

AliveCor® Heart Monitor

User Manual for iOS

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. The duration of the recording is customizable from 30 seconds to continuous. The software application can store thousands of recordings on your mobile device and these recordings are also accessible to authorized users on AliveCor, Inc. (AliveCor) servers (www.alivecor.com). The device consists of three components:

1. The Heart Monitor, which attaches to your compatible mobile device and has electrodes to transmit ECG rhythms to the mobile device.
2. The *AliveECG* mobile application (*AliveECG* app) used to collect, view, save, and wirelessly transmit recordings to the AliveCor server.
3. A user-supplied compatible mobile device.

CAUTION: The AliveCor Heart Monitor has features that are only available to those users who are under the care of a physician. These features are available to prescription users only.

The Heart Monitor enables all users to:

- Collect and store single-channel ECG recordings using the mobile device.
- 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.
- Request professional clinical interpretation and analysis of your ECG recordings.

After a user has enrolled in AliveInsights and received an ECG analysis, the Heart Monitor enables a user to:

- View ECG recordings real-time and after the recording
- View the output of the atrial fibrillation detection algorithm

1.1. Indications for Use

The AliveCor Heart Monitor is intended to record, store and transfer single-channel electrocardiogram (ECG) rhythms. The AliveCor Heart Monitor also displays ECG rhythms and detects the presence of atrial fibrillation (when prescribed or used under the care of a physician). The AliveCor Heart Monitor is intended for use by healthcare professionals, patients with known or suspected heart conditions and health conscious individuals.

1.2. Contraindications

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.

2. GENERAL SAFETY PRECAUTIONS

- The device should not be used near water, or in a wet environment.
- 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 mobile device power adapter may degrade signal detection. Do not use the monitor while charging the mobile device.
- 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.
- To prevent potential cross-infection of diseases between users, clean the device using alcohol prior to 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.
- Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional.
- 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 mobile device.
- ECG reports viewed or printed at any magnification other than 100% may appear distorted and could lead to misdiagnosis.
- The heart rate is based on the heart rhythm; therefore the rate is only valid if there is a valid rhythm (QRS complex visible).

5. SET UP THE HEART MONITOR AND TAKE THE FIRST ECG RECORDING

5.1. Decide which mobile device to use

Your Heart Monitor is compatible with all of the devices listed on AliveCor's website: <http://www.alivecor.com/compatibility>. These devices include:

- iPhone 4/4S, 5/5S, 5C
- iPad Air, iPad Mini
- iPod Touch 5G

The AliveECG App is compatible with iOS versions 5.1 - 7.1

5.2. Unpack the Heart Monitor

1. Remove the Heart Monitor from the box.
2. Choose Heart Monitor placement.
 - a) For Heart Monitor Cases, place the monitor on your phone as you would any standard phone case.
 - b) The Heart Monitor with Universal Attachment Plate can be attached to the mobile device directly or to the case of your choosing (the surface should be smooth and flat).

- c) For use with an iPad, AliveCor does not recommend you attach the Heart Monitor to your device. Instead, hold the monitor in both hands or place it on a flat surface less than one foot away from the iPad to record ECGs.

Caution: The Heart Monitor must be less than 1 foot from the mobile device to ensure communication between devices.

5.3. Download the *AliveECG* App

1. Using your mobile device, access the appropriate mobile application store.
2. Search for “AliveECG”
3. Download and install the *AliveECG* app.

5.4. Set up an AliveCor Account

You will use your AliveCor account to access, print and save your ECG recordings stored on the *AliveECG* app and 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. Signing up for an AliveCor account also enrolls you in AliveInsights. AliveInsights can be used any time you want a medical professional to interpret your ECG recording and is required if you would like to view your recordings or utilize AliveCor’s interpretive algorithms.

6. RECORD ECG RHYTHMS USING THE HEART MONITOR

Before taking each recording:

- Disconnect headphones, charger cables, or any other connected devices.
- Clean the two electrodes with alcohol-based hand sanitizer.
- Using your mobile device, launch the *AliveECG* app.

Rest the monitor on your fingers; your right hand should contact the electrode closest to the bottom of the mobile device, and your left hand should contact the electrode closest to the top of the mobile device. This is a Lead I ECG.

You may also choose from two other placements:

- For a Lead II ECG, the left knee should contact the electrode closer to the top of the mobile device and the right hand should contact the electrode closer to the bottom of the mobile device.
- For an Anterior Precordial Lead, the device can be placed on the lower left side of the chest, just below the pectoral muscle. The bottom of the mobile device should be pointing towards the center of the body.

NOTE: You will not be able to view your recordings or utilize any of AliveCor’s interpretive algorithms until you are under the guidance of a physician. To ensure you have access to professional medical analysis of your ECGs, you must submit your ECG recording through AliveInsights for review by a cardiologist. Once you have received the ECG analysis, you will have access to view that recording and subsequent recordings.

After your display is unlocked, you may swipe your finger across the screen to scroll through each ECG recording. Additionally you can add notes about the recording:

- Tap the “Annotate” icon in the upper right corner to add notes:
 - Medical 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.

NOTES:

- The monitor does not require a Wi-Fi or mobile connection to record an ECG and save it to the mobile device, however it does require one of these to: sync automatically with the AliveCor server, email, or print directly from the *AliveECG* app. If you do not have a Wi-Fi or mobile connection at the time of the ECG recording, you can email or print the data later when you have such a connection and the sync will happen automatically at that time.
- The monitor can be used up to a distance of 30cm (1 ft.) from the mobile device. Using the monitor at a distance greater than 30cm (1 ft) may lead to communication issues between the devices and your recording may not be successful.
- In order to reduce muscle noise, rest your arms on a flat surface to increase stability while you are recording.
- You must maintain contact with the electrodes for at least 10 seconds for the recording to be saved. 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.

7. ONCE THE RECORDING IS FINISHED

- Immediately after recording is complete, you will be prompted to choose who completed the recording. You may choose the currently logged in user, or a guest.
- You may select symptoms and activities on the next screen. After making your choices, tap the “Save” icon in the upper right of the screen to return to the ECG review screen.
- When you are finished reviewing the ECG recording (see *Review ECG Recordings* section below), tap the arrow on the top left of the screen, tap the Menu on the top left of the screen and tap “Record an ECG” to return to the main ECG capture screen. You may now initiate another ECG recording.

8. SETTINGS AND ADJUSTMENTS

8.1. Recording Adjustments

- **Paper Speed and Gain (or Zoom).** Changes to the paper speed and gain can be performed by medical professionals only. These changes are made while viewing in landscape orientation 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. Also, these changes can be made prior to the recording. Alternately, you can pinch and zoom when viewing the recording as a PDF (tap the box with the arrow in the lower left corner and tap “PDF”).
- **Enhanced and Original Filter.** The filter can be toggled by tapping the text labeled “Enhanced Filter” or “Original Filter”.

- **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”.

8.2. Adjustable Settings

To access the Settings screen in the *AliveECG* app, tap on the “Menu” icon (3 white bars) in the upper left corner of the screen and then tap on “Settings”.

- **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.
- **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.
- **Paper Size.** Paper Size of the PDF report can be changed to accommodate Letter and A4 paper sizes.
- **Reminders.** Reminders allow the ECG analysis reminder to be turned on or off. It also allows you to turn on or off the ECG reminder, set the frequency, and time for the reminder.
- **Mode.** Tap to modify device transmission settings. Normal mode is recommended for most users. If your facility or location limits wireless communication, the Airplane/ICU setting may be selected.

9. EMAIL, PRINT OR DELETE RECORDINGS

NOTE: If you are not enrolled in AliveInsights, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician.

You may email/print recordings from either the *AliveECG* app or your account on the server (www.alivecor.com).

To email a recording from the *AliveECG* app, you must have an email account set up on your mobile device. If you need assistance setting up an email account or troubleshooting your email account, please contact your mobile device provider for assistance.

1. After recording (or after selecting the desired ECG recording from ECG History), tap the square with the arrow in the lower left
2. Tap Email. The PDF version of the ECG recording will then be attached to a new email in whatever email account you have set up on your mobile device.

To email a recording from the server:

1. Go to www.alivecor.com
2. Click on “SIGN IN” in the upper right corner and enter your email address and password
3. Select the desired recording by clicking on the appropriate “VIEW ECG” button on the right
4. Email from your computer as you would any PDF

To print a recording from the *AliveECG* app, you must have an AirPrint compatible printer set up on your mobile device. If you need assistance setting up an AirPrint compatible printer or troubleshooting your AirPrint compatible printer, please contact your mobile device provider for assistance.

1. After recording (or after selecting the desired ECG recording from ECG History), tap the square with the arrow in the lower left
2. Tap Print

To print a recording from the server:

1. Go to www.alivecor.com
2. Click on “SIGN IN” in the upper right corner and enter your email address and password
3. Select the desired recording by clicking on the appropriate “VIEW ECG” button on the right
4. Print from your computer as you would any PDF

To delete a recording:

1. Tap on the “Trash” icon in the lower right corner.
2. Confirm the deletion, by tapping on “Delete ECG”

Deleting a recording from the *AliveECG* app also deletes it from the server. Deleted recordings cannot be retrieved.

10. VIEW PREVIOUSLY RECORDED ECG RECORDINGS ON YOUR MOBILE DEVICE

NOTE: If you are not enrolled in *AliveInsights*, 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 Menu in the top left corner of the screen. Tap ECG History to see a list of all ECG recordings on your mobile device (excluding any previously deleted).
- Tap the ECG recording you wish to view.

11. VIEW AN ECG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are not enrolled in *AliveInsights*, 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 www.alivecor.com and click on “SIGN IN”.
- Enter your email address and the password you created when you set up your *AliveCor* account. Click “Sign In”.
- The ECG recordings you collected were automatically synced to the *AliveCor* server and will appear in list form, and each transmission is stored as an Adobe Acrobat PDF file. Click on the “VIEW ECG” button.
- Click the back button in your browser to return to your *AliveCor* account homepage.

12. ALIVEINSIGHTS

The *AliveECG* app includes the ability to request professional clinical interpretation and analysis of your ECG recordings. Due to telemedicine restrictions outside of the U.S., your location may restrict your ability to use this service. AliveCor does not know your location; it is your responsibility to ensure this service is legal according to your local telemedicine laws. This service is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

To have a recording analyzed:

1. Tap the "ECG ANALYSIS" button that appears in the lower left of a new recording or when you view recordings from your history
2. Select the type of service desired
3. If you haven't already entered your name, date of birth and gender, you will be prompted to enter these details
4. Tap "Add new card"
5. Enter credit card information
6. Tap "Submit New Card"
7. Confirm and tap "PURCHASE" to proceed

You will receive a notification once your analysis has been returned.

NOTE: The ECG analysis option is only visible if the analysis service is available in your country.

To view an ECG analysis that has been returned:

1. Tap menu in the upper left corner
2. Tap "ECG Analysis"
3. Tap the desired report

13. AF DETECTOR

NOTE: If you are not enrolled in AliveInsights, you will not be able to view the recording. AliveCor will unlock this feature if you are under the guidance of a physician

AF Detector is an algorithm in the *AliveECG* app to detect atrial Fibrillation in an ECG tracing. After you take an ECG, if atrial fibrillation is detected you will be notified within the app. This finding is not a diagnosis, it is only a potential finding. You should contact your physician to review any ECG recording in which atrial fibrillation was detected. If you are experiencing any symptoms or concerns please contact a medical professional.

The AF Detector algorithm monitors for atrial fibrillation (AF) only. It will not detect other potentially life threatening arrhythmias, and it is possible that other cardiac arrhythmias may be present.

The AF Detector only monitors for AF as you are in contact with the device. It does not continuously monitor your heart and therefore cannot alert you if AF happens at any other time.

13.1. What is Atrial Fibrillation?

The most common type of non-sinus tachyarrhythmia is atrial fibrillation. In this case, disorganized electrical impulses that originate in the atria and pulmonary veins initiate the electrical activity in the conduction system of the heart. This causes what are commonly termed as “irregularly irregular” heart beats.

When a heart is in atrial fibrillation, its two upper chambers, the right and left atria essentially quiver, instead of beating efficiently. This does not allow for complete emptying of the atria and thus, blood may become stagnant and create blood clots. This can lead to major problems, namely, strokes, transient ischemic attacks (TIAs), and pulmonary emboli (PEs); depending which chamber of the heart has the blood clot in it.

Approximately 15 percent of strokes occur in people with atrial fibrillation. As age increases in a population, so too does the incidence of atrial fibrillation, which peaks at about 3-5% in people over the age of 65.

The most common presenting symptoms of atrial fibrillation are palpitations, dizziness, fast pulse rate, irregularly irregular rhythm, an abnormal heart sound (S1), chest pain, chronic shortness of breath, abnormal jugular venous pressure, fatigue, and impaired exercise tolerance. Other symptoms related to TIAs and strokes may be the initial symptoms of atrial fibrillation.

Some of the most common causes of atrial fibrillation are long-standing hypertension, congestive heart disease, cardiac valvular lesions, myocardial infarctions, history of coronary artery bypass grafts, hyperthyroidism, alcohol abuse, smoking, diabetes mellitus, and electrolyte imbalances.

13.2. AF Tags in ECG review screen and History List

All tracings analyzed as positive for AF will have “AF” tagged for future review. These tags will be visible on the ECG History List as well as on the ECG review screen

13.3. Activation of the AF Detector

The module can be activated/de-activated in the settings of the AliveECG App

14. GRAPHING TOOL

The incidences of AF identified by the AF Detector per day will be plotted against the day in the AliveECG app.

15. ACCESSING HELP

Tap Menu in the top left corner of the screen. Learn more about using your AliveCor Heart Monitor. Tap “HELP” to see all the options available for help

- **Tutorials.** Review these tutorials to learn about to navigate all the features of the app
 - **Quick Tutorial**
 - **Recording an ECG**

- **Sending for ECG analysis**
- **Retrieving ECG analysis**
- **Alternate positions**
- **Other Documentation.** Learn about ECG analysis; access the user manual, feedback and privacy and terms.
 - **What is ECG analysis**
 - **User Manual**
 - **Feedback**
 - **Privacy and terms**

16. EDITING USER PROFILE

- Launch the *AliveECG* app.
- Tap Menu in the top left corner of the screen.
- Tap “Profile”
- All user details can be edited by tapping the top right corner of the screen

17. ACCESSING EDUCATION

- Launch the *AliveECG* app.
- Tap Menu in the top left corner of the screen.
- Tap “Education”. Users have the ability to learn about
 - Cardiac Anatomy
 - What is an ECG
 - Arrhythmia Library
 - External Resources

NOTE: The information contained within this section is for educational purposes only. This information has been written and verified by medical professionals.

Do not attempt to use this information to interpret your own ECG. This information is not intended to replace medical advice, please seek professional medical assistance if you are suffering from any medical problem.

18. ACCESSING HEART STATS

- Launch the *AliveECG* app.
- Tap Menu in the top left corner of the screen.
- Tap “Heart Stats”. You will be able to access your range of heart rate and compare it to the range of a similar demographic in the AliveCor database. Range is defined as 67% of your recorded heart rates.

19. PROVIDER DASHBOARD

The Provider Dashboard allows medical professionals the ability to view their patients' recordings automatically from their own account. To create a medical professional account, download the *AliveECG* app and follow the prompts to create a new account.

In order to view a patient's future recordings, you must send them an invite via email. To send an email invite:

- Go to www.alivecor.com
- Click on "SIGN IN" in the upper right corner and enter your email address and password
- Click on "Invite a Patient"
- Type in the patient's email address (this must be the email address they use for their AliveCor account)
- Click "Send Email"

20. ELECTRONIC HEALTH RECORD (EHR) INTEGRATION

Send to EHR: If you are a physician and your AliveCor account has been setup for integration with an Electronic Health Record system (EHR) you can send ECG recordings to your EHR. You can see the option if you tap the bottom left corner of the review screen and choosing this option.

21. TROUBLESHOOTING

Problem	Solution
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Problem	Solution
<p>My monitor is not working.</p>	<p>If you're taking your first recording, please ensure that your Apple iPhone "Portrait Orientation Lock" is not on as you must be able to turn your phone to landscape orientation in order to take a recording.</p> <p>If you're using iOS 7 or greater, ensure that the <i>AliveECG</i> app has access to the iPhone microphone:</p> <ol style="list-style-type: none"> 1. Tap on iPhone "Settings" 2. Tap on "Privacy" 3. Tap on "Microphone" 4. Ensure that "<i>AliveECG</i>" is turned on (the background of the slider is green) <p>Change the battery:</p> <ol style="list-style-type: none"> 1. Use a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door. 2. Remove the used battery and replace it with a new 3V coin cell battery matched to your model. 3. Orient the battery with the positive terminal up, so that you can see the writing. Remove the protective sticker from the battery, as applicable.
<p>I have a lot of artifact, noise or interference in my recording.</p>	<p>Try the following tips for acquiring the best quality ECG recording:</p> <ul style="list-style-type: none"> • Ensure that the "Enhanced Filter" is on. • Clean the electrodes on the monitor with alcohol-based hand sanitizer. • If hands are very dry, use a water-based lotion before recording. • 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 monitor. • Ensure that your mobile device is not charging/syncing and you are not using headphones with your mobile device during the recording. • Make sure that both the mobile device 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 muscle in the mid line

Problem	Solution
The ECG rhythms appear upside down.	In the future, ensure that the left hand contacts the electrode closer to the top of the mobile device, and the right hand contacts the electrode closer to the bottom of the mobile device. To invert a recording on your mobile device, see “Invert the ECG recording” under “Recording Adjustments”.
I forgot my password and I’m unable to reset it.	<p>To reset your password, go to www.alivecor.com and click on "SIGN IN" 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.</p> <p>Follow the reset instructions in the email. Please note the reset link contained in the email is only active for a short while.</p>

22. 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.....	76 dB
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	Frequency Modulated Ultrasonic Audio Tone
Center Frequency	19 kHz
Frequency Deviation	200 Hz/mV

Power Requirements

Battery Type	3V Coin Cell
Battery life	min. 100 Hours Operational Time, 12 months typical use

Physical Characteristics

AC-001 (for iPhone 4/4s)	40 grams	118 x 62 x 15 mm
AC-003 (for iPhone 5/5s)	41 grams	128 x 62 x 15 mm
AC-004 & AC-007-I5-A (for iPhone 5/5s).....	33 grams.....	126 x 62 x 11 mm
AC-004 & AC-007-UA-A (w/Attachment Plate).	28 grams	89 x 48 x 9 mm

Environmental Specifications

Operational Temperature	+10 to +45 degrees C
Operational Humidity	10% to 95% (non-condensing)
Operational Altitude	based on your mobile device specification
Storage Temperature	-20 to +60 degrees C
Storage Humidity	10% to 95% (non-condensing)

Patient Interface

Two stainless-steel electrodes are exposed on the back of the Heart Monitor. These electrodes make contact with the user's skin.

23. INTERNATIONAL AVAILABILITY

The AliveCor Heart Monitor is available for use by medical professionals and by patients under the care and supervision of a physician in the USA. The Heart Monitor is available for use by any health-conscious individual in launched countries within the European Union. The AliveCor Heart Monitor is a non-notified medical device and approved for use in India.

24. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

www.alivecor.com

25. EUROPEAN AUTHORIZED REPRESENTATIVE

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy


26. 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	The AliveCor Heart Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	N/A	

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.
NOTE— U_T is the a.c. mains voltage prior to application of the test level.			

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
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 $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d 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: 

NOTE 1—At 80 MHz and 800 MHz, 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

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To 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.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3.5}{E_1}] \sqrt{P}$	80 MHz to 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
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.			

27. SYMBOLS USED SYSTEM OR PACKAGE LABELING

	Type CF Applied Part
	European Conformity Mark
	WEEE – Properly Dispose of Electronic Waste
	Consult Instructions for Use / User Manual
	Manufacturer
	Temperature Limits (Operational)
	Relative Humidity Limits (Operational)
REF	Model Number
SN	Serial Number
	Direct Current Power Source