fails. • **First time use** – The patient must call LifeWatch to receive instructions on how to proceed for the first time use. The first time the ACT monitoring system is activated and is attached, certain screens are displayed that are not seen during normal operation. These screens are used for calibration. Please refer to “First Time Activation” section of the manual for more details.

Caution 	• Please refer to the user manual of the manufacturer of the cell phone monitor for Health and Safety Information pertaining to the use and operation of the cell phone monitor. The cell phone monitor manual can be downloaded from the Internet. • Do not use the cell phone monitor for any reason outside of the designated monitoring function. • Keep kit contents away from children.

	**FCC Note** Important Safeguard in the Medical Environment

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:

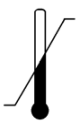
- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

	**Note** Modifications not expressly approved by the manufacturer could void the user authority to operate the equipment under FCC Rules. THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

Symbols on Equipment and Labeling

The following section contains a complete description of all symbols that may be located on either the equipment or labeling of ACT device and accessories.

Label	Description
	Warning, consult accompanying text or documents
	Caution, consult accompanying text or documents
	Notes, indicates important general information for using the system successfully.
	Tips, indicates important tips on using the system.
	Consult instructions for use
	Serial Number
	Date of Manufacture
	Type BF Applied Part

Label	Description
	Batch code
	Do not use if package is damaged
	Use by
	Keep dry
	Store at specified temperatures
	Electrical and Electronic Equipment
	MDD (Medical Device Directive certification)
	Bluetooth trademark indication conformity to specifications.
	Compliant with FCC Part 15

Glossary

ECG	Electrocardiogram; a representation of the heart's electrical activity recorded from electrodes on the body.
ACT	**A**mbulatory **C**ardiac **T**elemetry; Continuous ECG Monitor and Arrhythmia Detector (sensor and monitor)
ACT Ex	The service of collecting and analyzing recorded ECG data (usually 24 hours) using the ACT device.
Sensor	ACT device attached to patient
Monitor	Hand held device/cellular phone using ACT monitoring software
Heart Rate	Number of heart beats per minute, measured as bpm (beats per minute).
Bluetooth (BT)	Wireless communication protocol.
Monitoring Center	Monitoring center responsible for reviewing clinical data transmissions, and providing them to the physician.
Charger	Power supply for recharging cell phone monitor
Disposable electrode (electrode patch)	Adhesive connector that connects the lead wire to the body.

Arrhythmia	Irregular heartbeat
Manual event	Event manually recorded by a patient when he/she feels it is necessary

2. General Description

The ACT is an automatically activated cardiac monitoring system that requires no patient intervention to capture or transmit an arrhythmia when it occurs. When an arrhythmia is detected, the ACT monitoring system utilizes an integrated cell phone monitor to transmit the data to the Monitoring Center for analysis.

Sensor

The sensor records and transmits the data to the cell phone monitor. It can hold up to 6 hours (ACT III) or 2 hours (ACT I) of data in its memory. This means that if a patient is away from the cell phone monitor and wearing the sensor, the data is still being recorded. Once the patient is in range (within 30 feet /10 meters) of the cell phone monitor, the data will be transmitted.

Cell Phone Monitor

The cell phone monitor receives ECG data from the sensor via Bluetooth and can store up to 30 days of data. The cell phone monitor has a special application that converts the raw ECG data and sends it using a cellular network to the monitoring center for interpretation or, in the case of no cellular coverage, data can be sent using a landline and a modem. The cell phone monitor should be carried in the supplied pouch whenever possible.

Batteries

The sensor batteries are special batteries. DO NOT use over the counter AA batteries. DO NOT dispose of the batteries – they should be returned to LifeWatch when your monitoring session is completed.

About Bluetooth

Bluetooth is a wireless technology that enables the sensor and cell phone monitor to communicate with each other. The ACT system uses Bluetooth technology to transmit ECG data from the sensor to the cell phone monitor. The cell phone monitor internal Bluetooth component is on and running continuously (24 hours a day) for the entire monitoring period; therefore, the cell phone monitor must be ON at all times. Bluetooth operates like a radio and is susceptible to interference. If the sensor and cell phone monitor are more than 30 feet (10 meter) apart and a Bluetooth connection cannot be made, no data loss will occur as long as the sensor and cell phone monitor are reconnected within 6 hours (ACT III) or 2 hours (ACT I). When the sensor and cell phone monitor are within 30 feet (10 meter) of one another, the Bluetooth will automatically re-connect. Charge the phone every night for the whole night and whenever possible throughout the day.

For optimal system performance, the recommended distances between the cell phone monitor and sensor during the monitoring period should be as follows:

- Normal operation - within 20 inches (50 cm).
- During cell phone monitor charging - within10 feet (3 meter)

3. System Description

The ACT Continuous ECG Monitor and Arrhythmia Detector is designed for self-testing by patients at home and for analysis by trained technicians at a remote Monitoring Center.

The sensor is used for the acquisition and transmission of the ECG signal. The sensor is equipped with three (ACT I) or four (ACT III) electrodes on a harness and works in conjunction with a cell phone monitor.

The sensor houses a 3.6V AA lithium-thionyl chloride battery, an ECG channel circuit, an impedance measurement circuit, a pacemaker detection circuit, a flash buffer memory, a Bluetooth transceiver and a buzzer. The ECG signals are received, filtered and amplified in the input circuit, stored in the flash memory buffer and transmitted via Bluetooth to a cell phone monitor. The cell phone monitor runs a proprietary application that is configured to process and transmit the ECG recordings via a cellular network while storing them and the detected physiological events on a micro-SD memory card. When a physiological event is detected, the cell phone monitor transmits the recorded ECG automatically via cellular link, to a Monitoring Center for professional analysis. If the patient is out of the cellular network coverage area, the cell phone monitor will send all events that were stored when the cellular link is re-established. The cell phone monitor can also transmit ECG alarms via landline telephone with an additional POTS Bluetooth modem.

The sensor loops up to 2 hours (ACT I) or 6 hours (ACT III) cyclic buffer of ECG data in the internal flash memory in order to preserve the ECG in cases when the Bluetooth connection to the cell phone monitor is down.

	**Note** The cell phone monitor automatically transmits the detected ECG events to the monitoring center and the user has the ability to send manually recorded events. The data is saved on the storage card and the event data is deleted after a successful transmission to the monitoring center.

4. The ACT Kit

The ACT Kit provided may contain either the ACT 1-lead or ACT 3-lead sensor, one cell phone monitor and all the accessories needed for use of the system.

Contents

1. ACT sensor with integrated or detachable lead wires
2. ACT sensor batteries (3.6 V AA lithium-thionyl chloride)
3. Disposable electrodes
4. User Guide
5. Carrying pouch
6. ACT monitor (cell phone)
7. Monitor charger
8. PSTN modem (optional)
9. Pre-paid return envelope

ACT Sensor

ACT Sensor Batteries

Pre-Paid Return Envelope

ACT Monitor

Monitor Charger

CG-3800BT modem (optional)

Electrodes

Monitor Carrying Pouch

User Guide

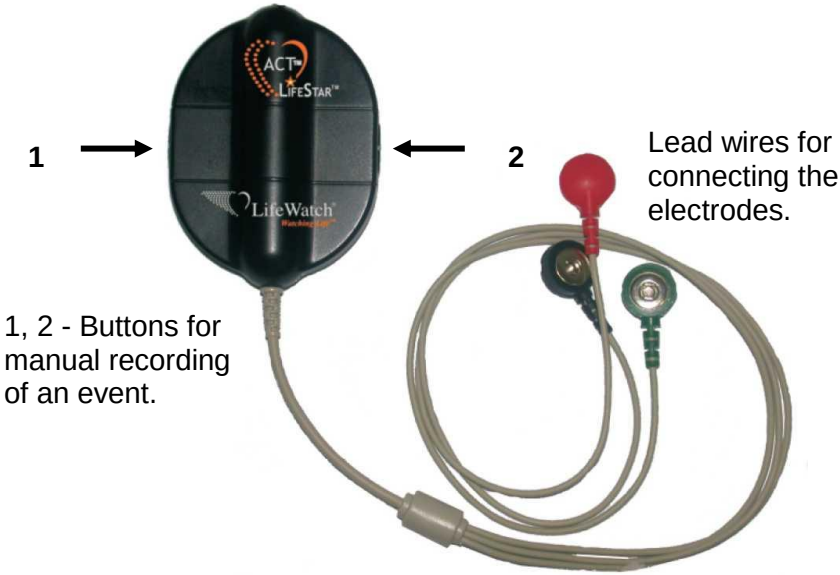


Figure 1. Front view of ACT I sensor

Battery cover closed Battery cover open

Figure 2. Rear view of ACT I sensor

The ACT III 3-lead Description

Sliding Battery Cover

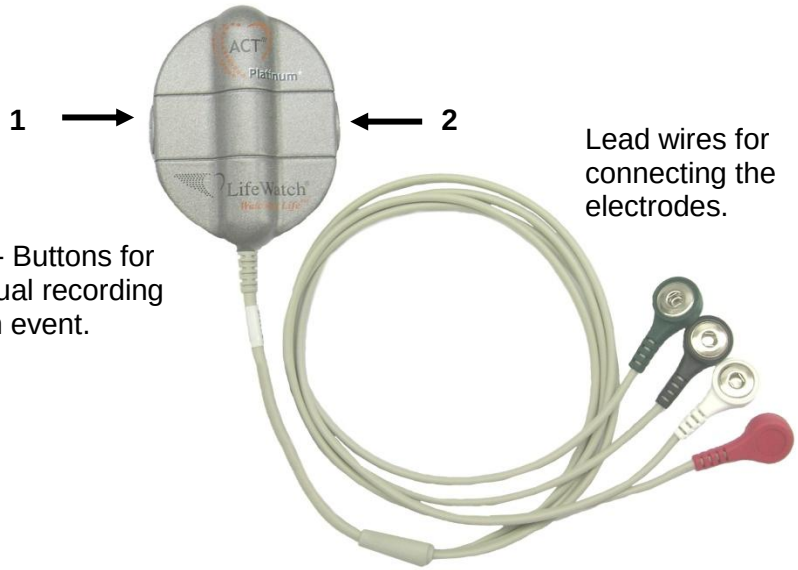


Figure 3. Front view of ACT III sensor (slide open battery cover)

Battery cover closed Battery cover open

Figure 4. Rear view of ACT III sensor

The ACT III 3-lead Description with Connectable Patient Lead Wires

Flip Open Battery Cover

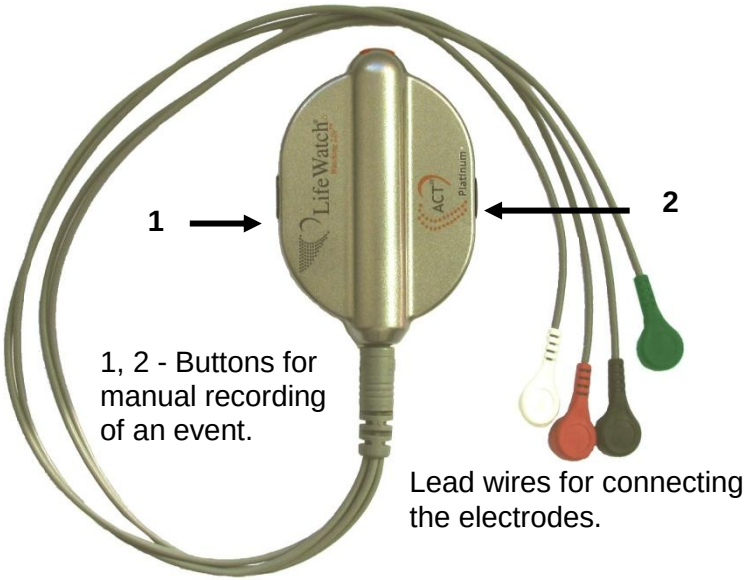


Figure 5. Front view of ACT III sensor (flip open battery cover)

Battery cover closed Battery cover open

Figure 6. Rear view of ACT III sensor

Cell Phone Monitor Information

One of the following cell phone monitors will be provided with the kit.

HTC Ozone mobile phone

HTC Ozone monitor keys and buttons

Samsung SGH-i617 mobile phone

SGH-i617 monitor keys and buttons

Samsung SGH-i637 mobile phone

SGH-i637 monitor keys and buttons

	**CAUTION** Please refer to the User Manual of the manufacturer of the cell phone monitor for Health and Safety Information pertaining to the use and operation of the cellular phone. The cell phone monitor manual can be downloaded from the internet. **CAUTION** • Do not change the cell phone monitor settings. • Do not turn the cell phone monitor sound off. • Do not mute the volume so that it is inaudible. • Do not use the cell phone monitor for any reason outside of the designated monitoring function • The ACT employs Bluetooth and cellular technology. The location of the device and the associated environment, including cellular phone coverage in the particular area may cause transmission loss or delay.

Important Information Before Use

General

The recommended ambient temperature for use of the ACT System sensor is between 50°F (10°C) and 104°F (40°C).

Remove the lead wires and the sensor before bathing.

The cell phone monitor and the sensor are not to be exposed to direct water contact. The sensor and the cell phone monitor should not be in the bathroom while bathing or showering.

Please consult your doctor or LifeWatch regarding the end of the service.

You must take the fully charged cell phone monitor with you and wear the sensor at all times (except when showering or bathing).

	**Caution** Do not use the provided cell phone monitor for any reason other than the designated monitoring function.

	**Note** **First time use** – Please call LifeWatch to receive instructions on how to use for the first time, see “First Time Activation” section.

Starting/Stopping the ACT Sensor

The insertion of the battery starts the sensor and connection to the cell phone monitor via Bluetooth.
Removing the battery will stop the sensor and end the connection to the cell phone monitor.
The ECG recording will start only after connection is established with the cell phone monitor.

No Connection with Cell Phone Monitor

When the sensor disconnects from the cell phone monitor (Bluetooth disconnection), the sensor will continue to record and store the ECG data (2 hours for ACT I; 6 hours for ACT III).
In case the disconnection period is longer than the maximum recording time, the sensor will store the LAST time period (2 hours for ACT I; 6 hours for ACT III) of the disconnection period.

Sensor Sound Prompts

The sensor will signal its status (through beeps), i.e., normal operation, battery level, system errors, manual events.

Sensor Sound	**Description:**
1 beep, one-time	Sensor activated
1 long beep then short beep, every ten minutes	Low battery level warning
1 long beep then short beep, repetitive	Critical battery level error, sensor stops recording
3 beeps, repetitive	Critical error, system stops
Continuous sensor sound	Manual event buttons pressed

5. Using the ACT Monitoring System

Before Starting

- Make sure you have all items needed to initiate the service:
    - ACT chest-worn sensor with battery and electrodes
    - ACT cell phone monitor with compatible application installed.
- Follow instructions for electrode placement.
- (For ACT III with flip open battery cover) Make sure that the sensor lead wire is well connected to the sensor.
  See Troubleshooting, “Sensor lead wire disconnected”, for instructions on reconnecting the lead wire.

	**Note** Contact LifeWatch to receive instructions on using the system for the first time as shown in “First Time Activation”, section.

Electrode Information

The ACT monitoring system comes with ECG lead wires that have standard snap connectors for quick and easy connection/removal to ECG electrodes. To ensure maximum safety and performance of the ACT monitoring system, use only the ECG electrodes supplied with the ACT monitoring system kit.

If electrodes irritate your skin, please contact LifeWatch for alternative electrodes.

Do not apply electrodes to skin that is broken or irritated.

Hypoallergenic electrodes are available for patients with a history of sensitivity and/allergy to adhesives. Hypoallergenic electrodes can be requested by calling LifeWatch.

Skin Preparation

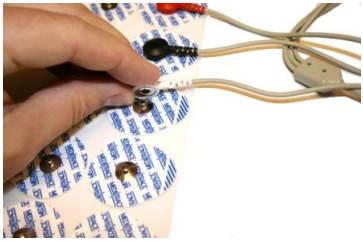
- Wash the skin on your chest and abdomen using warm water and gentle soap.
- Remove excess hair by carefully clipping with scissors. Avoid shaving in order to minimize irritation.
- Make sure that your skin is clean and fully dry before proceeding.
- Do not apply electrodes to skin that is broken or irritated.
- If you have any concerns contact LifeWatch.

	**Note** There are physiological conditions that may affect the cell phone monitor from detecting the electrode connection and can last for several hours. Even though the electrodes seem to be in good contact with the body, the message will continue to appear. Some examples are very dry skin or right after attaching the electrodes. If the condition does not resolve, contact LifeWatch.

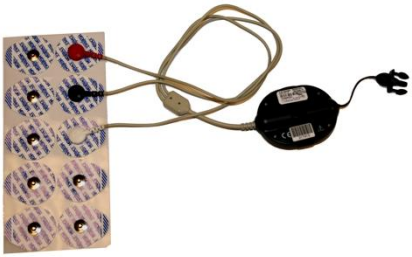
Electrode Placement

1. Place the electrodes as shown in Figures 7 (ACT I) and 8 (ACT III).
2. The electrodes should be replaced periodically, according to the electrode's manufacturer instructions as described below.

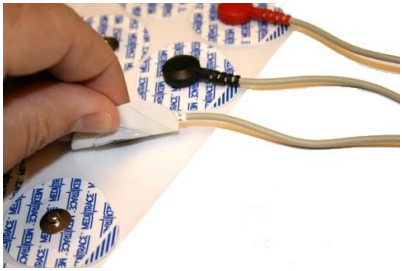
Preparing Electrodes (three for ACT 1 and four for ACT III)



Snap each lead wire onto an electrode.



Sensor with connected electrodes.



Remove the electrodes from the backing.

ACT I Electrode Placement

Attach the white lead wire with electrode under the second right rib. (3 fingers below the collarbone) towards the breastbone (center).

Attach the red lead wire with electrode on the lower right portion of your chest.

Attach the black lead wire with electrode to the lower left portion of your chest, between the fifth and sixth ribs.

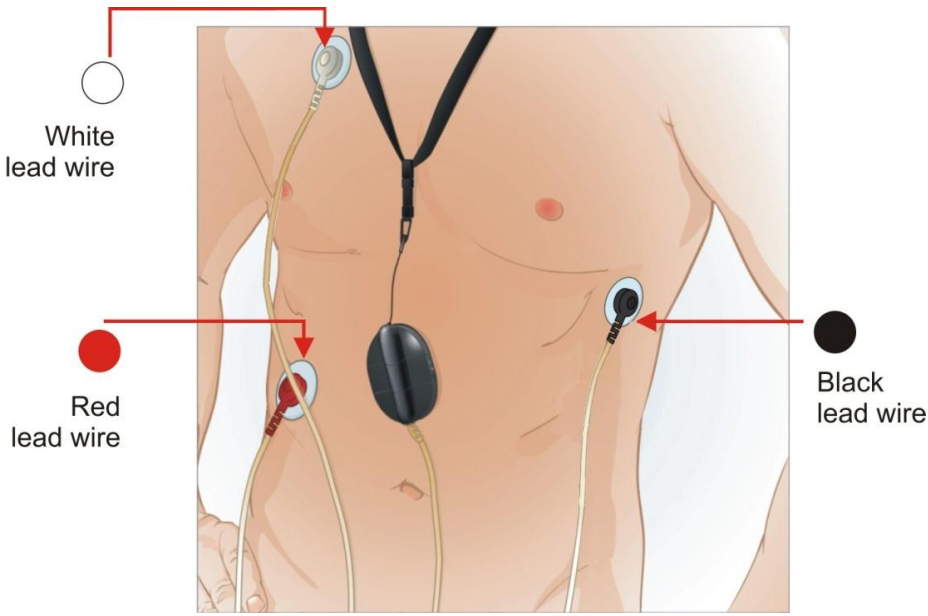


Figure 7. ACT I Electrode Placement

ACT III Electrode Placement

Attach the white lead wire with electrode under the second right rib. (3 fingers below the collarbone) towards the breastbone (center).

Place the red lead wire with electrode in a direct line from the end of the breastbone that intersects with the imaginary line that extends down from the midpoint of the collarbone, as shown in ACT III Electrode Placement figure.

Place the black lead wire with electrode at the point where a horizontal line from the red electrode intersects with the middle armpit line.

Note: For the red and black lead wires, if necessary lift the left breast to place the electrode properly.

Place the green lead wire with electrode on the left side of the abdomen.

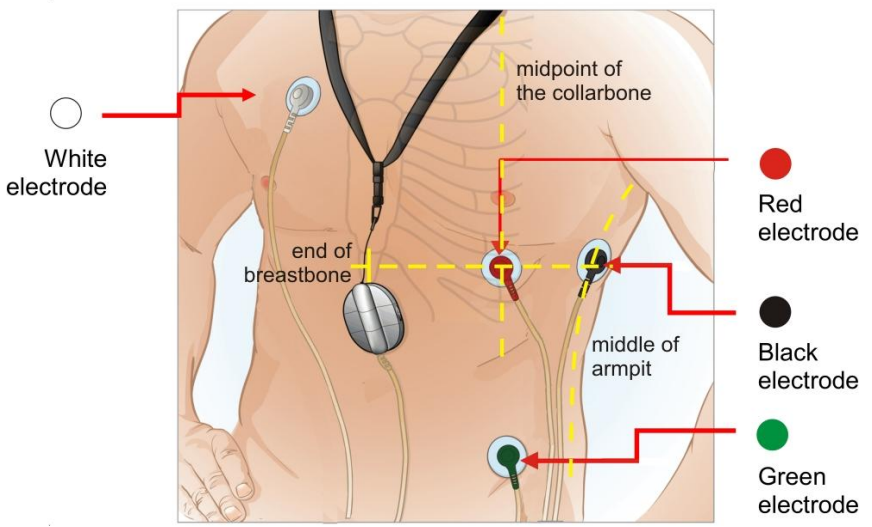


Figure 8. ACT III Electrode Placement

Changing Electrodes

- Replace electrodes (sticky patches) every three days or when the adhesive is not firmly attached to the skin.
- Check the electrodes daily by pulling gently to verify that the adhesive is firmly attached to your skin. If an electrode is not firmly attached, change all the electrodes per the instructions.
- Disconnect the lead wire from the electrode.
- Gently remove electrodes, by grasping the edge/tab of the electrode and peeling back in a slow continuous motion. You may want to remove the electrodes in the shower or by using a wet, warm washcloth. Do not rapidly remove the electrode to avoid skin damage.
- Remove any excess adhesive or dead skin between electrode changes, using a wet, warm washcloth or gauze pad. Completely dry the skin before attaching new electrodes.
- If electrodes become dislodged/loose prior to 3 days, replace all electrode(s) per instructions above.
- Minor skin irritation can occur with electrode use. If skin irritation occurs, do not re-apply electrode to the immediate area. Apply in close proximity to that location on healthy skin.
- If irritation worsens or becomes severe, contact LifeWatch.

Sensor Battery Insertion / Replacement

CAUTION:

1) Use only batteries supplied by LifeWatch for the sensor.
2) Replace the sensor battery only when the sensor and the cell phone monitor are within 20 inches (50 cm) of each other, so that a connection can be established. A low sensor battery message begins when there are up to three hours before the battery fails. As soon as you replace the sensor battery, the sensor and cell phone monitor will connect and the sensor will download stored ECG data to the cell phone monitor. After the download is completed, the sensor will start recording again. If for some reason connection is not established within 5 minutes, please call LifeWatch.
3) If the sensor battery is replaced when the sensor is out of Bluetooth range from the cell phone monitor, the sensor will not be able to record (including manual events) until the sensor is within Bluetooth range of the cell phone monitor. Once in range, the connection will be renewed after a few minutes.
4) If the sensor battery has been changed while disconnected from the cell phone monitor and **within** the maximum recording time of the sensor (ACT I up to 2 hours; ACT III up to 6 hours) then upon reconnection to the cell phone monitor the sensor will download the stored data to the cell phone monitor and will not record until the download is finished.
5) If the sensor battery (ACT I firmware version 0.1g and ACT III firmware version 1.0.4) has been changed, while disconnected from the cell phone monitor and **after** the maximum recording time of the sensor (ACT I up to 2 hours; ACT III up to 6 hours) then upon reconnection to the cell phone monitor the sensor will start a new recording that will immediately overwrite the stored data (stored data not downloaded).

	6) Place any used and unused batteries in the return envelope provided in the kit and return to LifeWatch at the end of your monitoring period.

ACT with Slide-off Cover

1. Change the sensor battery when the following occurs:

1. The sensor beeps two times, 1 long beep then 1 short beep.
2. A “Low sensor battery” message is displayed on the cell phone screen

	**Note** For a visually or hearing impaired patient, replace the sensor battery EVERY 48 HOURS.

2. Place sensor within 20 inches (50 cm) of the cell phone monitor, place the battery in the sensor:

a. Place your thumb on the depression of the battery cover and gently push the battery cover backwards, until the battery cover is free.

Figure 9.
Removing Battery Cover

b. Set the battery cover aside.

c. Remove a new battery from the plastic bag, place the new battery in the battery compartment (if a battery is already in place, remove the existing battery).

d. Pay careful attention to the battery polarity marks inside the battery compartment (plus sign on the neck strap side, minus sign on the sensor lead wire side). The sensor should beep once within 10 seconds of placing a new battery. If no sound is heard after ten seconds, verify that the battery has been placed in the correct position. If the position is correct, try another battery. If the second battery fails, contact LifeWatch.

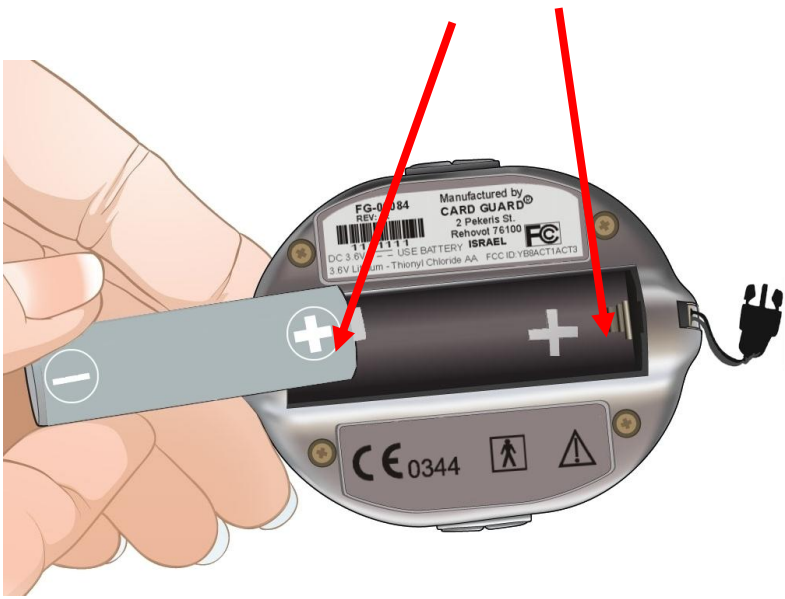


Figure 10. Replacing Battery

e. Place the battery cover back on the sensor as it was before it was removed. Put your thumb on the depression of the battery cover and gently push the battery cover towards the neck strap until you hear a click indicating the battery cover is now in place (see Figure 11).

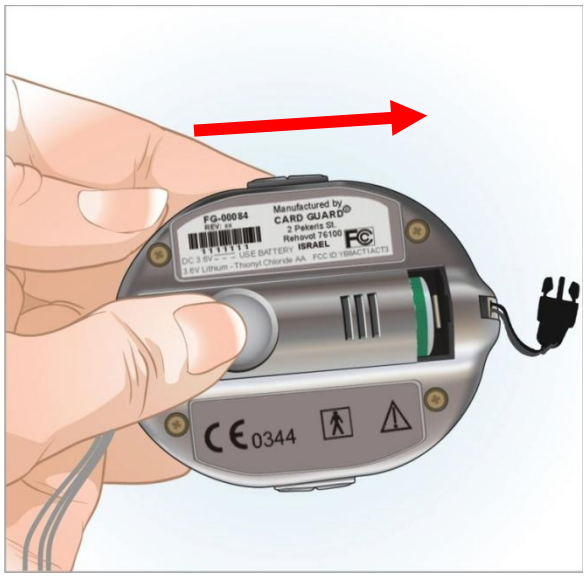


Figure 11.
Replacing Battery Cover

f. It may take up to 5 minutes for the cell phone monitor to display the default recording screen after inserting a new battery.

3. Connect the sensor to the neck strap (if it was not attached).

	Note ▪ Before changing the sensor battery, make sure the cell phone monitor is within range 20 inches (50 cm). ▪ If you are missing batteries, contact LifeWatch.

ACT III with Flip Open Battery Cover

1. Place sensor within 20 inches (50 cm) from the cell phone monitor, place the battery in the sensor:

a. Hold the ACT sensor with the battery compartment facing up. Press the orange button on the upper part of the ACT sensor to release the battery compartment cover.

Figure 12.
Opening Battery Cover

NOTE: Do not attempt to remove the battery cover. If the battery cover becomes separated from the device please refer to the troubleshooting section for replacing the battery cover.

b. Remove a new battery from the plastic bag, place the new battery in the battery compartment (if a battery is already in place, remove the existing battery using the battery strap).

c. Pay careful attention to the battery polarity marks inside the battery compartment (plus sign on the neck strap side, minus sign on the sensor lead wire side). The sensor should beep once within 10 seconds of inserting a new battery. If no sound is heard after ten seconds, verify that the battery has been place in the correct position. If the position is correct, try another battery. If the second battery fails, contact LifeWatch.

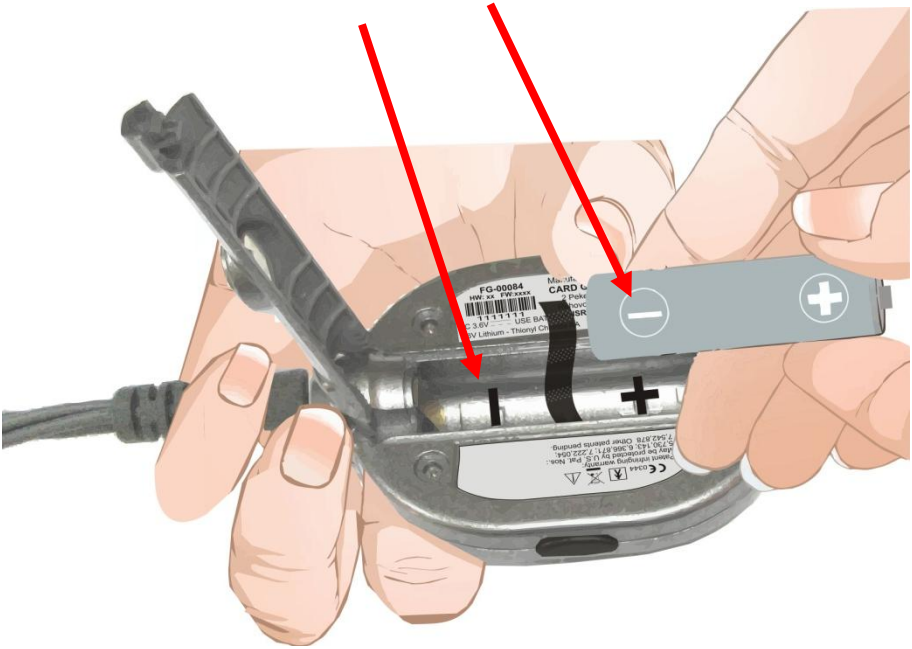


Figure 13. Replacing Battery

d. Gently push the battery cover down towards the neck strap (battery strap should be under the battery cover) until you hear a click indicating the battery cover is in place.

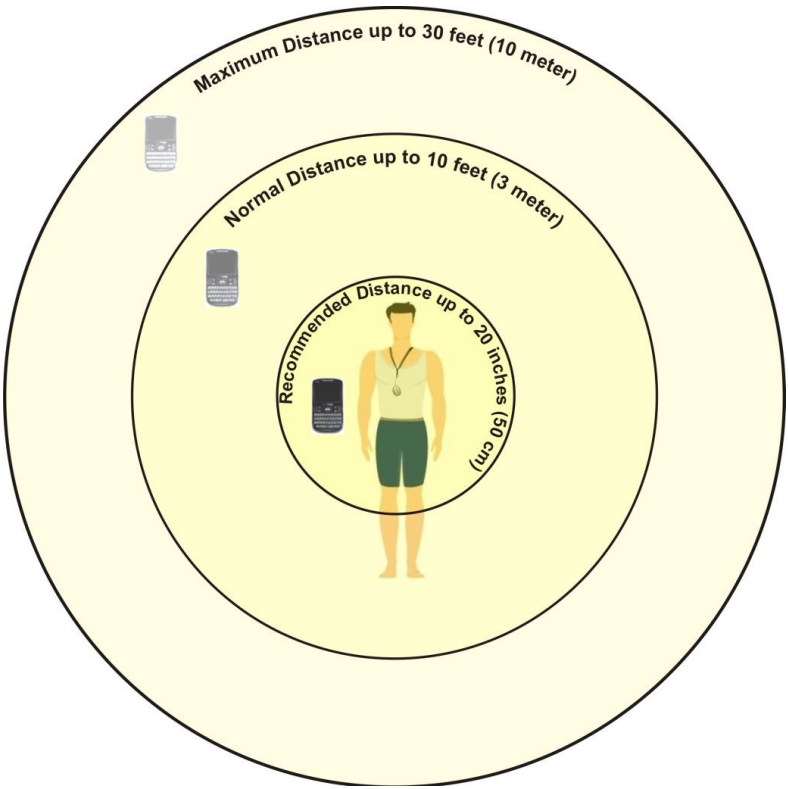
e. It will take up to 5 minutes for the cell phone monitor to display the default recording screen.

2. Connect the sensor to the neck strap (if it was not attached).

Cell Phone Monitor Placement

For optimal system performance, the recommended distances between the cell phone monitor and sensor should be as follows:

Within 20 inches (50 cm) for normal operation
Within 10 feet (3 meters) during cell phone monitor charging
Within 30 feet (10 meters) maximum distance



Cell Phone Monitor Recharging Procedure

Charge the cell phone monitor whenever possible during the day. In addition, charge the monitor every night (regardless of battery indicator status), making sure that it is within 10 feet (3 meters) of the sensor.

1. Plug the cell phone monitor charger power cord into the power socket on the cell phone monitor (see Figures 14 to 16 for location).
2. Plug the supplied cell phone monitor charger unit into a standard wall outlet.
   A red or yellow light (color depends on cell phone monitor type) indicating charging is needed will appear on the cell phone monitor when the charger is properly connected. When charging is complete, the light will turn green.
3. Disconnect the cell phone monitor charger from the wall outlet and then from the cell phone monitor.

Note
The cell phone monitor battery energy consumption in the first few days (up to 72 hours) of monitoring may be high. Always have a charged cell phone monitor and the charger with you during this time.

HTC Ozone mobile phone

Figure 14. HTC Ozone monitor power button and socket

Samsung SGH-i617 mobile phone

Figure 15. SGH-i617 monitor power button and socket

Samsung SGH-i637 mobile phone

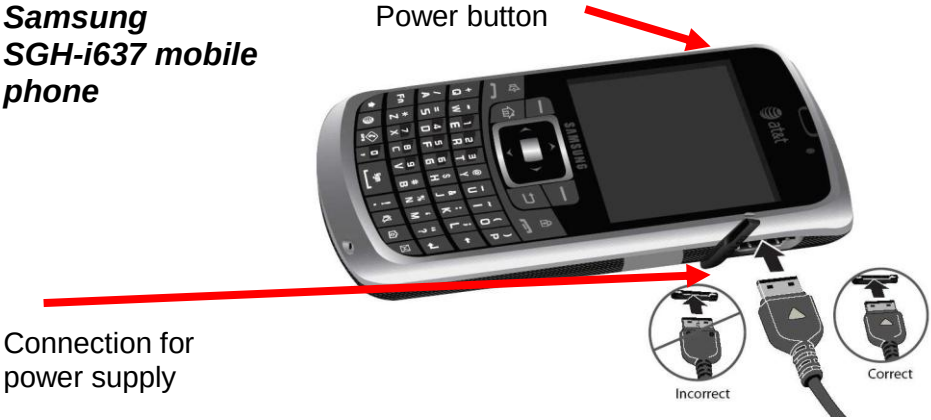


Figure 16. SGH-i637 monitor power button and socket

First Time Activation

The first time the ACT monitoring system is activated, it performs a baseline capture and calibration procedure. The screens you see during this process will only be seen once when the cell phone monitor is turned on for the first time.

1. Connect the sensor electrodes (as shown in Figures 7 and 8).
2. Turn on the cell phone monitor by pressing the POWER button of the cell phone monitor for 5 seconds until the screen lights up.

After a few seconds the screen on the cell phone monitor will display the ACT opening page.

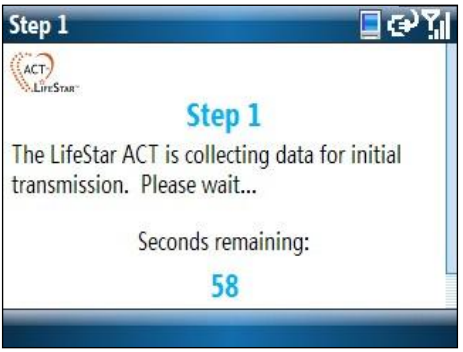
After a few seconds the application will start automatically.

3. When the welcome screen comes up, press Ok using the right soft key to continue or Exit to close the program."

	Note ACT III is used as an example for this section.

4. Place the battery in the sensor.
5. The cell phone monitor will display the following screen after the first connection is established (which can take up to five minutes). A picture of a beating heart will appear and will continue to appear as long as the ACT application is running. It is **not** a representation of your actual heartbeat.

6. Step 1 – Data collection and sending baseline recording. Remain relatively still, without moving or exerting yourself until the baseline recording is sent.



7. When Step 1 is finished the monitoring screen will be displayed for a few seconds, then Step 2 will be displayed.

	Note Step 1 and Step 2 may be performed in parallel by the system and the Step 2 screen may not be displayed.

8. Step 2 – Analyzing electrode contact. The electrode contact is being checked and will be used for calibration. This process may take up to ten minutes.

9. At the end of Step 2 the success message will be displayed and the service will begin automatically.

	Note If you have any questions on the use of the ACT Monitoring System, please contact LifeWatch.

	CAUTION Take a charged cell phone monitor with you and wear the sensor at all times during the monitoring period (except when showering or bathing).

Monitoring Period

This section describes the steps that you need to know if you exit the ACT application after first time activation and additional information about the monitoring period.
The recommended distance between the cell phone monitor and sensor is within 20 inches (50 cm) (see Cell Phone Monitor Placement section).
NOTE: verify the sensor lead wire is connected to the sensor, as described in the Troubleshooting section (for ACT III with Flip Open Battery Cover).

1. Connect the sensor electrodes (as shown in Figures 7 and 8).
2. Turn on the cell phone monitor, press and hold the POWER button of the cell phone monitor for 5 seconds until the screen lights up.
3. After a few seconds the screen on the cell phone monitor will display the ACT opening pages.

After a few seconds the screen on the cell phone monitor will display the ACT opening page.

After a few seconds the application will start automatically.

4. The following screens will be displayed.

ACT III

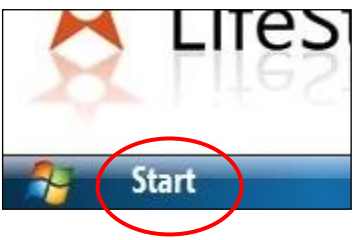
ACT I

5. Please place the battery in the sensor (as shown in Sensor Battery Insertion / Replacement section).

After the connection is established between cell phone monitor and sensor (which can take up to five minutes), the heart icon will be pulsing indicating the system is running (does not represent patient's actual pulse).

⚠	**Caution** **The ACT application should not be closed during the monitoring period.**

If the application needs to be restarted, press the Start button to display the cell phone monitor desktop to manually start the application using the icon.



	Note ACT Ex icon may be displayed during the service period.	

REMEMBER: The events that are recorded automatically will also be transmitted automatically while the application is running.

	Note If there is a problem with the cellular communication or CG-3800BT modem (if in use), the device will continue to function and store the recordings for sending later when the problem is resolved.

Manual Event Recording

If you experience dizziness, fatigue, chest pain or any other symptom, record a manual event.
There are two options for recording a manual event, by pressing the sensor side buttons or by pressing the cell phone monitor manual event button.

When you record a manual event, the ACT application will display a series of screens and a “doorbell” sound will be heard on the cell phone monitor. The screen will return to the normal display when finished.

⚠	**CAUTION:** The manual event recording is not available during the baseline process, even though pressing the manual event buttons will initiate the manual event recording beep. After sensor battery insertion and before connection to the cell phone monitor or during the process of downloading data from the sensor (reconnection after battery replacement) manual event recording is not available.

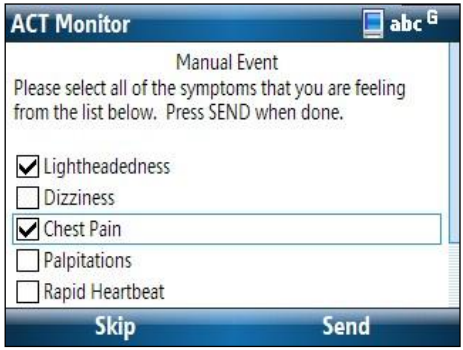
First Option Recording a Manual Event with the Sensor

Press the sensor side buttons simultaneously, then release the buttons when there is a beep.

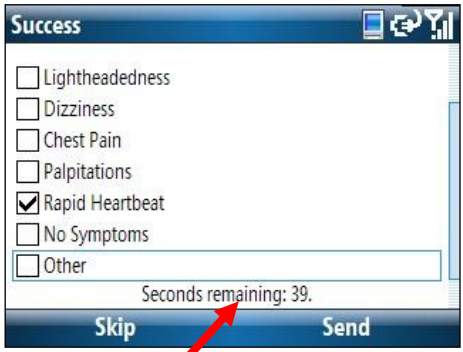
Figure 17. Sensor Manual Recording

The cell phone monitor’s manual event screen will be displayed after a few seconds (when connected to the cell phone monitor).

Select and mark the applicable symptom(s) then press the Send button to send the form. If your symptom is not on the list, select and mark “Other” and send the form. If you don’t have any symptom, select and mark “No Symptoms” and send the form.



Scroll

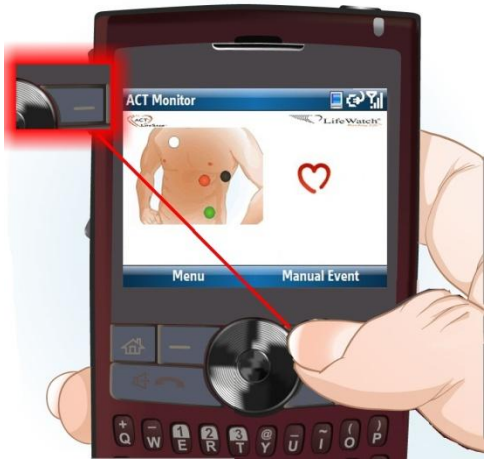


If “Send” is not pressed the manual event will be automatically sent at the end of the countdown without the form. The cell phone monitor screen will return to the normal operation screen.

	Note When there is a disconnection between the sensor and the cell phone monitor the manual event will be transmitted when there is reconnection to the cell phone monitor.

Second Option Recording a Manual Event with the cell phone monitor

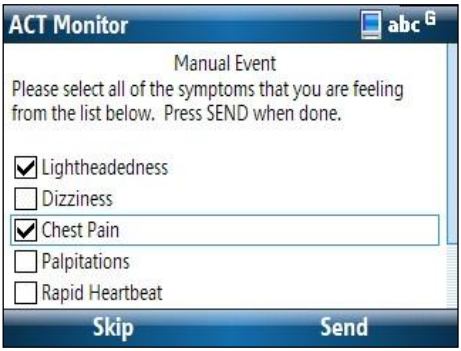
Press the cell phone monitor right soft key to initiate a Manual Event recording.



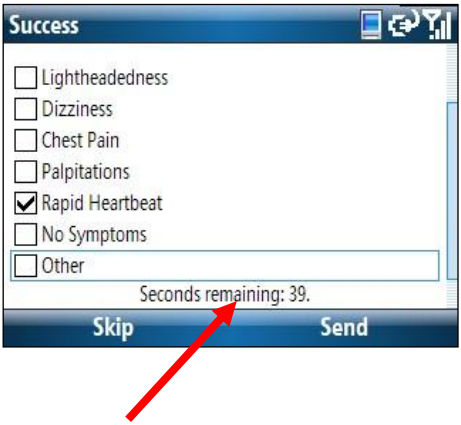
If you have pressed the cell phone monitor's Manual Event button the following confirmation screen will be displayed on the cell phone monitor. To send the manual event press Yes or press No to cancel the manual event (will resume to normal operation).

This screen disappears after a few seconds if no button was pressed and the event will not be sent.

When Yes has been pressed, the manual event form will be displayed. Select and mark the applicable symptom(s) then press the Send button to send the form. If your symptom is not on the list, select and mark “Other” and send the form. If you don’t have any symptom, select and mark “No Symptoms” and send the form.



Scroll



If “Send” is not pressed the manual event will be automatically sent at the end of the countdown. The cell phone monitor screen will return to the normal operation screen.

Note

Situations when it is not possible to record a manual event with the cell phone monitor.

During the process of collecting manual event data it is not possible to initiate a new manual event.

When the sensor and the cell phone monitor are disconnected for any reason, the manual event can be recorded with the sensor. It will be transmitted when the connection to the cell phone monitor is reestablished. Disconnections may occur if the sensor and cell phone monitor are out of range as described in the Cell Phone Monitor Placement section or immediately following sensor battery replacement.

During the process of downloading data from the sensor (reconnection after battery replacement), manual event recording is not available.

6. Cell Phone Monitor Messages

Messages inform you about a problem that might occur during operation of the ACT monitoring system. The message may include steps to resolve the problem (cellular coverage may resolve by itself). A message screen may be closed (by pressing OK), but if the underlying problem has not been resolved it will be indicated on the cell phone monitor screen.
The message will be accompanied by a sound prompt and cell phone monitor vibration (optional). It might take a few minutes to remove a message after a correction has been resolved.

Message Types

Sensor battery low level	
Cell phone monitor battery low level	
Sensor (Bluetooth) disconnection	
Cell phone monitor transmission problem	
Electrode connectivity	
Code Messages	
 **Note -** It is possible for multiple messages to be displayed on the cell phone monitor screen. The message will not be displayed when the correction has been registered.	

Sensor Battery Low

The low battery message appears when the sensor battery needs to be replaced. Please refer to “Sensor Battery Insertion / Replacement”, section, for information on how to replace the battery.

Be aware that the sensor alerts its low battery status with 1 long beep then a short beep from the sensor.

“Sensor battery needs to be replaced” screen, replace battery and press OK to continue.

After inserting the new battery it will take up to five minutes for the system to register the change and display the default recording screen.

This screen is displayed until the change is registered.

Cell Phone Monitor Battery Low

The cell phone monitor low battery message appears when the cell phone monitor needs to be charged. Please refer to “Cell Phone Monitor Charging Procedure” section for information on how to charge the cell phone monitor.

“Cell phone monitor low battery” message, press OK and charge the cell phone monitor.

Screen displayed until cell phone monitor is connected to charger and inserted in the wall outlet

Cell phone monitor low battery message that can be initiated from the cell phone monitor operating system. Press OK and charge the cell phone monitor.

Sensor (Bluetooth) Disconnection

The sensor disconnection message appears when there is Bluetooth disconnection from the cell phone monitor.

Be aware that a disconnection can be caused by the sensor being in low battery mode (accompanied by 1 long beep then a short beep from the sensor), please refer to “Sensor Battery Low” section.

“Connection lost between the sensor and the cell phone monitor” screen, make sure the cell phone monitor and sensor are within 20 inches (50 cm) and then press OK to continue.

Screen displayed until connection is re-established.

Cell Phone Monitor Transmission Problem

The cell phone monitor transmission message appears when there are transmission problems that could be caused by poor cellular coverage, cellular network problems or communication problems with the CG-3800BT modem (if modem is in use).

Make sure you have good cellular coverage by checking the cellular signal strength in the upper right corner and press OK to continue.

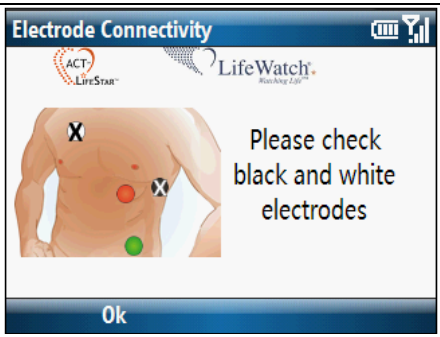
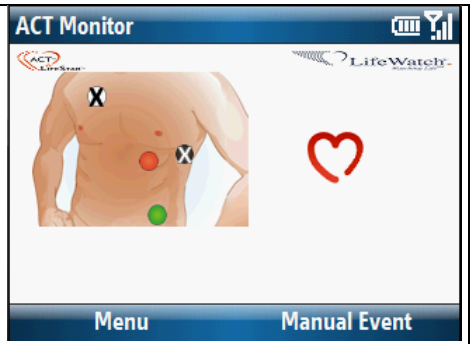
This screen will be displayed until the communication issue has been resolved.

Electrode Connectivity

The electrode connection message appears when there are problems with the contact of one or more electrodes.

Please check the electrode connections when you see these screens. When the electrodes are reconnected, it will take up to 3 minutes to update the screen (assuming that the Bluetooth link is up).

Electrode connectivity message screen examples:

	
Electrode connectivity message	Screen after pressing OK. The screen will return to normal operation after problem is solved.

Please follow these instructions to ensure proper contact of the electrodes:

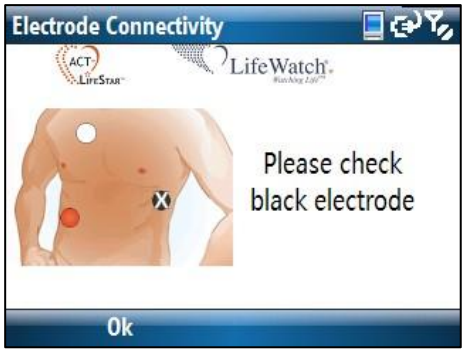
1) Make sure that the sensor lead wires are properly connected to the electrodes.
2) Make sure the electrodes are properly attached.

Please refer to “Electrode Placement” section for further information.

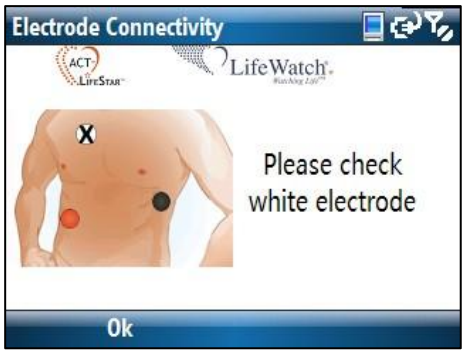
	**Note** - There are physiological conditions that may affect the cell phone monitor from detecting the electrode connection and can last for several hours. Even though the electrodes seem to be in good contact with the body, the message will continue to appear. Some examples are very dry skin or right after attaching the electrodes. If the condition does not resolve, contact LifeWatch.

Electrode Messages for ACT I

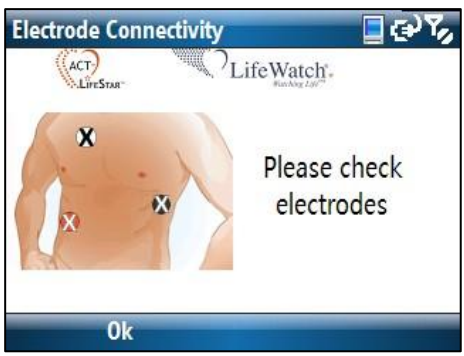
Black electrode problem



White electrode problem

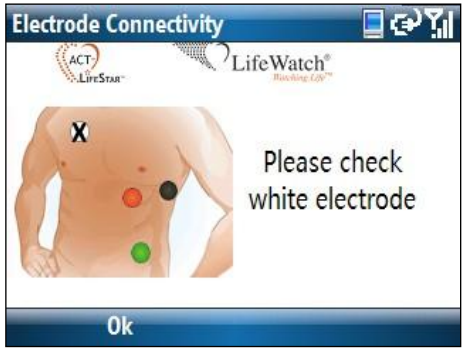


Red (or all) electrode(s) problem
Correct the problem and press OK.

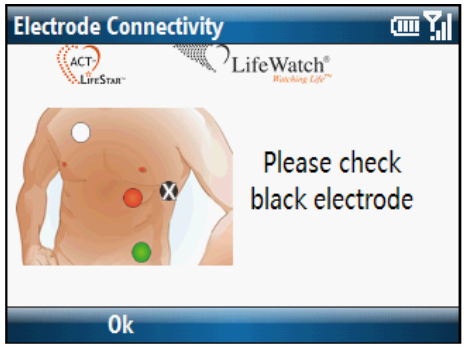


Electrode Messages for ACT III

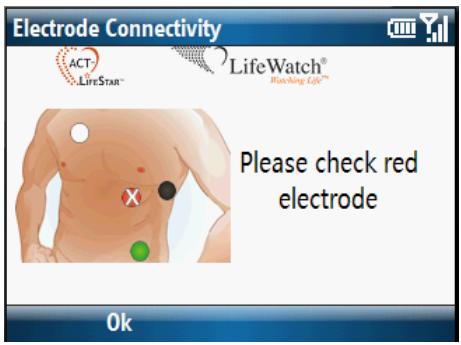
White electrode problem



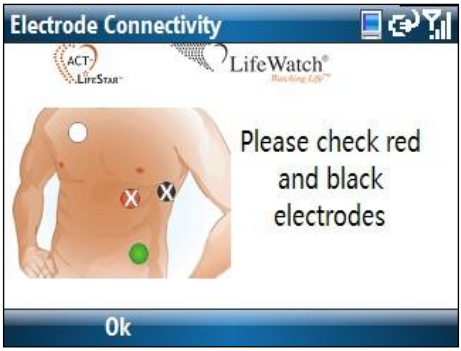
Black electrode problem



Red electrode problem

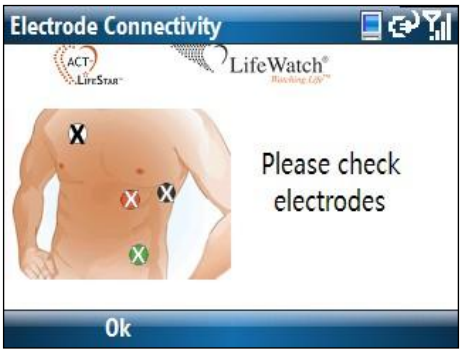


Red and black electrodes problem



	Note When two electrodes (white, red or black) have problems there will be a message indicating which two electrodes need to be checked.

Green (or all) electrode(s) disconnected or lead wire is disconnected from sensor (ACT III sensor with flip-open cover) Correct the problem and press OK.



Code Messages

Code messages are displayed on the cell phone monitor screen whenever an unexpected situation occurs. Please follow the instructions displayed in the screen. See Appendix B for a list of the message codes.

Code Message example

7. Maintenance

Conditions of Use

Your ACT system conforms to international standards as long as it is used under normal conditions and in accordance with the following instructions.

Caring for your ACT

CAUTION

- Do not open or attempt to repair the sensor or cell phone monitor yourself. Only authorized service personnel may repair the product.
- Do not drop your sensor or cell phone monitor or subject them to severe impact.
- Do not bend the sensor or the sensor lead wire.
- Do not use extreme force when pressing the sensor buttons.
- Do not use solvents to clean your ACT sensor or cell phone monitor.
- Do not spray perfume or other substances on the sensor.
- The ACT sensor is not waterproof. Do not use it or store it where fluids such as water can splash onto it. Raindrops, water spray, juice, coffee, steam, perspiration, etc. may also cause a malfunction.
- Do not expose the sensor batteries or battery contacts to fluids such as water, raindrops, water spray, juice, coffee, steam, perspiration, etc.
- Do not shower, bathe or swim with the cell phone monitor or the sensor. Keep the cell phone monitor and the sensor out of the bathroom when showering or bathing.

Environment

- Keep the ACT monitoring system away from extreme heat and cold. Do not leave any part on the dashboard of a car or near a heater.
- Do not leave any part of the ACT monitoring system in any place that is wet, damp or dusty.

Preventive Maintenance

The following simple preventive maintenance tasks should be performed monthly to ensure continued performance of the device at maximum capacity, and to reduce the possibility of a failure.

Mechanical Inspection

Check for splits, cracks or other related flaws in the ACT monitoring system. If you have any questions or doubts, call LifeWatch.

Cleaning

To clean the outside of the ACT monitoring system use a lint-free cloth lightly moistened with isopropyl alcohol.

Never use abrasives such as wire wool or metal polish.

During cleaning, make sure you do not expose the device to temperatures in excess of 113°F (45°C).

8. Troubleshooting

Please follow the steps listed below in order to resolve the problem. If this does not solve the problem contact LifeWatch.

Problem	Possible Cause(s)	Solution
No beep when the sensor is activated (up to 10 seconds after battery inserted).	Battery not placed properly/reversed polarity. The battery is very low or depleted.	1) Check the battery placement and polarity. 2) Sensor battery needs to be changed, refer to “Sensor Battery Insertion/Replacement ” section, for information on how to replace the battery.
Displays an electrode problem (message).	Electrode connection does not provide proper contact (loose, disconnected or bad contact with skin).	1) Make sure that the sensor lead wire is properly connected to the electrodes and sensor (for attachable leads). 2) Make sure the electrodes are properly attached to the skin. 3) There are physiological conditions that may affect the cell phone monitor from detecting the electrode connection and can last for several hours.

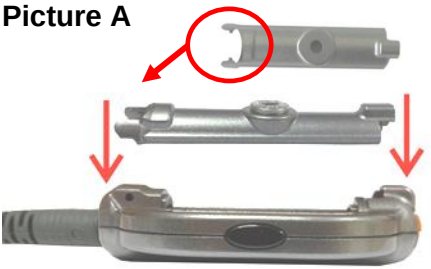
Problem	Possible Cause(s)	Solution
		Even though the electrodes seem to be in good contact with the body, the message will continue to appear. Some examples are very dry skin or right after attaching the electrodes. 4) Please refer to “Electrode Placement” section for further information.
Sensor disconnection message.	Lack of communication between sensor and cell phone monitor. Sensor low battery can cause disconnection (accompanied sound prompt of 1 long beep then a short beep from the sensor).	1) Make sure the sensor and cell phone monitor are within 20 inches (50 cm). 2) Sensor battery needs to be changed, please refer to “Sensor Battery Insertion/Replacement ” section for information on how to replace the sensor battery. 3) Cell phone monitor needs to be recharged, please refer to “Cell Phone Monitor Recharging Procedure” section for

Problem	Possible Cause(s)	Solution
		information on how to recharge the cell phone monitor.
Cell phone monitor low battery message.	The cell phone monitor low battery message appears when the cell phone monitor needs to be recharged.	The cell phone monitor needs to be recharged, please refer to “Cell Phone Monitor Recharging Procedure” section for information on how to recharge the cell phone monitor.
Sensor beeps 1 time.	Sensor activated.	Normal operation
Cell phone monitor communication message.	The cell phone monitor transmission message appears when there are transmission problems that could be caused by poor cellular coverage, cellular network problems or communication problems with the CG-3800BT modem (if modem is in use).	1) Make sure you have good cellular coverage. 2) Make sure you are within 30 feet (10 m) of the cell phone monitor and CG-3800BT modem (if in use). 3) Cell phone monitor needs to be charged, please refer to “Cell Phone Monitor Charging Procedure” section for information on how to charge the cell phone monitor.
Sensor beeps 3 times, repetitive.	Critical system error.	1) Remove sensor battery for 30

Problem	Possible Cause(s)	Solution
		seconds; then re-insert battery. Allow up to 5 minutes for sensor and cell phone monitor to reconnect. 2) Make sure that the sensor lead wire is properly connected to the sensor (for attachable leads).
Sensor beeps 1 long beep then short beep.	Sensor battery low or critical.	Sensor battery needs to be replaced, please refer to “Sensor Battery Insertion/Replacement” section, for information on how to replace the battery.

Problem	Possible Cause(s)	Solution
Battery cover separates from device *Note: Relevant to ACT III Flip Open Battery Cover ONLY*	Replace battery cover	1) Place battery cover on device in the proper place (see picture A and B) 2) Press down firmly on battery cover at point (1) as shown in picture C until you hear a click. 4) Press down firmly on battery cover at point (2) in picture D until you hear a click.

Picture A



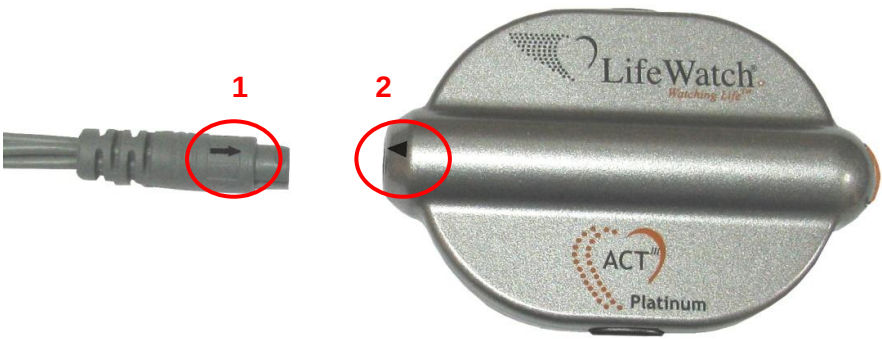
Picture C

Picture B

Picture D

Battery Cover Properly Placed

Problem	Possible Cause(s)	Solution
Sensor lead wire disconnected *NOTE: for ACT III with Flip Open Battery Cover*	Sensor lead wire detached from sensor	Verify the sensor lead wire is connected to the ACT sensor socket by first aligning the arrow on the lead wire (1) with the arrow on the ACT sensor (2) and then push firmly. This will make the proper connection.



9. Technical Specifications

IMPORTANT

This device complies with Part 15 of the FCC 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.

Declaration of Conformity

Conformance to Standards – non-clinical testing demonstrated conformance to voluntary Safety standard IEC 60601-1:1998 (with Amendments 1 & 2)
and to EMC standard IEC 60601-1-2:2001 Class B
Card Guard's Quality System conforms to ISO-9001:2008, ISO 13485:2003, and complies with CE MDD requirements
Tested for compliance with FCC 47 CFR Part 15, subpart B and subpart C

ACT I Sensor Technical Specifications

Parameter	Min	Max	Typical	Units
Input Impedance	19.5	20.5	20	MΩ
Input dynamic range			+/- 5	mV
Average current consumption	4	12	6.5	mA
Peak current Consumption	N/A	80	75	mA
CMRR			75	dB
ADC sample rate	250	250	250	samples/sec
DC offset correction			150	|mV|
LPF cutoff frequency	61.8	90.45	76	Hz
HPF cutoff frequency	.043	.065	.005	Hz
Impedance measurement range	0	793		KΩ
Arrhythmia algorithm detection voltage range	0.4	5		|mV|
System noise			32	µV
Pacemaker pulse width marking	0.2	2		msec
Pacemaker pulse amplitude marking	2	250		mV
ECG data buffer			32	MBit
ECG buffering time			2:19	Hrs
Manual ECG event triggering			Yes	
PM detection			Yes	

Parameter	Min	Max	Typical	Units
Bluetooth transmission range - open space	N/A	20	10	meters
Bluetooth protocol	SPP profile, Sniff mode, Auto-connection mode			
Battery type	3.6V lithium-thionyl chloride AA			
Battery life (dependent upon Bluetooth connectivity)	2	4		Days
MTBF (hours)			36,305	Hrs
Operating temperature	10 (50)	40 (104)		°C (°F)
Transport & storage temperature	-20 (-4)	65 (149)		°C (°F)
Relative humidity (non-condensing)	30	85		%
Dimensions (max.)			75 x 58 x 23	mm
Net weight (w/o battery)			42.2	gr.

ACT III Sensor Technical Specifications

Parameter	Min	Max	Typical	Units
Input operating DC voltage	3.0	3.6	3.5	V
Input Impedance	19.5	20.5	20	MΩ
Input dynamic range	+/- 4.5	+/- 5.5	+/- 5	mV
Average current consumption	5	25	15	mA
Peak current consumption	N/A	80	75	mA
CMRR	60	N/A	75	dB
ADC sample Rate	246	254	250	samples/sec
DC offset correction	0	+/- 150	+/-115	mV
LPF cutoff frequency	99.6	157.9	115.7	Hz
HPF cutoff frequency	.035	.055	.041	Hz
Impedance measurement range	0	793	N/A	KΩ
Arrhythmia algorithm detection voltage range	0.4	5	N/A	mV
System noise	0	50	35	µV
Pacemaker pulse width marking	0.2	2	N/A	msec
Pacemaker pulse amplitude marking	2	250	N/A	mV
ECG data buffer (storage memory)	32	32	32	MB

Parameter	Min	Max	Typical	Units
ECG buffering time	6:13	N/A	6:19	Hours:Minutes
Manual ECG event triggering	N/A	N/A	Yes	None
PM detection	N/A	N/A	Yes	None
Bluetooth Transmission range - open space	N/A	20	10	meters
Bluetooth protocol	SPP profile, Sniff mode, Auto-connection mode			None
Battery type / output	lithium-thionyl chloride AA			N/A
Battery life (dependent upon Bluetooth connectivity)	2	3	Use dependent	Days
MTBF (hours)	N/A	N/A	26,058	Hours
Operating temperature	10 (50)	40 (104)	N/A	°C (°F)
Transport & storage temperature	-20 (-4)	65 (149)	N/A	°C (°F)
Relative humidity (non-condensing)	30	85	N/A	%
Dimensions (max.)	N/A	N/A	75 x 58 x 23	mm
Net weight (w/o battery)	55	60	57	gr.

10. Appendix A Monitor (Cellular Phone) Warnings

Using Your Phone Near Other Electronic Devices

Most modern electronic equipment is shielded from radio frequency (RF) signals.

However, certain electronic equipment may not be shielded against the RF signals from your wireless phone. Consult the manufacturer to discuss alternatives.

Implantable Medical Devices

A minimum separation of six (6) inches (15 cm) should be maintained between a handheld wireless phone and an implantable medical device, such as a pacemaker, to avoid potential interference with the device.

Persons who have such devices:

- Should ALWAYS keep the phone more than six (6) inches (15 cm) from their implantable medical device when the phone is turned ON;
- Should not carry the phone in a breast pocket;
- Should use the ear opposite the implantable medical device to minimize the potential for interference;
- Should turn the phone OFF immediately if there is any reason to suspect that interference is taking place.
- Should read and follow the directions from the manufacturer of your implantable medical device. If you have any questions about using your wireless phone with such a device, consult your health care provider.

Hearing Aid Compatibility with Mobile Phones

FCC Hearing-Aid Compatibility (HAC) Regulations for Wireless Devices

On July 10, 2003, the U.S. Federal Communications Commission (FCC) Report and Order in WT Docket 01-309 modified the exception

of wireless phones under the Hearing Aid Compatibility Act of 1988 (HAC Act) to require digital wireless phones be compatible with hearing-aids. The intent of the HAC Act is to ensure reasonable access to telecommunications services for persons with hearing disabilities.

While some wireless phones are used near some hearing devices (hearing aids and cochlear implants), users may detect a buzzing, humming, or whining noise. Some hearing devices are more immune than others to this interference noise, and phones also vary in the amount of interference they generate.

The wireless telephone industry has developed a rating system for wireless phones, to assist hearing device users find phones that may be compatible with their hearing devices. Not all phones have been rated. Phones that are rated have the rating on their box or a label located on the box.

The ratings are not guarantees. Results will vary depending on the user's hearing device and hearing loss. If your hearing device happens to be vulnerable to interference, you may not be able to use a rated phone successfully. Trying out the phone with your hearing device is the best way to evaluate it for your personal needs.

M-Ratings: Phones rated M3 or M4 meet FCC requirements and are likely to generate less interference to hearing devices than phones that are not labeled. M4 is the better/higher of the two ratings.

T-Ratings: Phones rated T3 or T4 meet FCC requirements and are likely to be more usable with a hearing aid's telecoil than phones that are not rated. T4 is the better/higher of the two ratings.

Hearing devices may also be rated. Your hearing device manufacturer or hearing health professional may help you find this rating. Higher ratings mean that the hearing device is relatively immune to interference noise. The hearing aid and wireless phone rating values are then added together. A sum of 5 is considered acceptable for normal use. A sum of 6 is considered for best use.

In the above example, if a hearing aid meets the M2 level rating and the wireless phone meets the M3 level rating, the sum of the two values equal M5. This should provide the hearing aid user with "normal usage" while using their hearing aid with the particular

wireless phone. “Normal usage” in this context is defined as a signal quality that is acceptable for normal operation.

The M mark is intended to be synonymous with the U mark. The T mark is intended to be synonymous with the UT mark. The M and T marks are recommended by the Alliance for Telecommunications Industries Solutions (ATIS). The U and UT marks are referenced in Section 20.19 of the FCC Rules. The HAC rating and measurement procedure are described in the American National Standards Institute (ANSI) C63.19 standard.

Some digital wireless phones may interfere with some hearing aids. In the event of such interference, you may wish to consult your hearing aid manufacturer to discuss alternatives.

Other Medical Devices

If you use any other personal medical devices, consult the manufacturer of your device to determine if it is adequately shielded from external RF energy. Your physician may be able to assist you in obtaining this information. Switch your phone off in health care facilities when any regulations posted in these areas instruct you to do so. Hospitals or health care facilities may be using equipment that could be sensitive to external RF energy.

Children Using Wireless Phones

The scientific evidence does not show a danger to users of wireless phones, including children and teenagers. If you want to take steps to lower exposure to radio frequency energy (RF), the measures described above would apply to children and teenagers using wireless phones. Reducing the time of wireless phone use and increasing the distance between the user and the RF source will reduce RF exposure.

Some groups sponsored by other national governments have advised that children be discouraged from using wireless phones at all. For example, the government in the United Kingdom distributed leaflets containing such a recommendation in December 2000. They noted

that no evidence exists that using a wireless phone causes brain tumors or other ill effects. Their recommendation to limit wireless phone use by children was strictly precautionary; it was not based on scientific evidence that any health hazard exists.

Body-worn Operation

To comply with RF exposure requirements, a minimum separation distance of 0.50 inch (1.5 cm) must be maintained between the user's body and the handset, including the antenna. Third-party belt-clips, holsters, and similar accessories used by this device should not contain any metallic components. Body-worn accessories that do not meet these requirements may not comply with RF exposure requirements and should be avoided.

Use only the supplied or an approved antenna. Unauthorized antennas, modifications, or attachments could impair call quality, damage the phone, or result in violation of regulations. Do not use the phone with a damaged antenna. If a damaged antenna comes into contact with the skin, a minor burn may result. Please contact your local dealer for replacement antenna.

11. Appendix B Message Codes

Message displayed
CODE 201 Please call LifeWatch at 1-800-517-6330
CODE 211 To resolve: Turn phone OFF and then ON If not resolved call LifeWatch at 1-800-517-6330
CODE 212 Monitoring has not started Please call LifeWatch at 1-800-517-6330 to begin monitoring
CODE 213 To resolve: Turn phone OFF and then ON If not resolved call LifeWatch at 1-800-517-6330
CODE 220 Please call LifeWatch at 1-800-517-6330
CODE 221 Please call LifeWatch at 1-800-517-6330
CODE 222 Please call LifeWatch at 1-800-517-6330
CODE 223 Please call LifeWatch at 1-800-517-6330
CODE 230 Please call LifeWatch at 1-800-517-6330
CODE 240 To resolve: Turn phone OFF and then ON If not resolved call LifeWatch at 1-800-517-6330
CODE 241 To resolve: Turn phone OFF and then ON If not resolved call LifeWatch at 1-800-517-6330
CODE 242

To resolve: Turn phone OFF and then ON If not resolved call LifeWatch at 1-800-517-6330
CODE 250 Please call LifeWatch at 1-800-517-6330
CODE 260 Please call LifeWatch at 1-800-517-6330
CODE 270 Please call LifeWatch at 1-800-517-6330
CODE 280 Please call LifeWatch at 1-800-517-6330
CODE 290 Please call LifeWatch at 1-800-517-6330
CODE 401 ACT Monitor will restart If this re-occurs please call LifeWatch at 1-800-517-6330
CODE 403 Please remove and then re-insert battery into sensor If not resolved call LifeWatch at 1-800-517-6330
CODE 700 Please remove and then re-insert battery into sensor If this re-occurs please call LifeWatch at 1-800-517-6330
CODE 701 Please remove and then re-insert battery into sensor If this re-occurs please call LifeWatch at 1-800-517-6330
CODE 901 Please call LifeWatch at 1-800-517-6330

12. Limited Warranty

1. This Card Guard® Device ("CG Device") is warranted against defective material and workmanship for a warranty term of 1 year following shipment from Card Guard facility of this product to the customer ("Warranty Term"). If this product or any part thereof, in the judgment of Card Guard, is proven to be defective in material or workmanship within the warranty term, Card Guard will at its sole discretion either repair the item or replace it with a similar one (refurbished device), to enable the designated use of the Card Guard Device (the “Hardware Services”) free of charge for parts or labor.

2. The Hardware Services shall not include any of the following:

    i. Replacement of consumable items, supplies or accessories (such as printer consumables, disks, paper, disposable electrodes, disposable mouthpieces etc.);

    ii. Services required as a result of failure of electrical power, air conditioning, dust or humidity control;

    iii. Services required as a result of the use of attachments or any other devices which are not compatible with the CG Device or with the system in which they are installed and do not meet Card Guard's specifications or standards;

    iv. Services required as a result of fire, lightning, flood, wind, accident, theft, abuse, negligence, misuse, vandalism, corrosion, natural disaster, or any causes other than ordinary use for which the CG Device was designed;

    v. CG Device which has been damaged by accident or which has been misused, abused, altered or repaired by anyone other than Card Guard;

    vi. Customer abuse, such as, marks, scratches, broken parts corrosion etc.; and

    vii. Electrical work the necessity of which is not related to the regular function of the CG Device. Card Guard holds the sole discretion to decide which of the CG Devices will not validated under this warranty.

3. The warranty period for the repaired / refurbished CG Device is for a three (3) month period following the Hardware Services’ delivery to Card Guard.

4. Without derogating from any other provisions of this warranty, the customer shall only use attachments or any other devices which, at Card Guard’s discretion and as approved by Card Guard in writing, are compatible to the CG Device in

which they are installed or to which they are connected; this Section 4 pertains to the importance of liability for Card Guard Products;

5. CARD GUARD SHALL NOT BE LIABLE TO ANY PERSON FOR ANY SPECIAL, CONSEQUENTIAL OR INDIRECT DAMAGES, INCLUDING, BUT NOT LIMITED TO, DAMAGES TO OR LOSS OF PROPERTY OR EQUIPMENT, LOSS OF PROFIT, LOSS OF USE OF DATA, LOSS OF REVENUES OR DAMAGES TO BUSINESS OR REPUTATION ARISING FROM ANY CAUSE WHATSOEVER ARISING FROM OR IN ANY WAY CONNECTED WITH THE MANUFACTURE, SALE, HANDLING, REPAIRS MAINTENANCE OR USE OF THE CG DEVICE, WHETHER OR NOT CARD GUARD SHALL HAVE BEEN MADE AWARE OF THE POSSIBILITY OF SUCH LOSS PROVIDED THAT IT IS NOT OTHERWISE REGULATED BY THE APPLICABLE LAW. NOTWITHSTANDING ANY OF THE FOREGOING, CARD GUARD'S LIABILITY FOR ANY CLAIMS ARISING OUT OF OR IN CONNECTION WITH THIS WARRANTY, SHALL IN THE AGGREGATE, BE LIMITED TO THE TOTAL PRICE PAID FOR THIS PRODUCT, IF SUCH LIABILITY DOES NOT ARISE FROM THE GROSS NEGLIGENCE OR FAULT OF CARD GUARD.

6. This warranty is in lieu of all other warranties expressed or implied, including any implied warranty of merchantability or fitness for a particular purpose, and no person is authorized to assume for Card Guard any other liability in connection with the sale of this product.

7. To obtain factory service, this product should be shipped to Card Guard. The customer shall bear the cost of shipment to Card Guard, and similarly, Card Guard shall bear the cost of shipment from Card Guard.

8. All repaired or replaced parts will be released by Card Guard within 30 days from receiving.

9. The customer may, 60 days prior to the end of the Warranty Term, notice Card Guard of its request to receive from Card Guard, post warranty services according to Card Guard's policies and upon signing a Post Warranty Services Agreement.

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PLEASE CALL

1.800.517.6330

FOR 24/7 CUSTOMER SUPPORT