

Aera CT 3G

Mobile Cardiac Monitor



Operator Manual

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Description

Caution: US Federal law restricts this device to sale by or on the order of a physician.

The Aera CT is a battery operated ambulatory electrocardiograph recorder for use in mobile cardiovascular telemetry. It is capable of storing 3 channels of patient ECG data acquired from three or five surface electrodes adhered to the body for over 28 days of continuous recording. The Aera CT employs a rechargeable Lithium-Ion battery to achieve such an extended recording duration.

The Aera CT provides the ability to automatically detect and record pacemaker pulses as well as several common arrhythmias in accordance with the applicable standards of the Association for the Advancement of Medical Instrumentation (AAMI).

The Aera CT contains an internal cellular modem to allow access to the patient ECG data and analysis results. Any piece of data recorded on the device may be queried wirelessly during the course of the study. Additionally, data transmissions may be triggered automatically or manually as a result of arrhythmia analysis, or manual patient input, respectively.

The Aera CT provides a multitude of options to control recording parameters such as bit resolution, sampling rate, and frequency response as well as analysis parameters such as heart rate thresholds. These settings may be updated wirelessly during the course of a study to allow the device to dynamically adapt to the needs of the operator.

The Aera CT does not provide interpretive or diagnostic statements. Interpretation and diagnosis are the responsibilities of a trained healthcare professional or physician.

Indications for Use

The Aera CT is intended for acquiring ambulatory ECG signals from patients who either are at risk of having cardiac disease or have intermittent symptoms indicative of cardiac disease and who have demonstrated a need to be monitored on a continuing basis.

Indications for conducting ambulatory recording include:

- Patients requiring monitoring for non life-threatening arrhythmias such as supraventricular tachycardias and ventricular ectopy.
- Patients requiring monitoring for evaluation of bradyarrhythmias and intermittent bundle branch block including after cardiovascular surgery and myocardial infarction.
- Patients requiring monitoring for arrhythmias associated with co-morbid conditions such as hyperthyroidism or chronic lung disease.
- Patients experiencing symptoms such as a) syncope of unknown etiology or b) shortness of breath which may be due to cardiac arrhythmias.
- Patients with palpitations with or without known arrhythmias to obtain correlation of arrhythmias with symptoms.
- Patients who require monitoring of the effects of drugs to control ventricular rate in atrial arrhythmias.
- Patients recovering from cardiac surgery that are indicated for outpatient arrhythmia monitoring.
- Patients with diagnosed sleep disordered breathing including sleep apnea (obstructive central) to evaluate possible nocturnal arrhythmias.
- Patients requiring arrhythmia evaluation of etiology of stroke or transient cerebral ischemia, possibly secondary to atrial fibrillation or flutter.

Data from this device may be used by another device to analyze, measure, or report QT interval. The device is not intended to sound any alarms for QT interval changes.

Contraindications

The Aera CT is not intended for use under the following conditions:

- Infants weighing less than 10 kg. (22 lbs.).
- Patients with potentially life-threatening arrhythmias who require inpatient monitoring.
- Patients who the attending physician thinks should be hospitalized.

Recorder Components

Figure 1

1. Color Display
2. Patient Event Button
3. Up Key
4. Left Key
5. Select Key
6. Right Key
7. Down Key



Front view of the Aera CT.

Figure 2

1. Battery Compartment
2. microSD Card Holder
3. Serial Number



Back view of the Aera CT.

Recorder Components (continued)






Figure 3

1. Patient Cable Receptacle
2. Power Cable Receptacle
3. Power Receptacle Plug



Side view of the Aera CT.

Equipment Symbols

	Consult the Directions For Use
	Type B device
	Electrically Isolated
	Manufacturer Info
	Emits Non-ionizing Radiation
RX Only	Prescription Only

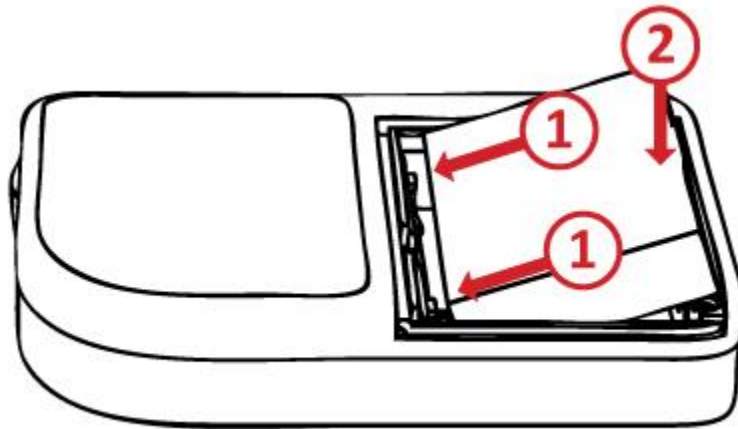
Precautions

- Use only a TZ Medical, Inc. certified microSD memory card for recording.
- Do not connect anything other than the battery charger provided by TZ Medical, Inc. to the charge port on the Aera CT.
- Use only patient cables provided by TZ Medical, Inc. with the Aera CT.
- Observe the procedures for early recording cessation. Failure to do so may result in the loss of recorded data. (*Page 17*)
- Disconnect patient leads before defibrillation.
- False positive and false negative pacemaker pulse detects may occur when using Pacemaker Pulse Detection.
 - False positives – may result from poor electrode connection to the patient or a large amount of electrical interference from nearby source.
 - False negatives – may occur with pacemakers that are bipolar because of a weak pacemaker pulse signal at the patient's skin.
- When viewing the ECG data, the presence of pacemaker signals in the ECG trace should not be considered true representations of the actual pacemaker stimulus amplitude.
- To avoid unintended battery discharge, do not leave the battery in the recorder when it is not in use.
- To receive the best recording results, instruct patients to stay away from heavy electrical equipment or other sources of electromagnetic interference. This includes equipment such as electric blankets and heating pads.
- Avoid exposing device to water or excessive moisture.
- Do not expose device to extreme temperatures (beyond the limits shown in the environmental specifications).

Battery Installation Instructions

1. Align slots in battery with tabs in device.
2. Push battery down on side opposite the tabs.

Figure 4



Battery Insertion.

Initial Device Setup

When you first receive your Aera CT device, the wireless system must be configured to communicate with your receiving software. To achieve this, follow the instructions from your software provider to load the necessary wireless settings onto the provided microSD card.

Insert the configured microSD card into the card holder, located in the battery compartment, of the Aera CT. Insert the battery and replace the battery cover.

On power-up, the Aera CT will detect the wireless settings and attempt to connect to the new server to verify the new settings. This process may take a few moments to complete.

Figure 5



This screen will be displayed while the Aera CT is verifying new wireless settings.

Once the Aera CT has successfully connected to the new server, it will store the wireless settings internally for future use. The device will then delete all settings from the microSD card for security purposes and begin normal operation.

If the Aera CT cannot connect to the server using the settings provided on the microSD card, it will display an error message on the screen. The Aera CT will not function properly until it has been successfully configured with valid wireless settings.

User Interface

The Aera CT employs a graphical user interface consisting of a color LCD and 5 touch-sensitive keys for configuration and patient hookup procedures. The only touch-sensitive areas of the device are the 5 keys. The LCD is NOT a touch screen.

Note: Aggressive attempts to use the LCD as a touch-screen can result in irreparable damage to the LCD.

The 5 keys are arranged in the shape of a plus sign (+) with a blue light in the center of each key. (See Fig. 1)

The center key is the **select key**, and the 4 surrounding keys are the **directional keys**, which can be used to scroll left, right, up, and down.

The keys can be used by lightly touching and then releasing the blue light. Each key must be released before any additional key may be pressed. This helps protect against accidental selections. The keys will only be lit when they are usable. There may be times where none, or only some, of the keys are functional.

To interact with the Aera CT menu system, choose an on-screen element using the **directional keys** and then select it with the center, **select key**. The currently selected icon on the screen will always be highlighted, while all non-selected elements will be dimmed. (See Figs. 4 and 5)

Figure 6



On this screen, the Power Off element is currently selected.

Figure 7



On this screen, the New Study element is currently selected.

The status bar found at the top of the display on the Aera CT displays information about cellular connectivity, battery life, and the current date and time. On the Aera CT, the date is always displayed in the format year-month-day (yyyy-mm-dd). The time is always displayed as a 24-hour clock in the format hours:minutes (hh:mm).

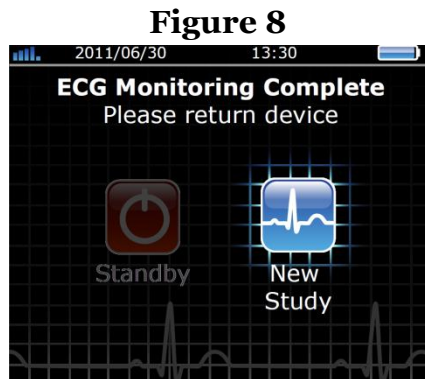
Starting a Study

To begin a new patient study, the receiving software must first be configured. Follow the instructions from your software provider to set all of the relevant parameters and prepare the server for the new patient study. If it is anticipated that the patient hookup procedure will be performed in a location that does not have reliable wireless connectivity, this process should include loading the settings for the study onto the microSD card in the device, according to the instructions from your software provider.

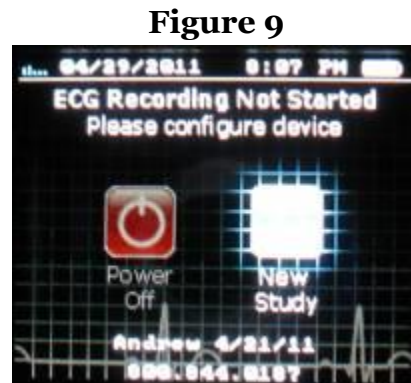
Once the server has been properly configured, the Aera CT device may be synchronized with the server.

Begin by powering on the device by inserting the Lithium-Ion battery into the battery compartment. Upon power-up, you should see one of two screens: a screen indicating that a recording has been completed or a screen indicating that a recording has not yet been configured. Both of these screens provide options to either power off the device or to start a new study.

Note: If the screen indicates that the Aera CT is recording, or attempting to record data, the current study must be ended before a new study may be configured.



This device has old data in its memory that must first be erased.



This device has no old data in its memory and is ready to start a new study.

Once the Aera CT has been powered up, select the **NEW STUDY** option to begin the new study process. If there is still data present on the microSD card from a previous study, you will be prompted to erase the data before continuing.

In order to erase the microSD card from the user interface, you will be required to enter a security code. This code is the first 4 digits of the device's serial number. After entering the code, you will be asked one more time if you are sure you want to erase the data.

Select **ERASE** to continue.

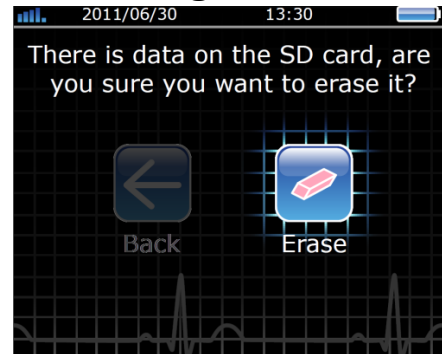
Starting a Study (continued)

Figure 10



This device needs to erase the SD card before it can continue with a new study.

Figure 11



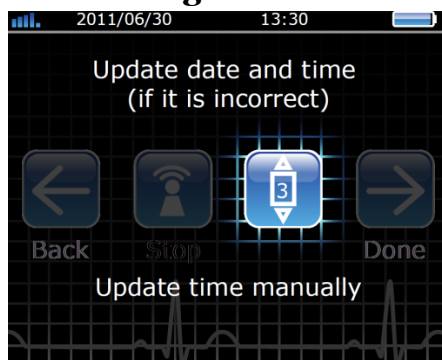
The device will double check to make sure that you want to erase all the data.

When there is no data on the microSD card, you will be prompted to update the device's clock. See *User Interface* section on pg. 8 for information on the display format for date and time. If a network connection is available, the time should be automatically updated. If a network connection is not available, it may be necessary to manually update the data and time using prompts on the device.

To Set the Time and Date Manually:

Select the **ADJUST DATE/TIME MANUALLY** option and follow the on-screen instructions to update the device clock. Once the device is displaying the proper date and time, select the **SAVE** option to continue.

Figure 12



The device will prompt you to check that the device time is correct.

Figure 13



Use this page to manually enter the time when the network is unavailable.

Starting a Study (continued)

Once the device time has been verified, the Aera CT must load the proper settings for the new study.

If the settings were previously loaded onto the microSD card, select the **KEEP CURRENT** option to continue. This could be used when poor wireless reception is expected.

If you wish to have the settings updated, select the **UPDATE** option to connect to the server and download the latest device settings.

Note: If the server has not been properly configured, or if wireless reception is poor, selecting UPDATE will result in an error message.

Figure 14



This device needs to download the settings for the study to continue.

Figure 15



This device has been loaded with settings prior to this setup procedure.

Starting a Study (continued)

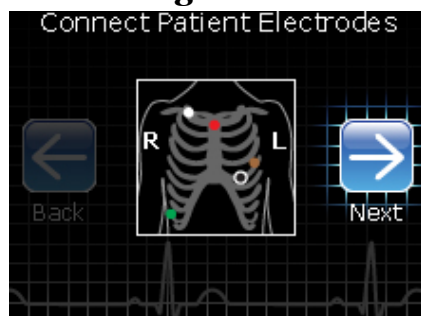
Once the device has successfully downloaded the latest settings, it will automatically prompt you to connect the patient to the device by displaying the selected electrode configuration on the display. It will also silently report the successful settings download action to the server in the background.

Apply the electrodes to the patient and connect the patient cable to the device.

Note: if the Aera CT has been configured for use with a 3-electrode cable, it will not work with a 5-electrode cable and vice-versa. If an error message appears and indicates that you are using the wrong patient cable, you must either change the configuration on the server and update the settings on the device or switch to a compatible patient cable.

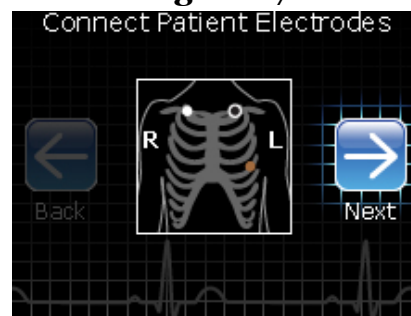
Once all of the electrodes have been connected, the Aera CT will automatically proceed to the signal quality check screen. If necessary, select the **NEXT** option to manually proceed to the **signal quality check**.

Figure 16



This device has been configured to use a 5-electrode patient cable.

Figure 17



This device has been configured to use a 3-electrode patient cable.

Starting a Study (continued)

On the “ECG Quality” screen, the Aera CT will draw the ECG trace from one of its three input channels in real time.

Toggle which channel is being drawn by highlighting the **LEAD** option and pressing **SELECT**. If necessary, highlight the **SCALE** option and press **SELECT** to change the dynamic range of the display. Once all three channels are showing acceptable ECG traces, select the **right-arrow icon** to continue.

Note: changing the scale here is for previewing purposes only; it does change the scale of the recording.

Figure 18



A typical ECG signal as seen during the hookup procedure.

Once the signal quality has been verified, the Aera CT will display the message **DEVICE READY**, and prompt you to begin the study. Select the **BEGIN STUDY** option to start the recording. As soon as this option is pressed, the Aera CT will begin recording and analyzing ECG data. After successfully recording the first 60 seconds of data, the device will silently report that the recording has started, and send the first minute of data to the server.

Figure 19



The last screen before the study begins.

Monitoring a Study

Once a study has been started, the Aera CT will silently record and transmit ECG data with no intervention from the patient. The patient can wake the display by briefly pressing the patient event button to view a status screen with instructions on how to mark an event.

If enough of the patient electrodes are disconnected so that the Aera CT cannot continue recording ECG on any channel, the device will automatically wake the display and show a message to the patient instructing him or her to reconnect the patient cable.

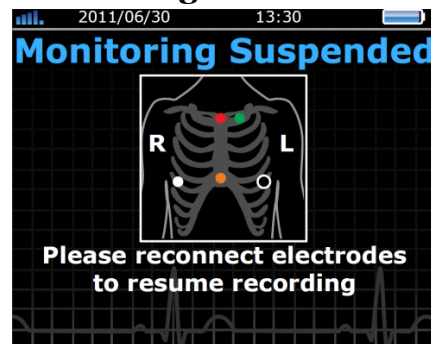
The bottom 2 lines of text on these screens may be programmed to display the name and phone number of the monitoring center. Follow the instructions from your software provider to change this text.

Figure 20



The device is currently recording and analyzing ECG data from the patient.

Figure 21



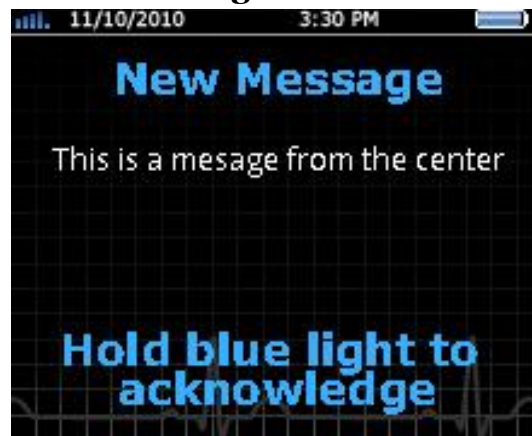
The device has stopped recording ECG data because the leads are disconnected.

Monitoring a Study (continued)

For the duration of the study, the Aera CT will periodically upload files to the receiving server. These event files provide information on the status of the device, (such as battery life, recording state, and electrode connection status), as well as information on detected arrhythmias and patient activated events. Follow the instructions from your software provider to monitor the server for these event files.

The Aera CT also provides the means to request specific data from the device and to send messages in plain text to the patient. In the event that the device's operating settings need to be adjusted to reduce the amount of data being reported to the server, the Aera CT provides the tools to wirelessly download new settings from the server. Follow the instructions from your software provider to access this functionality.

Figure 22



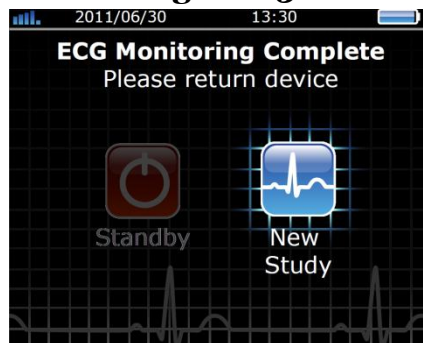
A text message being displayed to the patient on the Aera CT's screen.

Ending a Study

The Aera CT provides 2 automated methods and 2 manual methods for ending a study. When the Aera CT is configured at the beginning of the study, it can be programmed to automatically end the study after a specific length of data has been recorded, or to end the study at a specific date and time. Follow your software provider's instructions to control the Aera CT with these parameters. When either of these preconfigured stopping points is reached, the Aera CT will stop the study and report the completion to the server.

When the study is ended by reaching a preconfigured stopping point, the Aera CT will wake the display and report to the patient that the study is complete. If necessary, the study may be resumed by simply adjusting the study end parameters and performing a wireless settings update.

Figure 23



*The patient will be notified
once the study is complete.*

The Aera CT can also be wirelessly instructed by the server to end the study immediately. If this method is used to end the study, the device cannot be instructed to resume recording; a new study will have to be configured and started as before.

Ending a Study (continued)

It is also possible to end the study from the device itself using the *early-out procedure*:

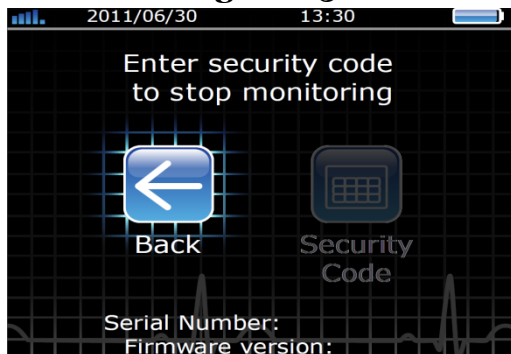
1. Make sure the recording is suspended by disconnecting the patient cable from the device.
2. Simultaneously hold the **left key** on the keypad while briefly pressing the **patient event button** to access the “security code screen”. (See fig. 22)
3. Select the **SECURITY CODE** option to display the numeric keypad. Enter the first 4 digits of the device’s serial number as the security code and then select **OK** to continue.

Figure 24



Hold the left key while pressing the patient event button to access the security screen.

Figure 25



This is the screen that appears when performing the early-out procedure.

Figure 26



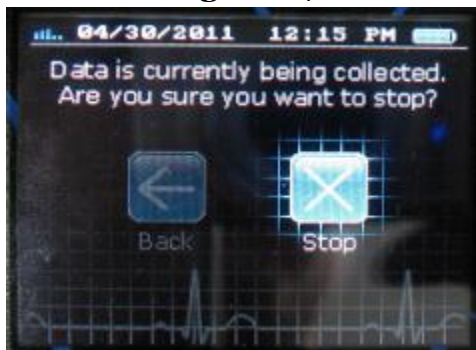
Enter the first 4 digits of the device’s serial number as the security code.

Ending a Study (continued)

After entering the first 4 digits of the device's serial number, the Aera CT will prompt you one last time to make sure that you wish to end the study. Select the **STOP** option to end the study and transmit any remaining pending data to the server.

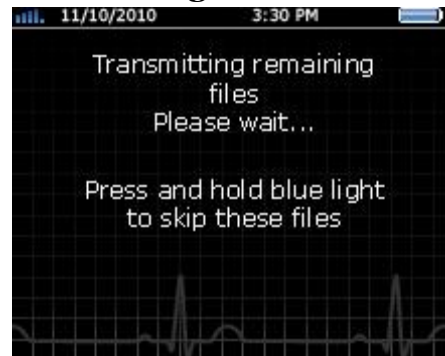
If necessary, it is possible to skip the final data transmissions when ending a study by holding the **select key** for 1 second. When this is done, the remaining data will be removed from the queue and the device will proceed to the startup screen. Once the recording has been ended using this method the device cannot resume recording; a new study will have to be configured and started as before.

Figure 27



The device will give you one last chance to cancel after entering the code.

Figure 28



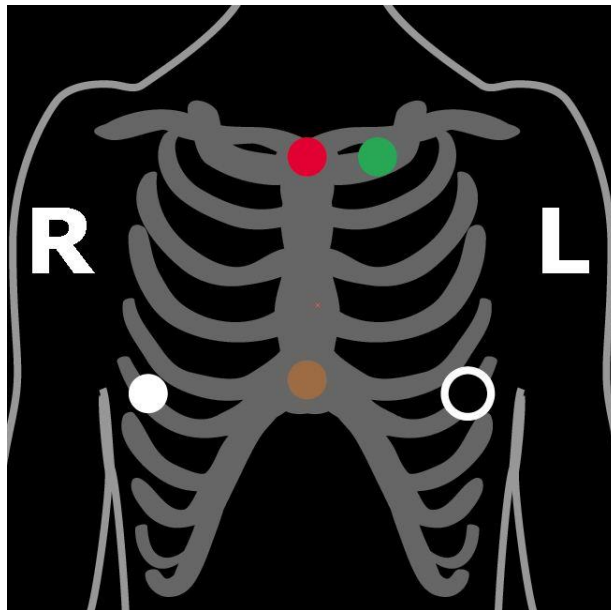
The device has to finish transmitting its data before the study is finished.

Electrode Application

Employ the following procedure when applying electrodes to a patient and connecting them to the Aera CT:

1. Select electrode sites to match the configured electrode configuration shown in the following figures or as instructed by the physician. Select areas over bone, avoiding muscle areas and breast tissue.
2. Clean electrode sites with alcohol and use a razor to remove hair.
3. Abrade electrode sites with a scrub pad or gauze. Allow sites to dry before applying electrodes.
4. Connect the patient lead wire to the electrode snap.
5. Remove the protective backing from the electrode.
6. Apply the electrode to the patient's skin, matching electrodes to the selected configuration from the following figures or as instructed by the physician.
7. Press adhesive border firmly for consistent adhesion.
8. To alleviate tension on electrode snaps, loop patient lead wires and tape down.

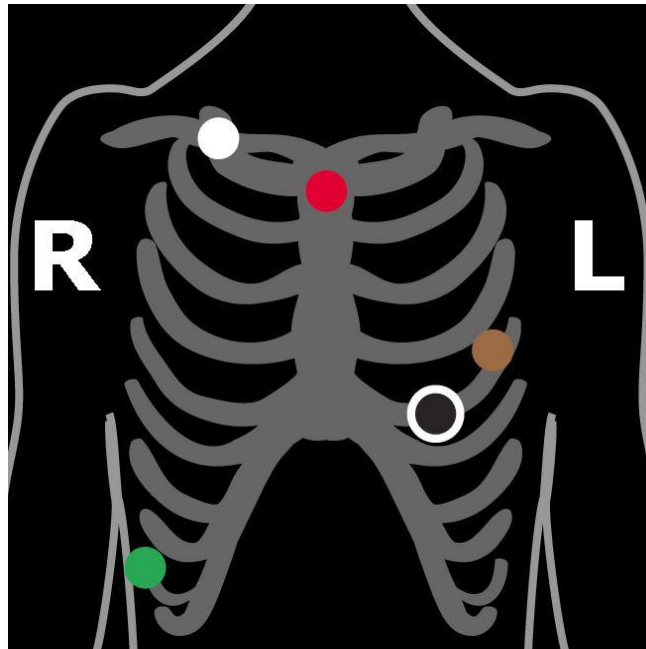
Figure 29



Electrode Configuration #1 (5 electrodes)

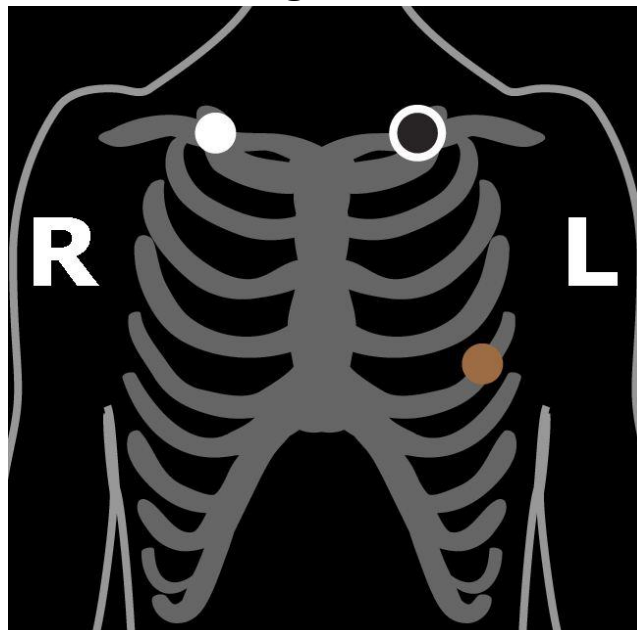
Electrode Application (Continued)

Figure 30



Electrode Configuration #2 (5 electrodes)

Figure 31



Electrode Configuration #3 (3 electrodes)

Patient Use Precautions

The Aera CT contains sensitive electronic circuitry. Please observe the following precautions while using the Aera CT. Failure to do so may result in serious damage to the device.

Avoid Exposure to Moisture

The Aera CT should not be used while swimming, showering, bathing, or participating in any aquatic activities. Use caution to avoid inadvertent submersion in water.

Avoid Sharp Impacts

While the Aera CT has been designed to survive minor drops, it is possible to damage the internal structure, or outer casing, if the device suffers a sharp impact or is otherwise traumatized. Such use may irreparably damage the Aera CT and void its warranty.

Avoid Pulling on Wires

Always disconnect cables from the device by grasping the rubberized connector, not by pulling directly on the wire. Yanking on the wires may result in irreparable damage to the cables.

As the patient, it is your responsibility to fulfill the following responsibilities while using the Aera CT in order to ensure proper detection and analysis of your heart's symptoms.

Keep Electrodes Connected

The Aera CT can only record data when it is properly connected to the electrodes on your body. The device will emit a short beep whenever it detects that one of the electrodes has been disconnected. If too many of the electrodes become disconnected, the Aera CT will stop recording and prompt you to reconnect the electrodes.

Keep the Battery Charged

The Aera CT can record for up to 48 hours on a single battery charge. Connect the provided wall charger to the charge port on the device to recharge the battery when wearing the Aera CT for more than 48 hours. You may keep the Aera CT connected to the electrodes so that it can continue to record data while it is recharging.

Report Any Heart-Related Events

Hold the Patient Event Button, located opposite the cable connector on the device, for 3 seconds to mark when you feel any heart-related symptoms.

Charging

The Aera CT employs a rechargeable lithium-ion battery to meet the demanding power requirements of cellular data transmissions. This battery can be recharged in the device without interrupting the data recording.

To charge the battery, connect the battery charger to the charge port on the device. The Aera CT will indicate that the battery is charging by replacing the battery status indicator on the screen with a charging indicator. (See fig. 30) It will also emit 2 short vibrations each time the charger is connected or a charging cycle starts.

Figure 32



The screen will display the charging indicator in the top left corner.

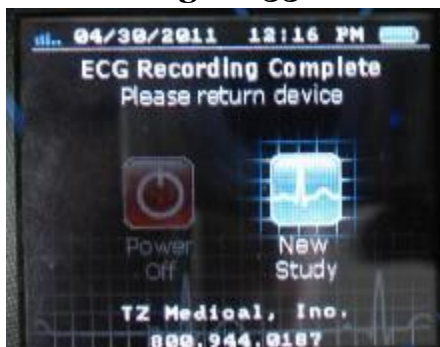
Storage

When not being used for recording data, the Aera CT provides an option to power down the device to reduce the amount of power drawn from the rechargeable battery.

To power down the device, select the **POWER OFF** option. The Aera CT will ask you to confirm that it should power down. Select the **POWER OFF** option again to confirm that you wish to power down the device.

To wake the Aera CT after it has been powered down, press the *patient event button* for 1 second.

Figure 33



Select Power Off to power down the device.

Figure 34



Confirm power off to finish the power down process.

Even in power down mode, the device will still drain the battery over the course of a week. It is therefore highly recommended that the Aera CT be stored either with the battery removed or with the battery charger connected to the device. The battery will continue to charge even when the device is powered off.

Cleaning

- **Do not** attempt to submerge, autoclave, or steam clean the Aera CT or the patient cable.
- **Do not** use acetone, ether, Freon, petroleum derivatives, or other solvents to clean the device.

Observe the following procedure to clean the Aera CT between patient uses:

1. Remove the battery and close the battery cover.
2. Disconnect the patient cable.
3. Wipe the exterior of the Aera CT and its accessories with a damp cloth. Use mild detergent diluted in water. Take care not to allow water or moisture to enter the Area CT, especially around the cable receptacles.
4. Dry with a clean cloth or paper towel.
5. Reconnect the patient cable to the device.
6. Clean the patient cable in the same manner before each procedure.

Testing

Observe the following procedure to periodically verify hardware functionality on Aera CT devices. This procedure is meant to detect hardware failures before a device is connected to a patient. It is not intended to verify conformance with any electrical performance specifications.

1. Make sure the device is idle, with no study ongoing.
2. Power on the device and connect the Aera CT Device Tester to the patient cable port on the Aera CT device.
3. When properly connected, the blue LED on the Device Tester will be illuminated.
4. The Aera CT will automatically switch into device test mode once the Device Tester has been connected.
5. Follow the onscreen instructions to step through each of the device tests.
6. Each test typically ends with a success message after which you may press the **patient event button** to continue.
7. In case of a failure, the Aera CT will generally attempt the test again, rather than displaying a failure message.

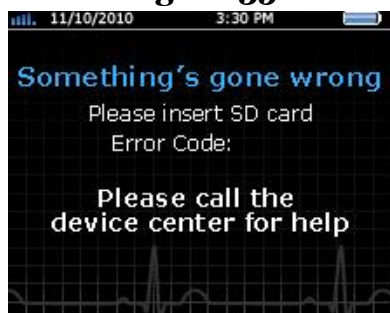
Note: If an Aera CT device repeatedly fails any of the device tests, the device will need to be returned to TZ Medical for servicing.

Error Messages

The Aera CT has been designed to detect and recover from error conditions automatically, if at all possible. Unfortunately, there are situations that may occur where the device simply cannot recover on its own. This is generally limited to situations such as the microSD card being forcibly ejected from its holder due to an abrupt impact, or a short-circuit due to water ingress.

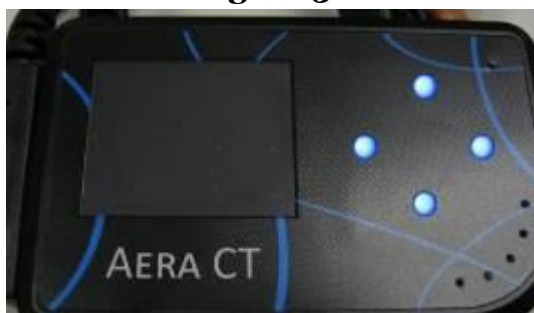
In most such cases the Aera CT will display an informative error message to the user. If an error has occurred that prevents the device from displaying this error message, the Aera CT will attempt to notify the user by lighting the **directional keys** and emitting a short vibration once per second.

Figure 35



An error message displayed on the Aera CT screen.

Figure 36



An error has occurred that is preventing the Aera CT from displaying anything.

These errors can often be resolved by removing the battery and microSD card, formatting the card, and then re-inserting the card and battery.

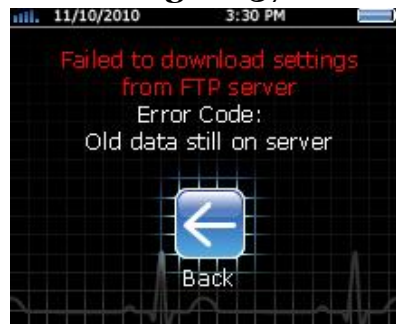
If the error message persists, the device will need to be returned to TZ Medical Inc. for servicing. See the Warranty section of this manual for instructions on returning a device for service.

On rare occasions, the electrostatic discharge (ESD) protection system in the battery will prevent the device from powering up when the battery is inserted. If this happens, simply connect the battery charger to power on the device and reset the ESD protection system.

Server Errors

The Aera CT may also display an error message when attempting to download settings from the server. In this case, the error message is typically not indicative of a failure with the device; it is generally an indication of a server error that is preventing the Aera CT from operating properly. Follow the instructions from your software provider to resolve these error messages.

Figure 37



A problem on the server has prevented the Aera CT from downloading new settings.

Wireless Compliance

FCC ID: ZIMTZMR3G

FCC Compliance Statement

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.

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.

The Aera CT contains a radio transmitter and receiver. It is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on standards that were developed by independent scientific organizations through periodic and thorough evaluation of scientific studies. The standards include a substantial safety margin designed to assure the safety of all persons, regardless of age and health.

The exposure standard for wireless mobile devices employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the device transmitting at its highest certified power level in all tested frequency bands. Although the SAR is determined at the highest certified power level, the actual SAR level of the device while operating can be well below the maximum value. This is because the device is designed to operate at multiple power levels so as to use only the power required to reach the network. In general, the closer you are to a wireless base station antenna, the lower the power output.

Before a device model is available for sale to the public, it must be tested and certified to the FCC that it does not exceed the limit established by the government-adopted requirement for safe exposure. The tests are performed in positions and locations (for example, worn on the body) as required by the FCC for each model. Changes or modifications made to this equipment not expressly approved by (manufacturer name) may void the FCC authorization to operate this equipment.

This device has been tested and meets FCC RF exposure guidelines when worn on the body using using the Aera CT Leather Carrying Case (PN: 7110-02) or Aera CT Plastic Holster (PN: 7214-08) available from TZ Medical. In cases other than the above carrying accessories is used it should not contain any metal parts and provide a minimum distance of 2 cm from the body. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

The highest reported SAR value for this body-worn device is: 0.91 W/kg.

The FCC has granted an Equipment Authorization for this wireless electro-cardiovascular monitor with all reported SAR levels evaluated as in compliance with the FCC RF exposure guidelines. SAR information on this device is on file with the FCC and can be found under the “Display Grant” section of: <http://transition.fcc.gov/oet/ea/fccid/> after searching on FCC ID: ZIMTZMR3G.

IC ID: 9647A-TZMR3G

License Exempt (Canada)

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) this device may not cause interference, and
(2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

- (1) l'appareil ne doit pas produire de brouillage, et
- (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Specifications

Functional

ECG Channels	3
Sample Rate	256 or 512 Samples per Second
User Interface	Color graphic display with direction pad and select

Memory

Total Recording Time	28 Days
Maximum Event Duration	11 minutes
Media	microSDHC card*
Data Retention	10 years

* Use only TZ-supplied memory cards or the recorder will not function properly

Physical

Case Dimensions	4.25 x 2.70 x 0.89 inches (108.0 x 68.6 x 22.6 mm)
Weight with Battery	6.4 oz. (181 g)

Electrical

Input Impedance	>10M Ohms
CMRR	>60 dB
AC Signal Range	± 6 mV
DC Signal Range	± 300 mV
Resolution	3 μ V (12 bits)
Frequency Response	0.05 Hz to 40 Hz (default) [LPF adj: 30 Hz – 100 Hz]
Pacemaker Detection	ANSI/AAMI EC38:2007

Environmental

Operating Temperature	0 C (32 F) to 50 C (122 F)
Operating Humidity	10% to 95%, non-condensing
Storage Temperature	-20 C (-4 F) to 70 C (158 F)
Storage Humidity	5% to 95%, non-condensing
Operating Shock	75mm drop on a hard surface
Vibration	10 minutes, 3 axis, 0.3G RMS to 500 Hz, random

Specifications

Wireless Transmission

Service Bands	Dual Band UMTS/HSPA+, Dual-Band GSM 850/1900 MHz
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Battery

Type Life	Single Cell, Lithium-Ion Rechargeable 24 to 48 hours, from full charge
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Additional equipment classification information as required in EN 60601-1

EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE

IPX0-Ordinary Equipment (enclosed equipment without protection against ingress of water)

Internally Powered Equipment

Mode of Operation – Continuous

Conformance to Regulatory Standards

TZ Medical, Inc. declares that his device complies with the essential requirements of Article 3 of the R&TTE 199/5/EC Directive, if used for its intended use and that the following standards have been applied:

BS EN 62209-2: 2010

ETSI EN 301 489-1 V1.8.1

ETSI EN 301 489-7 V1.3.1

ETSI EN 301 511 V9.0.2

International Electrotechnical Commission (IEC)

IEC 62209-2: 2010

American Advancement of Medical Instrumentation (AAMI)

ANSI/AAMI EC38:2007

Limited Warranty

This TZ Medical product is warranted to be free from manufacturing and material defects for a period of one (1) year from the date of shipment from TZ Medical to the original purchaser (“Warranty Period”). If a hardware defect arises and a valid claim is received within the Warranty Period, TZ Medical will either repair or replace the defective product free of charge for parts or labor.

Excluded from this warranty are expendable supply items including, but not limited to, electrodes, patient cables, charging adapters, and batteries. This warranty does not apply to any product which TZ Medical determines has been modified or which has been damaged due to customer abuse or misuse (e.g. corrosion from water ingress or cracking of the LCD glass).

Except for the express warranties stated above, TZ Medical disclaims all warranties including implied warranties of merchantability and fitness. The stated express warranties are in lieu of all obligations of liabilities on the part of TZ Medical for damages, including but not limited to, special indirect or consequential, arising out of or in connection with the use or performance of TZ Medical products.

Any action for breach of warranty shall be commenced within one (1) year of said breach or be forever barred. Any repairs made to the product that are not covered by the warranty shall be billed to the customer.

Obtaining Warranty Service

To obtain repairs, the device should be shipped pre-paid to TZ Medical at the address shown below. Units that are repaired under warranty will be returned postage paid. Any device serviced by TZ Medical will be factory reset, removing all custom device settings and formatting all data storage devices.



TZ Medical
Sparked by your ideas

TZ Medical, Inc.
17750 SW Upper Boones Ferry Rd
Suite 150
Portland, OR 97224

Phone: 800.944.0187
Fax: 503.639.0239

Accessories

The following accessories are available for use with the Aera CT.

Part Number	Description
3500-02	Aera CT Rechargeable Li-Ion Battery
5500-29	Aera CT 4GB microSDHC Card
6111-02	Aera CT 5-Electrode Patient Cable
6111-03	Aera CT 3-Electrode Patient Cable
6111-04	Aera CT Shortened 3-Electrode Patient Cable
6111-05	Aera CT 4-Electrode Patient Cable
7110-02	Aera CT Leather Carrying Case
7200-01	Aera CT Wall Charger
8510-00	Aera CT Device Tester
8520-00	Aera CT Multi-Battery Charger Unit
7200-22	Aera CT Multi-Battery Charger Power Supply

The following materials are provided with the Aera CT device.

Part Number	Description
3500-02	Rechargeable Li-Ion Battery
5500-29	MicroSD Card (4 GB)
7200-01	Aera CT Wall Charger