AliveCor

AliveCor® Heart Monitor

User Manual for iOS

OTC

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

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08LB05 Revision D | MAR 2014

Contents

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 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 mobile device operating a compatible operating system

The Heart Monitor enables a physician or patient to:

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

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

- Collect and store an ECG recording using the mobile device.
- 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 professional clinical interpretation and analysis of your ECG recordings.

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.

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.

1.3. 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.
- 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 device 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.
- 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. PREPARE THE HEART MONITOR FOR USE

5.1. Unpack the Heart Monitor

- Remove the Heart Monitor from the box.
- Place the Heart Monitor onto the back of your mobile device according to the instructions provided with your packaging

5.2. Download the *AliveECG* App

- Using your mobile device, access the appropriate mobile application store.
- Search for “AliveECG”
- 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 “Menu” icon in the upper left corner of the screen and then tap on “Settings”.

- **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.
- **Turn on/off 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.

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 mobile device.

NOTE: The monitor can be used up to a distance of 30cm (1 ft) from the mobile device, although, using the monitor at a distance from the mobile device may decrease the signal quality.

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

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 mobile device. 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.

- 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.

NOTE: If you are a health-conscious individual (non-prescribed), you will not be able to view the recording immediately. 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. REVIEW ECG RECORDINGS

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

On the ECG review screen 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 (or zoom) (if you are a medical professional), invert the ECG recording, toggle between the Enhanced and Original Filter, print, email 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 are 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. (This is available if you are a medical professional)
- **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".
- **Print, Email 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 mobile device, 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 the arrow to return to the main ECG capture screen. You may now initiate another ECG recording.

- **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.**

8. VIEW PREVIOUSLY RECORDED ECG RECORDINGS ON YOUR MOBILE DEVICE

NOTE: If you are a non-prescribed user, 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.
- To add notes, change the paper speed and gain (or zoom), toggle between the Enhanced or Original Filter, invert the ECG recording, print, email 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 the arrow on the top left corner of the screen to return to the list.
- Go to the Menu on the top left of the screen and Tap "Record an ECG" to return to the main ECG capture screen

9. VIEW AN ECG RECORDING ON THE ALIVECOR SERVER

NOTE: If you are a non-prescribed user, 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 "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. Roll over the transmission you would like to view and click on the "View ECG" button.
- Click the back button in your browser to return to your AliveCor account homepage.

10. REQUEST CLINICAL INTERPRETATION AND ANALYSIS OF ECG RECORDINGS

The *AliveECG* app includes the ability to request professional clinical interpretation and analysis of your ECG recordings. Follow on-screen instructions within the *AliveECG* app to send your ECG recording for analysis. Due to telemedicine restrictions, 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.

- 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.
- On the review screen of the recording tap "ECG Analysis" button to send the ECG for analysis

- Select one of the listed Analysis Report options
- If you haven't already entered your name, date of birth and gender, you will be prompted to enter these details. Enter the required details and tap "SAVE"
- You will be prompted to select or enter your credit card information. Enter your card details and tap "Next"
- Confirm that the purchase order is correct and tap "Purchase" to place the order
- Your order is then processed and you will be sent an email confirmation. Another email will be sent when the report is available

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

To view an ECG Analysis Report:

- You will be sent a notification when your analysis report is available. After you receive a notification, open the notification and select the notification to view the report
- Alternatively, go to the Menu and navigate to "ECG Analysis" under AliveInsights. Your report will be there for review
- Tap on the report item to view more details, where you can also view, share, or email the PDF report

11. 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**

12. 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

13. 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.

14. 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.

15. 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 Heart Monitor from the mobile device.
- Using a 1.6mm Phillips screwdriver, press down firmly and turn counterclockwise to remove the screw in the battery door.
- 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. Remove the protective sticker from the battery, as applicable.

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.

16. TROUBLESHOOTING

Problem	Solution
I do not see an ECG signal in the *AliveECG* 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, noise or interference in my recording.	Try the following tips for acquiring the best quality ECG recording: • Ensure that the "Enhanced Filter" is on by tapping the filter text on the main record screen • Clean the electrodes on the monitor with alcohol-based sanitizer before each use • If hands are very dry, use a water-based 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 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 *AliveECG* 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 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 Review ECG Recordings.
I forgot my password and I'm unable to reset it.	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. Follow the reset instructions in the email. Please note, the reset link contained in the email is only active for a short while.

17. 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	125 x 61 x 16 mm
AC-004 & AC-007-UA-A (w/Attachment Plate)	28 grams	89 x 50 x 7 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)

Standards Compliance

ANSI/AAMI EC38	IEC 60601-1	IEC 60601-2-47
ISO 10993	IEC 60601-1-2	

Patient Interface

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

18. INTERNATIONAL AVAILABILITY

The AliveCor Heart Monitor is available for use by licensed 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 the European Union. The AliveCor Heart Monitor is a non-notified medical device and approved for use in India.

19. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

www.alivecor.com

20. EUROPEAN AUTHORIZED REPRESENTATIVE

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

21. 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.			

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration—electromagnetic immunity</th></tr>
<tr><td colspan="4">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.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 Vrms
150 kHz to 80 MHz</td><td>3 V</td><td rowspan="2">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
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:
  </td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.5 GHz</td><td>3 V/m</td></tr>
<tr><td colspan="4">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</td></tr>
<tr><td colspan="4">[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.</td></tr>
</table>

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.

22. 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)**
RxOnly	**Prescription Use Only in The United States**
REF	**Model Number**
SN	**Serial Number**
	**Direct Current Power Source**