

AliveCor Heart Monitor User Manual iPhone[®] 4/4S/5/5S OTC

NOTE: For the current information on your product please visit www.alivecor.com/manuals

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1. PRODUCT DESCRIPTION

The AliveCor[™] Heart Monitor (Heart Monitor) is a mobile, clinical-quality electrocardiogram (ECG) recorder for use by physicians, patients and health conscious individuals. The duration of the recording is customizable from 30 seconds to continuous. The software application can store thousands of recordings on your iPhone[®] 4, 4S or 5 (iPhone), and these recordings are also accessible to authorized users on AliveCor, Inc. (AliveCor) servers (www.alivecor.com). The device consists of three components:

- The Heart Monitor snaps onto the iPhone and has electrodes to transmit ECG rhythms to the iPhone.
- The *AliveECG* mobile application (*AliveECG* App) used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
- An Apple iPhone 4, 4S or 5 operating with iOS 5.1 or greater. Note: the iPhone must be purchased separately.

The Heart Monitor enables a physician or patient to:

- Collect and store single-channel ECG recordings using the iPhone.
- View ECG recordings real-time and after the recording.
- Edit user information data associated with the recording.
- Wirelessly transmit ECG recordings to the AliveCor server.
- Access ECG recordings stored on the AliveCor server.
- Print or save the recording in PDF format.

The Heart Monitor enables a health conscious individual (non-prescription) to:

- Collect and store an ECG recording using the iPhone.
- View heart rate in real-time and after the recording.
- Edit user information data associated with the recording.
- Wirelessly transmit ECG recordings to the AliveCor server.
- Request analysis by a medical professional.

1.1. Indications for Use

The *AliveCor Heart Monitor* is intended to record, display (when prescribed or used under the care of a physician), store and transfer single-channel electrocardiogram (ECG) rhythms.

There are no known contraindications for the Heart Monitor, although care should be taken when considering using the device according to the warnings and precautions below.

1.2. Intended User

The device is intended to be used by licensed medical professionals, patients under the care and supervision of a physician or health conscious individuals.

2. GENERAL SAFETY PRECAUTIONS

• The device should not be used near water, or in a wet environment.

XliveCor[®]

- Do not use this unit in locations subject to high or low temperatures or humidity. It should be used within the temperature and humidity range according to the product label.
- Do not sterilize this unit with an autoclave or glass sterilizer.
- Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording.
- Do not take recordings in a location where the unit will be exposed to strong electromagnetic forces, such as near an arc welder, high-power radio transmitter, etc.
- Signal quality may degrade by detecting signals from other ultrasonic acoustic sources. Do not use the device in close vicinity to other equipment emitting ultrasonic acoustics such as espresso machines, some ventilation systems or another AliveCor Heart Monitor.
- The iPhone power adapter may degrade signal detection. Do not use the device while charging the iPhone.
- Disperse any static electricity from your body before using the unit.
- Do not take recordings in a moving vehicle.
- Do not expose the unit to strong shocks or vibrations.
- Do not disassemble, repair, or modify the unit.
- Do not insert battery with polarity reversed.
- Do not use batteries of a type other than that specified for use with the device.
- Do not take a recording if the electrodes are dirty. Clean them first.
- Do not use for any purpose other than obtaining an electrocardiogram.
- If the portion of the body where the electrode is applied has too much body fat, body hair or very dry skin, a successful recording may not be possible.
- Some children and adults with very sensitive auditory ability may hear a high pitched hum or buzz emitting from the device when activated. This is due to normal device function.

3. STORAGE, HANDLING AND MAINTENANCE

Do not store the unit in:

- Locations exposed to direct sunlight,
- Locations subject to high temperatures and high humidity,
- Wet or damp locations where water may get on the unit,
- Dusty locations,
- Near fires or open flames,
- Locations exposed to strong vibration, or
- Locations exposed to strong electromagnetic fields.

No maintenance of this system is required, except:

- The battery should be replaced when necessary.
- The electrodes should be cleaned using an alcohol-based sanitizer before each use.

4. WARNINGS

- This device is not designed or intended for complete diagnosis of cardiac conditions. This device should never be used as a basis for starting or modifying treatment without independent confirmation by medical examination.
- This device records heart rate and heart rhythm only.

- This device does not detect or measure all heart rate, heart rhythm and heart waveform changes, especially those related to ischemic heart conditions.
- Do not attempt self-diagnosis or self-treatment based on the recording results and analysis. Self-diagnosis or self-treatment may lead to deterioration of your health.
- Users should always consult their physician if they notice changes in their health.
- Do not use in the presence of flammable anesthetics, drugs or pressurized oxygen (such as in a hyperbaric chamber, ultraviolet sterilizer or oxygen tent).
- Do not use this device during an MRI scan.
- Keep out of reach of infants, small children, or anyone incapable of using the device properly.
- The device has not been tested for use on infants weighing less than 10kg. AliveCor does not recommend using on humans less than 10kg.
- It is not recommended to place a mobile phone directly next to a pacemaker on the chest.
- Do not use this device with a defibrillator.
- AliveCor does not recommend using on patients with a cardiac pacemaker, ICDs or other implanted electronic devices.
- Do not attempt ECG data acquisition while there is an external microphone plugged in to the iPhone.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.

5. PREPARE THE HEART MONITOR FOR USE

5.1. Unpack the Heart Monitor

- Remove the Heart Monitor from the box.
- Snap the Heart Monitor onto the back of your iPhone, making sure to align the cutout with the camera on the back of your iPhone.

5.2. Download the AliveECG App

- Using your iPhone, access the App Store.
- Search for AliveCor.
- Download the *AliveECG* App. Note: there may be several available "*AliveECG*" applications available for download. Choose the appropriate application for your device.
- For further instructions tap the Settings icon in the App to access the User Manual.

5.3. Set up an AliveCor Account

You will use your AliveCor account to access, print and save your ECG recordings stored on the AliveCor server. Follow the instructions presented when you open the *AliveECG* App for the first time. You can go back later and change your information if necessary.

5.4. Configure Software Settings

To access the Settings screen in the *AliveECG* App, from the main ECG capture screen, tap on the "Settings" icon in the lower right corner.

- Set the Recording Duration. Recording Duration is the maximum length of time the *AliveECG* App will record a single ECG recording. For example, if the recording duration is set to 30 seconds, the *AliveECG* App will automatically stop recording after 30 seconds of data has been collected. The recording duration can also be set to Continuous, where the system will record as long as the user maintains proper electrode contact (up to 10 minutes).
- Adjust the Mains Filter. The Mains Filter removes any mains interference from the ECG; it should be set to match the frequency of the alternating current (AC) used in your location. For the United States, Canada and Mexico, this is 60 Hz; in most other countries, it is 50 Hz.
- **Modify Paper Size**. Paper Size of the PDF report can be changed to accommodate Letter and A4 paper sizes.
- User Type. Tap to choose the type of user: Health Professional (On or Off)
- User Details. Tap to edit User Details.
- **Mode**. Tap to modify device transmission settings. Normal mode is recommended for most users. If your facility or location limits wireless communications, the Airplane/ICU setting may be selected.
- User Manual. Tap to access a digital version of the User Manual.
- **Privacy**. Tap to review AliveCor's privacy policy.

6. RECORD ECG RHYTHMS USING THE HEART MONITOR

Before taking your first recording, read these instructions carefully and make sure you observe the following instructions each time you take a recording.

• Make sure the Heart Monitor is properly attached to your iPhone.

NOTE: The monitor can be used up to a distance of 1m (3 ft) from the iPhone, although, using the monitor at a distance from the iPhone may decrease the signal quality.

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based sanitizer.
- Using your iPhone, launch the *AliveECG* App.
- Hold the system using two hands; the left hand should contact the electrode closer to the top of the iPhone, and the right hand should contact the electrode closer to the bottom of the iPhone. Recording will begin automatically when both electrodes make contact with skin. The green bars in the upper left corner of the *AliveECG* App indicate when there is a connection between the patient and the electrodes.

NOTE: Alternatively, the Heart Monitor can be placed on the user's chest to obtain a recording.

NOTE: The ECG rhythms will record best when the Heart Monitor is held steady. It may be helpful to rest your arms on a flat surface to increase stability.

• The *AliveECG* App will record ECG rhythms for the selected Recording Duration (see Configure Software Settings above). When the recording is complete, the recording will be saved to your iPhone. If you remove contact after 10 seconds but before the selected recording duration is complete, the ECG will be saved and you will be able to review it.

NOTE: If you remove contact before 10 seconds of recording has occurred, the ECG will not be saved, and you will not be able to review it.



• When you are finished reviewing the ECG recording (see *Review ECG Recordings* section below), tap "Record" to return to the main ECG capture screen. You may now initiate another ECG recording.

NOTE: If you are a health conscious individual (non-prescribed), you will not be able to view the recording. You may enroll in the optional clinical service at which time AliveCor can unlock your device so you can view the recording to share with your personal physician.

7. REMOVE THE HEART MONITOR FROM YOUR IPHONE

To remove the device from your iPhone, press gently on the iPhone through the camera hole and peel from that corner. The iPhone should partially pop out of the device and be easily removed.

8. REVIEW ECG RECORDINGS

NOTE: If you are a Non-Prescribed Patient, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

After the recording finishes you may swipe your finger across the screen to scroll through the ECG recording. Additionally you can add notes, change the paper speed and gain, invert the ECG recording, print or view a PDF report of the recording or delete the recording.

- Add Notes and Add/Edit Patient information. Tap the "Annotate" icon in the upper right corner to add notes about the recording:
 - Health Professional Add patient details such as Patient ID, Name, etc.
 - Patient Edit patient details such as Name, Comments, etc.

Tap "Save" to return to the review screen. This information will be automatically synchronized with the AliveCor server.

- **Paper Speed and Gain**. Changes to the paper speed and gain is performed by tapping the text in the lower left portion of the review screen and selecting the preferred setting. The scaling will adjust on the screen automatically.
- **Invert the ECG recording**. In the event that the Heart Monitor was oriented improperly while the ECG rhythms were recorded, it may appear inverted. To correct the orientation, tap on the center of the review screen, and then tap "Invert".
- **Print or View PDF**. You may print or view a PDF of the recording by tapping the icon in the bottom left corner of the screen and choosing your appropriate option.
- **Delete the Recording**. If you wish to delete the ECG recording so that it is not saved to your iPhone, tap the "Trash" icon in the bottom right of the screen. This will also delete the recording from the AliveCor server.
- **Return to the ECG Capture Screen**. When you are finished reviewing the ECG recording, tap "Record" to return to the main ECG capture screen. You may now initiate another ECG recording.

9. VIEW PREVIOUSLY RECORDED ECG RECORDINGS ON YOUR IPHONE

NOTE: If you are a Non-Prescribed Patient, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

- Launch the *AliveECG* App.
- Tap "ECGs" in the top right corner of the screen. You will see a list of all ECG recordings on your iPhone (excluding any previously deleted).
- Tap the ECG recording you wish to view.

- To add notes, change the paper speed and gain, invert the ECG recording, print or view a PDF report of the recording or delete the recording, see the instructions in the section *Review ECG Recordings*.
- When you are done viewing your ECG recordings, tap "ECGs" on the top left corner of the screen to return to the list.
- Tap "Record" to return to the main ECG capture screen

10. VIEW AN ECG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are a Non-Prescribed Patient, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

- On your web browser, go to http://www.alivecor.com and click on "My Account".
- Enter your email address and the password you created when you set up your AliveCor account. Click Sign In.
- The ECG recordings you collected and transmitted to the AliveCor server will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file. Roll over the transmission you would like to view and click on the "View PDF" button.
- Click the back button in your browser to return to your AliveCor account homepage.

11. REPLACE THE BATTERY IN YOUR HEART MONITOR

The battery in the Heart Monitor should last approximately one year or up to approximately 10,000 30 second ECGs; however the actual life will depend on how often you use the device.

- Remove your iPhone from the Heart Monitor. To remove the device from your iPhone, press gently on the iPhone through the camera hole while holding the device from the edge. The iPhone should partially pop out of the device and be easily removed.
- Using a small screwdriver, remove the screw and battery door from the center of the Heart Monitor.
- Remove the used battery and replace it with a new 3V coin cell battery matched to your model. Orient the battery with the positive terminal up, so that you can see the writing.
 - iPhone[®] 4/4S: CR2016 Coin Cell (3V lithium manganese dioxide battery)
 - iPhone[®] 5: CR2025 Coin Cell (3V lithium manganese dioxide battery)

NOTE: Replacement batteries are available for sale at most general stores.

- Replace the screw and battery door.
- Dispose of the used batteries according to the local law.



12. TROUBLESHOOTING

Problem	Solution		
I do not see an ECG signal in the <i>AliveECG</i> App.	Check that you have good contact with the electrodes. Clean the electrodes. Clean and moisten the skin preferably with alcohol hand sanitizer or water. Note: Some hand lotions will prevent good skin contact. Ensure the contact between the skin and the electrodes is not obstructed.		
	If the problem persists, replace the battery in your Heart Monitor.(See Replace the Battery in your Heart Monitor.)		
I have a lot of artifact,	Try the following tips for acquiring the best quality ECG recording:		
noise or interference in my recording.	 Clean the electrodes on the monitor with alcohol-based hand sanitizer before each use 		
	If hands are very dry, use a water based little lotion before trying to record		
	 When recording from the hands, relax the arms and hands to reduce muscle noise. Rest the forearms and hands on a flat surface and let the heart monitor rest on the hands. Do not squeeze the electrodes 		
	 Ensure that your iPhone is not charging/syncing and you are not using headphones with your iPhone during the recording 		
	 Make sure that both the iPhone and the user remain still during ECG recordings. Movement during recordings will cause noise in the tracing 		
	 Make sure Mains Filter is set appropriately for your geographical location. This can be adjusted under the <i>AliveECG</i> app Settings 		
	• Try recording from the chest, right under the pectoral muscles in the mid line		
The ECG rhythms appear upside down.	In the future, ensure that the left hand contacts the electrode closer to the top of the iPhone, and the right hand contacts the electrode closer to the bottom of the iPhone. To invert a recording on your iPhone, see Invert the ECG recording under Review ECG Recordings.		
I do not see the ECG recording on my AliveCor server account.	Ensure that you've downloaded the <i>AliveECG</i> App on your phone. Launch the <i>AliveECG</i> App on your iPhone, tap the Settings icon, and then tap "AliveCor Account". Ensure that the correct email and password are entered into the corresponding fields. (See Configure Software Settings under Prepare the Heart Monitor for Use). Ensure that you are logging into www.alivecor.com (not www.alivecorvet.com).		



Problem	Solution
I forgot my password and I'm unable to reset it.	Ensure that you've downloaded the <i>AliveECG</i> App on your phone. Similarly, ensure that you are logging into www.alivecor.com (not <u>www.alivecorvet.com</u>).
	To reset your password, go to www.alivecor.com and click on "My Account" in the upper right corner and click on the "Forgot your password?" link below the Password field. On the Forgot Password screen, enter your email address and click Submit. You will receive the following message:
	"PASSWORD SENT
	We've sent password reset instructions to your email address.
	You should receive instructions within a few minutes. If you do not receive an email within 5 minutes, please check your spam and junk filters. Otherwise, please try resending your request.
	If you are still experiencing trouble, please visit our Customer Support page."
	Follow the reset instructions in the email. Please note, the reset link contained in the email is only active for a short while.



13. ALIVECOR HEART MONITOR SPECIFICATIONS

Performance Characteristics

ECG Channel		Single Channel		
Input Dynamic Range		10mV Peak-to-Peak		
Memory length		Practically Unlimited		
Recording Format		Continuous		
Shelf Life		Estimated 2 years		
Circuitry				
Frequency Response		0.5 Hz to 40 Hz		
CMRR				
Input Impedance		> 100 MOhm		
Differential Range		+/- 5 mV		
A/D Sampling Rate		300 samples/second		
Resolution		16 bit		
DC Offset Correction		+/- 300 mV		
Output				
Modulation	Frequ	ency Modulated Ultrasonic Audio Tone		
Center Frequency		19 kHz		
Frequency Deviation		200 Hz/mV		
Power Requirements				
Battery Type	iPhone® 4/4S	CR2016, iPhone [®] 5 CR2025 3V Coin Cell		
Battery life	100 Hours C	Operational Time, 12 months typical use		
Physical Characteristics				
Dimensions		118 x 62 x 16.5 mm		
Weight		40 grams		
Environmental Specifications				
Operational Temperature		+10 to +45 degrees C		
Operational Humidity		10% to 95% (non-condensing)		
Operational Altitude		based on iPhone 4/4S or 5 specification		
Storage Temperature		20 to +60 degrees C		
Storage Humidity		10% to 95% (non-condensing)		
Standards Compliance				
ANSI/AAMI EC38	IEC 60601-1	IEC 60601-2-47		
ISO 10993	IEC 60601-1-2			
Dationt Interface				

Patient Interface

Two stainless-steel electrodes are exposed on the back of the Heart Monitor, which are either held in the patient's hands or placed on the patient's chest.

14. ALIVECOR CONTACT INFORMATION

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15. EUROPEAN AUTHORIZED REPRESENTATIVE

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16. ELECTRICAL SAFETY

Guidance and manufacturer's declaration - electromagnetic emissions			
The AliveCor Heart Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Heart Monitor should assure that it is used in such an environment.			
Emissions test	Compliance	Electromagnetic environment - guidance	
RF emissions CISPR 11	Group 1	The AliveCor Heart Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.	
RF emissions CISPR 11	Class B		
Harmonic emissions IEC 61000-3-2	N/A	The AliveCor Heart Monitor is suitable for use in all establishments other than domestic and those directly	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	 connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. 	



Guidance and manufacturer's declaration—electromagnetic immunity

The AliveCor Heart Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the AliveCor Heart Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	<5 % U _T (>95 % dip in U _T) for 0.5 cycle 40 % U _T (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 sec	<5 % U _T (>95 % dip in U _T) for 0.5 cycle $40 % U_T$ (60 % dip in U _T) for 5 cycles 70 % U _T (30 % dip in U _T) for 25 cycles <5 % U _T (>95 % dip in U _T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AliveCor Heart Monitor requires continued operation during power mains interruptions, it is recommended that the AliveCor Heart Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.



			e electromagnetic environment specified below. The customer sure that it is used in such an environment.
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the AliveCor Heart Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol:
	z and 800 MHz, the h delines may not apply		inge applies. Electromagnetic propagation is affected by absorption and

assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AliveCor Heart Monitor is used exceeds the applicable RF compliance level above, the AliveCor Heart Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AliveCor Heart Monitor.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between

portable and mobile RF communications equipment and the AliveCor Heart Monitor

The AliveCor Heart Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AliveCor Heart Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AliveCor Heart Monitor as recommended below, according to the maximum output power of the communications equipment.

Dated marine autout	Separation distance according to frequency of transmitter m			
Rated maximum output power of transmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	80 MHz to 2.5 GHz	
W	$d = [\frac{3.5}{V_1}]\sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



17. SYMBOLS USED SYSTEM OR PACKAGE LABELING

	Type CF Applied Part	
C E 0 1 2 0	European Conformity Mark	
X	WEEE – Properly Dispose of Electronic Waste	
ĺĺ	Consult Instructions for Use / User Manual	
	Manufacturer	
	Temperature Limits (Operational)	
<u>%</u>	Relative Humidity Limits (Operational)	
RxOnly	Prescription Use Only in The United States	
REF	Model Number	
SN	Serial Number	
	Direct Current Power Source	