Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Alivecor, Inc.
Michael Righter
Director, Regulatory Affairs
30 Maiden Lane, 6th Floor
San Francisco, CA 94108 US

Re: K130921
Trade/Device Name: Alivecor Heart Monitor OTC
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 10, 2014
Received: January 15, 2014

Dear Michael Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

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.

Prescription Use ____X____		Over-The-Counter Use ____X____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.02.06 16:29:36 -05'00'

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 6, 2014

Alivecor, Inc.
Michael Righter
Director, Regulatory Affairs
30 Maiden Lane, 6th Floor
San Francisco, CA 94108 US

Re: K130921
Trade/Device Name: Alivecor Heart Monitor OTC
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 10, 2014
Received: January 15, 2014

Dear Michael Righter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

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.

Prescription Use ____X____ AND/OR Over-The-Counter Use ____X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by
Owen P. Faris -S
Date: 2014.02.06
16:29:36 -05'00'

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

K130921

AliveCor

FDA CDRH DMC
APR 0 3 2013
Received

510(k) PREMARKET NOTIFICATION

TRADITIONAL 510(k) COVER LETTER

April 1st, 2013

Frank Lacy; Orlando Lopez, PhD
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern;

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market a software revision of our previously cleared medical device (K122356) for Over-The-Counter (OTC) use. As mentioned in the previous submission, AliveCor chose the CardioComm, Inc. *HeartCheck Pen* as the predicate device because it has clearance for OTC use and we anticipated there was going to be some level of demand for the *AliveCor Heart Monitor* for OTC. Since the original submission, an exceptionally *similar* device from Cardiac Design LLC called the *ECG Check* was cleared for OTC use (K122184), but for simplicity and continuity, the *HeartCheck* Pen remains as the predicated comparison.

Currently known with the proprietary name of *AliveCor Heart Monitor for iPhone*, AliveCor submitted an addition to the indications for use (K130409 pending FDA clearance) with the intent to remove "*for iPhone*" from the product name and expanded the scope of use to other Mobile Computing Platforms (MCPs) that AliveCor verifies and validates as compatible with the applicable mechanical configuration of the *AliveCor Heart Monitor* and associated *AliveECG* mobile application.

This 510(k) submission is essentially a carbon copy of K130409 (pending clearance) with two changes:

1. Indications for use to include OTC designation:

   After successful FDA clearance, marketing and design validation of the AliveCor Heart Monitor (K122356), we have received a great deal of feedback from medical professionals, patients and health conscious individuals related to the availability of our device for Over-The-Counter use. We believe with minor changes to the software and labeling we can support OTC users and provide a product that encourages a healthcare system that promotes preventive medicine practices.

2. *AliveECG* App modification to hide ECG waveform:

   In response to this market need, AliveCor commenced work on a modification to the *AliveECG* app that hides the ECG waveform from a 'consumer' while still providing an informative user interface (similar to a heart-rate-monitor) that allows the user to send their recording to a medical professional for review and interpretation. The proposed change allows the app to be unlocked to view the ECG waveform for physicians, and patients under the guidance of a physician.

By following Memorandum K97-1 to determine if a new 510(k) application is necessary for the change, AliveCor determined that due to the expanded indications for use, a Traditional 510(k) was necessary.

1/67

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

Submission Content, in accordance to 21 CFR 807.92:

Submitter's Name:	AliveCor, Inc.
Submitter's Address:	30 Maiden Lane, 6th Floor, San Francisco, CA 94108
Facility Registration Number:	3009715978
Contact Person:	Michael S. Righter
Contact Person Title:	Director, Regulatory Affairs
Telephone:	415.795.9812
Fax:	415.397.0440
Email:	mike@alivecor.com
510(k) Submission Type:	Traditional 510(k)
Date Prepared:	February 1, 2013
Classification Name:	Electrocardiograph
Common Name:	ECG Event Recorder
Proprietary Name:	AliveCor Heart Monitor
Model Number:	AC-00X
Product Code:	DPS
C.F.R. Section:	870.2340
Recommended Classification:	Class II
Classification Panel:	Cardiovascular
Reason for Submission:	Additional Indications (OTC)

Confidentiality Statement, in accordance to 21 CFR 807.95

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA during the evaluation process, in accordance with (21 CFR 807.95).

Design and Use of the Device

The following table summarizes the principal factors about the design and use of the devices

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor™

510(k) PREMARKET NOTIFICATION

ELECTRONIC COPY CERTIFICATION

An electronic copy (eCopy) is supplied with this premarket notification [510(k)] submission in accordance with Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The eCopy is an exact duplicate of the paper copy.

Source files are included under the "Misc Files" directory for the convenience of the reviewer.

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor™

AliveCor, Inc.

AliveCor Heart Monitor (OTC)

Traditional 510(k) Submission

Electronic

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	(b) (4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ALIVECOR INC 30 Maiden Lane, 6th Floor San Francisco CA 94108 US	Michael Righter
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1679	2.1 E-MAIL ADDRESS mike@alivecor.com 2.2 TELEPHONE NUMBER (include Area code) 415-7959812 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

08-Mar-2013

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/01/2013	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
AliveCor, Inc.	3009715978		
Division Name *(if applicable)*	Phone Number *(including area code)*		
San Francisco	415.795.9812		
Street Address	FAX Number *(including area code)*		
30 Maiden Lane, 6th Floor	415.397.0440		
City	State / Province	ZIP/Postal Code	Country
San Francisco	CA	94108	USA
Contact Name			
Michael Righter			
Contact Title	Contact E-mail Address		
Director, Regulatory Affairs	mike@alivecor.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

FORM FDA 3514 (12/10)

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent/Applicant
  - ☐ Design/Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DPS	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☒ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K121009	1	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	1	CardioComm Solutions, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrocardiograph

	Trade or Proprietary or Model Name for This Device		Model Number
1	AliveCor Heart Monitor OTC	1	AC-00X
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- ☒ Laboratory Testing
- ☐ Animal Trials
- ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DPS	870.2340	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The AliveCor Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4) [redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - Part 1: General requirements for safety	2005	10/31/2005
2	60601-1-2	AAMI/ANSI/IEC	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	2007	06/10/2010
3	60601-2-47	IEC	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	1.0	07/10/2001
4	EC38	ANSI/AAMI	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	2007	09/09/2008
5	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009	10/04/2010
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   AliveCor, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   04/01/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   30 Maiden Lane, 6th Floor
   San Francisco, CA 94108

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 415.795.9812
   (Fax) 415.397.0440

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Common Name: ECG Event Recorder

   Classification Name: Electrocardiograph

   Proprietary Name: AliveCor Heart Monitor

   Model: AC-00X

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☑ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

   ☑ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

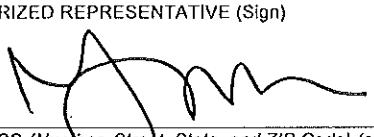
   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)



12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Michael S. Righter
    (Title) Director, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    30 Maiden Lane, 6th Floor
    San Francisco, CA 94108

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 415.795.9812
    (Fax) 415.697.0440

15. DATE OF CERTIFICATION
    04/01/2013

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information, unless it displays a currently valid OMB control number

Form FDA 3674 (3/12) (BACK)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

TRADITIONAL 510(k) COVER LETTER

April 1st, 2013

Frank Lacy; Orlando Lopez, PhD
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern;

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market a software revision of our previously cleared medical device (K122356) for Over-The-Counter (OTC) use. As mentioned in the previous submission, AliveCor chose the CardioComm, Inc. *HeartCheck Pen* as the predicate device because it has clearance for OTC use and we anticipated there was going to be some level of demand for the *AliveCor Heart Monitor* for OTC. Since the original submission, an exceptionally *similar* device from Cardiac Design LLC called the *ECG Check* was cleared for OTC use (K122184), but for simplicity and continuity, the *HeartCheck* Pen remains as the predicated comparison.

Currently known with the proprietary name of *AliveCor Heart Monitor for iPhone*, AliveCor submitted an addition to the indications for use (K130409 pending FDA clearance) with the intent to remove "*for iPhone*" from the product name and expanded the scope of use to other Mobile Computing Platforms (MCPs) that AliveCor verifies and validates as compatible with the applicable mechanical configuration of the *AliveCor Heart Monitor* and associated *AliveECG* mobile application.

This 510(k) submission is essentially a carbon copy of K130409 (pending clearance) with two changes:

1. Indications for use to include OTC designation:

   After successful FDA clearance, marketing and design validation of the AliveCor Heart Monitor (K122356), we have received a great deal of feedback from medical professionals, patients and health conscious individuals related to the availability of our device for Over-The-Counter use. We believe with minor changes to the software and labeling we can support OTC users and provide a product that encourages a healthcare system that promotes preventive medicine practices.

2. *AliveECG* App modification to hide ECG waveform:

   In response to this market need, AliveCor commenced work on a modification to the *AliveECG* app that hides the ECG waveform from a 'consumer' while still providing an informative user interface (similar to a heart-rate-monitor) that allows the user to send their recording to a medical professional for review and interpretation. The proposed change allows the app to be unlocked to view the ECG waveform for physicians, and patients under the guidance of a physician.

By following Memorandum K97-1 to determine if a new 510(k) application is necessary for the change, AliveCor determined that due to the expanded indications for use, a Traditional 510(k) was necessary.

Questions? Contact FDA/CDRH/OCE/DECAL at CDRH-510(K)STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

Submission Content, in accordance to 21 CFR 807.92:

Submitter's Name:	AliveCor, Inc.
Submitter's Address:	30 Maiden Lane, 6th Floor, San Francisco, CA 94108
Facility Registration Number:	3009715978
Contact Person:	Michael S. Righter
Contact Person Title:	Director, Regulatory Affairs
Telephone:	415.795.9812
Fax:	415.397.0440
Email:	mike@alivecor.com
510(k) Submission Type:	Traditional 510(k)
Date Prepared:	February 1, 2013
Classification Name:	Electrocardiograph
Common Name:	ECG Event Recorder
Proprietary Name:	AliveCor Heart Monitor
Model Number:	AC-00X
Product Code:	DPS
C.F.R. Section:	870.2340
Recommended Classification:	Class II
Classification Panel:	Cardiovascular
Reason for Submission:	Additional Indications (OTC)

Confidentiality Statement, in accordance to 21 CFR 807.95

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA during the evaluation process, in accordance with (21 CFR 807.95).

Design and Use of the Device

The following table summarizes the principal factors about the design and use of the devices

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

Questions? Contact FDA/CDRH/OCE/DECA/CDRH-RQIS STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DECA/CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

Indications for Use:

The *AliveCor Heart Monitor* is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use _____X_____ AND/OR Over-The-Counter Use _____X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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AliveCor

510(k) PREMARKET NOTIFICATION

510(k) STATEMENT

(as required by 21 CFR 807.93)

I certify that, in my capacity as *Director, Regulatory Affairs* of *AliveCor, Inc.*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____

(Signature of Certifier)

Michael S. Righter

(Typed Name)

April 1, 2013

(Date)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank

Questions? Contact FDA/CDRH/OCE/DECAD at 510(K)STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *Director, Regulatory Affairs* of *AliveCor, Inc.*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Michael S. Righter
(Typed Name)

April 1, 2013
(Date)

_____
*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

CLASS III CERTIFICATION AND SUMMARY

(As Required by 21 CFR 807.94)

(To be submitted when claiming equivalence to a Class III device)

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

Financial Certification or Disclosure Statement

(As Required by 21 CFR 54)

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY TO INDUSTRY STANDARDS

The following table is a list of the FDA recognized standards used to evaluate the *AliveCor Heart Monitor* device.

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

A declaration of conformity is provided below for each of the standards in the table above.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

Declaration of Conformance

IEC 60601-1 (2005)

The *AliveCor Heart Monitor* is in compliance with IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1.

IEC 60601-1-2 (2007)

The *AliveCor Heart Monitor* is in compliance with IEC 60601-1-2: Medical Electrical Equipment – Part 1: General Requirements for Safety, Collateral Standard: Electromagnetic compatibility – Requirements and Tests. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1-2.

ANSI/AAMI EC38 (2007)

The *AliveCor Heart Monitor* is in compliance with ANSI/AAMI EC38: Ambulatory Electrocardiographs. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for EC38.

ISO 10993-1 (2009)

The *AliveCor Heart Monitor* is in compliance with ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for ISO 10993-1.

Questions? Contact FDA/CDRH/OCE/DECAL/CDRH-RECALLSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

THIRD PARTY LABORATORIES USED FOR TESTING CONFORMANCE TO STANDARDS

Biocompatibility:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (2005)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2: Med. Elec. Equip. - Gen. Req. for Safety; Electromagnetic Compatibility - Reqs. and Tests (2007)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-54	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI EC38: Part 2-47: Particular req's for the safety, including essential perf., of ambulatory electrocardiographic systems (2007)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-65	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
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Were there any deviations or adaptations made in the use of the standard?	☐	☒
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1: Use of International Standard ISO-10993, 'Biological ... Testing'

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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Questions? Contact FDA/CDRH/OCE/Standards and Conformance Program STATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5	Part 5: Tests for in vitro cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Cytotoxicity tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10	Part 10: Tests for irritation and skin sensitization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Irritation and Sensitization tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL OTHER		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION
All other parts not applicable to the he AliveCor Heart Monitor for iPhone according to the standard

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AliveCor

510(k) PREMARKET NOTIFICATION

EXECUTIVE SUMMARY

1. INTRODUCTION

AliveCor, Inc. (AliveCor) has developed and plans to market the *AliveCor Heart Monitor* for Over-The-Counter (OTC) use. The device hardware and mechanical components are identical to the previously cleared *AliveCor Heart Monitor for iPhone.* The *HeartCheck Pen Handheld Heart Rhythm with GEMS Home* device (*HeartCheck Pen* or predicate device) manufactured for CardioComm Solutions, Inc. intended for OTC remains as the predicate device. We believe that the *AliveCor Heart Monitor* is substantially equivalent to the *HeartCheck Pen Handheld Heart Rhythm with GEMS Home* (K121009).

This 510(k) submission is essentially a carbon copy of K130409 (pending clearance) with two changes:

1.1. Indications for use to include Over-The-Counter

We believe with minor changes to the software we can support OTC use of the device. This change requires modifications to the appropriate labeling.

1.2. *AliveECG* App modification to hide ECG waveform:

A modification to the *AliveECG* app is required that hides the ECG waveform from a 'consumer' while still providing an informative user interface (similar to a consumer heart-rate-monitor) that allows the user to send their recording to a medical professional for review and interpretation. The proposed change allows the app to be unlocked to view the ECG waveform for physicians, and patients under the guidance of a physician.

2. BACKGROUND

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market a revision of our previously cleared medical device (K122356) for Over-The-Counter (OTC) use. Currently known with the proprietary name of *AliveCor Heart Monitor for iPhone*, AliveCor submitted an addition to the indications for use (K130409 pending FDA review and clearance) with the intent to remove "*for iPhone*" from the product name and expanded the scope of use to other Mobile Computing Platforms (MCPs) that AliveCor verifies and validates as compatible with the applicable mechanical configuration of the *AliveCor Heart Monitor* and associated *AliveECG* mobile application. This submission outlines the additional changes necessary for OTC use.

3. INTENDED USE

The *AliveCor Heart Monitor* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (*e.g.* physician, nurse, EMT) with the ability to perform an immediate assessment of a user's ECG rhythm. Additionally, the simple user interface allows a user to directly acquire a recording from their body for transmission-to and assessment-by a medical professional.

4. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

The *AliveCor Heart Monitor* has no known contraindications; however, the device should be used in accordance with the instructions as indicated in the User Manual and as directed by a physician.

Questions? Contact FDA/CDRH/OCE/Director CDRH-PRGSTATUS@fda.hhs.gov or 301-796-8118

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Refer to Section 13: Proposed Labeling for additional warnings and precautions.

5. DEVICE DESCRIPTION

The *AliveCor Heart Monitor* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the computing power of a MCP while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the user's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor* uses acoustic waves in the non-audible ultrasonic wavelength. The medical device consists of the combination of the *AliveCor Heart Monitor* (electro-mechanical assembly), the *AliveECG* mobile application (App), a compatible MCP, and the auxiliary AliveCor Database WebApp for editing metadata online.

6. SUBSTANTIAL EQUIVALENCE

Legally marketed predicate device:

510(k) Number: K121009

Product: *HeartCheck Pen Handheld Heart Rhythm with GEMS Home*

Manufacturer: CardioComm Solutions, Inc.

The major differences between the currently marketed *HeartCheck Pen* and the *AliveCor Heart Monitor* are summarized below and detailed in Section 12: Substantial Equivalence discussion.

Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor***
Indications for Use:	The *HeartCheck™ Pen Handheld with GEMS Home* software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The *HeartCheck™ Pen Handheld device along with GEMS Home* software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The *AliveCor Heart Monitor* is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.
Standards: Essential Performance AECG Safety General Safety EMC Safety	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2

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Specification	*HeartCheck Pen* Handheld Heart Rhythm with GEMS Home	*AliveCor Heart Monitor*
Data Acquisition: Frequency Response ECG channels Resolution Sample Rate	 **1 Hz** – 40Hz Single Channel Unknown **250** Samples/Second	 **0.5 Hz** – 40 Hz Single Channel 16 bit **300** Samples/Second
Memory Capacity:	**20** recordings	Essentially **unlimited** due to real-time transmission to MCP memory
Device Classification:	DPS: Electrocardiograph	DPS: Electrocardiograph
Power Supply: Battery Battery Life (typical)	 2 AAA batteries Unknown	 1 Lithium Manganese Dioxide Cells 100 hours operational
User Interface: Primary Lead Data upload Software platform	 Lead I, Left to Right Hand **USB** **PC based software**	 Lead I, Left to Right Hand **Ultrasonic transmission** **MCP OS based software with web access to user data**
Physical Specs: Dimensions, inches Weight	 **130 x 30 x 20 mm** **110 grams**	 **118 x 62 x 16.5 mm** **40 grams**
Electrodes: Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel
Lead Wires:	None	None
Where used:	Ambulatory outpatient use	Ambulatory outpatient use
Prescribed:	**Over-the-Counter**	**Over-the-Counter**
Environmental: (minimum) Operating Temp Storage Temp	 **5 to 40 degrees C** **-20 to 55 degrees C**	 **10 to 45 degrees C** **-20 to 60 degrees C**

None of the above differences in specification affect the safety or efficacy of the *AliveCor Heart Monitor* compared to the *HeartCheck Pen* system as discussed in Section 12: Substantial Equivalence Discussion.

In addition to Section 12: Substantial Equivalence Discussion, additional testing was performed to demonstrate the safety and efficacy of the device in Sections 16: Software, Section 17: Electromagnetic Compatibility and Electrical Safety and Section 18: Performance Testing – Bench. The results of performance, safety and bench testing suggest that the main functional characteristics of the *HeartCheck Pen* and *AliveCor Heart Monitor* are comparable for key metrics, thus confirming their substantial equivalence.

7. COMPLIANCE TESTING

The *AliveCor Heart Monitor* was evaluated for conformity to the following list of standards. The *AliveCor Heart Monitor* demonstrated compliance with all applicable tests. Greater detail is discussed in Section 9: Declaration of Conformity, Industry Standards.

Safety and Compliance Standards and Guidelines:

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and

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		essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

8. CONCLUSION:

The *AliveCor Heart Monitor for Over-The-Counter use* represents a logical modification to the technology of the predicate device and an obvious extension of the previously cleared *AliveCor Heart Monitor for iPhone*. The extension of the *AliveCor Heart Monitor* product line to include OTC use is in response to user requests/needs. The clinical use of the device remains identical to the predicate device. AliveCor has concluded that the *AliveCor Heart Monitor* is substantially equivalent to the predicate device and the differences between them do not adversely affect safety and effectiveness of the device.

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AliveCor™

510(k) PREMARKET NOTIFICATION

DEVICE DESCRIPTION

Figure 1: User Interface

Figure 2: *AliveCor Heart Monitor*

1. BASIC DESCRIPTION:

The *AliveCor Heart Monitor* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the processing power of a *mobile computing platform* (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the user's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor* uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the *AliveCor Heart Monitor*, *AliveECG* mobile App (App), and a MCP such as a Smartphone.

Auxiliary functionality on the AliveCor website (WebApp) allows users to access their ECG data and any data shared with them that is stored on the AliveCor Database. The majority of the functionality associated with these features are MDDS (Medical Device Data System), although editing of the metadata (Patient Name, Date of Birth, measurement position, comments, symptoms, etc.) is considered a component of the medical device.

2. INTENDED USE:

The *AliveCor Heart Monitor* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (*e.g.* physician, nurse, EMT) with the ability to perform an immediate assessment of a patient's ECG rhythm. Additionally, the simple user interface allows a user to directly acquire a recording from their body for transmission-to and assessment-by a medical professional.

3. PATIENT BENEFITS:

Traditional ECG monitors that use telephone transmission techniques require the user to record their ECG then at some later time, use a phone (typically a land-line) to transmit the data to a service center. The *AliveCor Heart Monitor* simplifies the process for the user by removing the need to manually transmit the data. The device automatically records the data on the MCP and the associated App uploads the data with minimal user interaction.

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AliveCor, Inc. (AliveCor) believes that by removing the complexity of electronics hardware from the device, we can improve accessibility to care. In other words, reducing the cost of the medical device, strategic use of the computing horsepower within MCPs, and prevalent accessibility to MCPs such as Smartphones will allow improved patient compliance and efficacy of the device as compared to other ECG event recorders currently on the market. Patients can perform an ECG recording almost anywhere and during normal daily activities without major interruption to their lives.

4. CLINICAL USE MODEL:

The *AliveCor Heart Monitor* is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of user (medical professional, patient or consumer).

4.1. Users:

In the hands of a medical professional, the *AliveCor Heart Monitor* is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip.

In the hands of a patient using the device under the prescription of a physician, the *AliveCor Heart Monitor* is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional on the AliveCor Database. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional on the AliveCor Database.

In the hands of a consumer, the AliveCor Heart Monitor is a real-time heart rate monitor that collects the same clinical quality ECG as in the physician or patient modes, but the ECG data is hidden from the consumer. The ECG is uploaded to the AliveCor website for review by a trained professional.

4.2. User Interaction:

The most common method of using the *AliveCor Heart Monitor* is to hold the device such that the users left and right hands are in contact with the left and right electrodes on the back of the device, see Figure 3. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the physician or patient can experiment to minimize muscle noise and maximize the ECG signal quality. The consumer user is given a signal quality metric to help ensure a clean signal. Alternatively, the device may be held directly to the chest for data acquisition, See Figure 4.

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Figure 3: Handheld monitoring

Figure 4: Chest Placement on sternum

5. OPERATING PRINCIPLE AND DETAILED DESIGN DESCRIPTION:

In layman's terms, the *AliveCor Heart Monitor* wirelessly communicates to the MCP with human-silent, ultra-low power data transmission protocol. It has extremely accurate front end electronics with high resolution analog-to-digital conversion processed by the *AliveECG* App. The MCP provides the computing horsepower for the App to digitally filter the data and process it to create a high resolution human readable ECG strip. The website (AliveCor WebApp) allows access to user data and the ability to edit metadata such as patient name, date-of-birth, comments, etc.

5.1. AliveCor Heart Monitor

5.1.1. Mechanical Configurations

The *AliveCor Heart Monitor's electronics are* configured into several different mechanical constructs or configurations to adapt to different form factors of many MCPs. Each mechanical configuration has identical hardware performance characteristics and they utilize the same materials as defined below.

Figure 5 and 6 show two such mechanical configurations of the *AliveCor Heart Monitor*.

Figure 5: *AliveCor Heart Monitor* for iPhone 4/4S

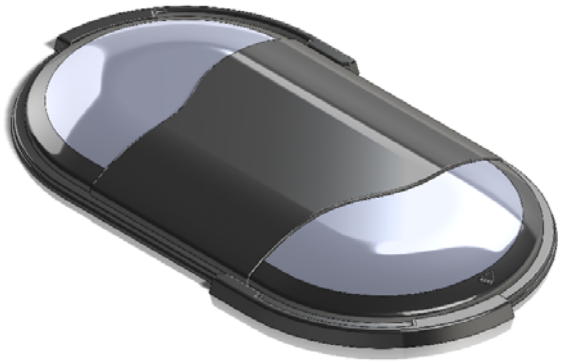

Figure 6: *AliveCor Heart Monitor* for Android

5.1.2. Hardware Functionality

The following is applicable to any mechanical configuration:

There are just two modes of operation for the device, STANDBY and ON. In the STANDBY mode, the electronic circuitry is actively looking for a connection between the electrodes (impedance).

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When the device detects presence of a conductive path between the electrodes (hands or skin contact), it turns ON and begins to emanate a modulated ultrasonic frequency (inaudible pressure wave) with a piezo oscillator, see Figures 7 and 8. After the electrodes are removed from the conductive path, the device returns to the STANDBY mode.

5.1.3. Hardware Design

(b) (4)

The battery used in each configuration may change due to size restrictions or excess space in a particular mechanical construct, but the battery chemistry will remain as a lithium coin cell, typical of a wrist watch battery. The *AliveCor Heart Monitor* circuit has an "OFF" current drain of less than 1 microamp and an "ON" current drain of 600 microamps. This provides an operating battery life for the ECG acquisition and transmission circuit of no less than 100 hours (6,000 minutes) of use for any mechanical/hardware configuration. At a model of 5 minutes per day of use, the operational battery life (to 83% of capacity) is 1200 days. We conservatively estimate a battery life of 1 years and recommend that the battery be changed at that interval which will provide a large margin of safety.

When the MCP is attached to the *AliveCor Heart Monitor*, the ultrasonic signal level from the device will be much greater than the signal from another reasonably powered acoustic emitter in the same vicinity and the effect on the demodulated ECG signal is negligible. The piezo is specifically located close to the microphone when the MCP is attached the device so that the Signal-to-Noise Ratio (SNR) is high.

The *AliveCor Heart Monitor* occupies an ambient acoustic environment (18-20 kHz) at least 20-30 dB quieter at than the typical 1500-2000 Hz spectra. This superior signal-to-noise environment holds true in quiet rooms, noisy indoor urban places and inside jets at 35,000 feet while next to a wing-mounted engine.

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(b) (4)

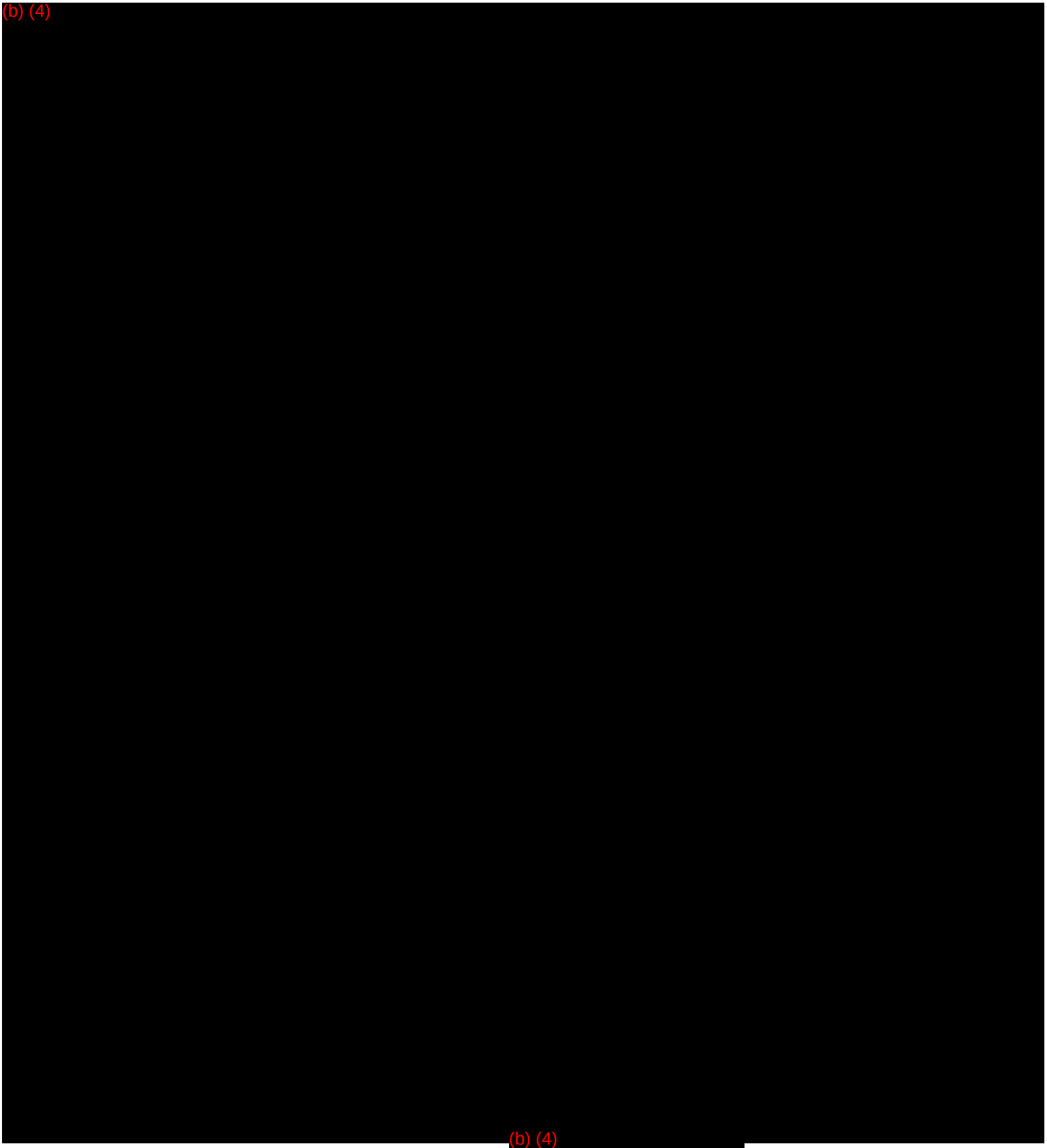

Figure 7: Typical exploded view of the device (b) (4)

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(b) (4)

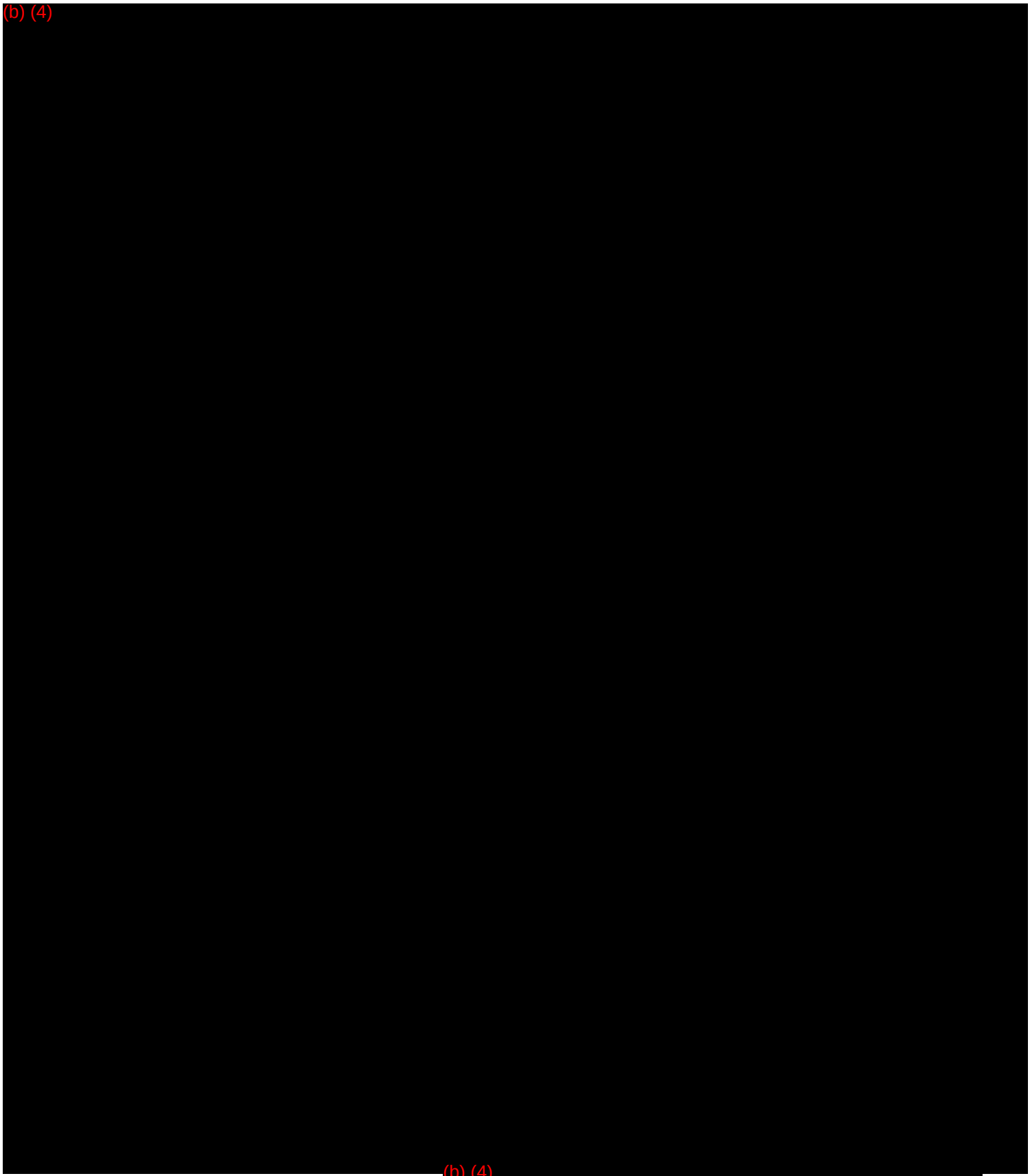

Figure 8: Typical exploded view of the devic (b) (4)

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5.2. Mobile Computing Platform (MCP)

The frequency modulated ultrasonic ECG signal is acquired by the built-in microphone on the MCP. The MCP provides the ability to process the data as requested by the App.

Only compatible MCPs may be used with the *AliveCor Heart Monitor* as defined by AliveCor's Mobile Computing Platform Compatibility Chart shown below. Compatible MCPs are state-of-the art, touch interface, typically handheld devices with wireless connectivity to 2G, 3G, 4G, WiFi, Bluetooth and/or GPS radio systems.

5.3. Software Design of the *AliveECG* App

(b) (4)

5.4. AliveCor ECG WebApp

As opposed to entering information on the typically small screens of MCPs, users may find it more useful to enter metadata on any personal computer with web access. Authenticated with a valid login and password, users have the ability to edit existing metadata such as Patient Name, Date of Birth, measurement position, comments, symptoms, etc. that are associated with individual ECG recordings. Additionally, sharing functionality allows physicians to access and view their patients ECG data at any time from a PC terminal.

6. MATERIALS:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the device, touching the stainless steel-electrodes, or replacing the battery.

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Primarily two components of the device may contact skin: the top housing, and more significantly the stainless-steel electrodes. The required biocompatibility tests according to ISO10993-1 were performed to ensure user safety while handling the device for its utility purpose (as an accessory to a MCP), and using the device for its medical purpose.

*The biocompatibility studies are presented in Appendix B and are summarized in Section 15.

The housing material consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages available). Besides passing Biocompatibility testing as required, these materials are commonly used in consumer products that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products.

The electrodes are made from 304SS which is a medical grade stainless-steel. Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

7. MOBILE COMPUTING PLATFORM COMPATIBILITY

In a previous 510(k) submission, we noted:

> *"Future test protocol improvements are underway to expand the potential use of the device to other Smartphone platforms or iOS versions. Deployment of software for other Smartphone platforms will not be launched for commercial distribution until review and clearance by FDA. AliveCor has plans for future regulatory filings that may include specific Android devices, or future iPhone devices that meet necessary acoustic reception requirements for proper functionality with AliveCor's data transmission technology."*

To date, the test methodology/protocol described above has been deployed on the following MCP hardware and operating system (MCP/OS) combinations:

AliveCor's Mobile Computing Platform Compatibility Chart

MCP Version	iOS 5.1	iOS 6.X	Android OS: TBD
iPhone 4 (GSM)	S	S	X
iPhone 4 (CDMA)	S	S	X
iPhone 4S	S	S	X
iPhone 5 (GSM)	X	S	X
iPhone 5 (GSM + CDMA)	X	S	X
iPod touch 4th gen	O	O	X
iPod touch 5th gen	X	O	X
iPad 2	X	O	X
The New iPad (all versions)	X	O	X
Various Android devices: TBD	X	X	O

S = Currently supported MCP/OS by verification and validation testing on file at AliveCor
O = Pending supported MCP/OS
X = Will not be supported or MCP is incompatible with OS

AliveCor intends on providing this compatibility matrix to its users (through our website and other means deemed necessary). Commercialization of the additional MCP/OS combinations will occur

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only after our design control process concludes that the MCP/OS is covered under the scope of this 510(k) and it has passed all applicable verification and validation testing as necessary.

We anticipate that there will be some MCP/OS combinations that will not be compatible with the *AliveCor Heart Monitor*, e.g. the MCP does not have the ability to receive the ultrasonic transmission from the device. To determine this, minimum hardware and software requirements have been defined for the *AliveCor Heart Monitor* family of products.

7.1. Minimum Hardware Requirements:

The MCP must have a built-in microphone capable of receiving ultrasonic acoustics up to 20 kHz. ECG signal is acquired by the built-in microphone on the MCP. The MCP provides the ability to process the data as requested by the App.

Only compatible MCPs may be used with the *AliveCor Heart Monitor* as defined by AliveCor's Mobile Computing Platform Compatibility Chart. Compatible MCPs are state-of-the art, touch interface, typically handheld devices with wireless connectivity to 2G, 3G, WiFi, Bluetooth and/or GPS radio systems.

7.2. Minimum Software Requirements:

To date, we have completed verification testing with our device in conjunction with the iPhone Operation System (iOS) version 5.1 and greater listed in AliveCor's Mobile Computing Platform Compatibility Chart.

To date we have verified compatibility and/or modified the *AliveECG* App supported by a letter-to-file within about 10 days of iOS release. We believe this is a sustainable engineering practice and our reaction time will only decrease as we further improve our software V&V and deployment procedures. If we cannot meet those timelines, we believe that sufficient precautions in our labeling (and/or notification within the *AliveECG* App) will appropriately notify our users of the risk of incompatibility with OS upgrades, but we do not feel it is necessary to promote that mitigation at this time based on the severity of the risk.

We have not officially tested our *AliveECG* App on any of the Android operating systems. Performing the analysis of which MCP/OS combinations we need to support to meet the needs of our user base is a significant amount of research and development work. AliveCor made the decision to propose the support of Android MCP/OS in this 510(k) prior to dedicating those resources.

Currently we do not foresee there will be any software operating system that will restrict the use of the *AliveECG* App. If we determine there are restrictions, that particular operating system simply will not be included on AliveCor's Mobile Computing Platform Compatibility Chart.

8. WIRELESS COEXISTENCE

The *AliveCor Heart Monitor* uses non-RF, wireless communication between the hardware and the MCP which allows ECG recording in RF-sensitive environments like in-flight airplanes and ICUs when the MCP is in airplane mode with all radios turned off. Due to the ambulatory nature of the *AliveCor Heart Monitor*, it is highly likely that it will be exposed to wireless communication frequencies and networks. While being exposed to those energies, it is likely that the MCP component of the *AliveCor Heart Monitor* system will attempt data communication, thereby performing a task within the same wireless communication bandwidth. This suggests that

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evaluation of wireless coexistence is necessary to prove safety and efficacy of the medical device, but it is important to note that the MCP is a component of the *AliveCor Heart Monitor* medical device system and works independently of the medical device hardware produced by AliveCor. The AliveCor hardware does not use RF transmission technology and the *AliveCor Heart Monitor* system works independently of the wireless RF communications on the MCP. The MCP is constantly performing wireless communication duties with or without the *AliveCor Heart Monitor* as an attachment. The only wireless function that the MCP performs is data upload to the AliveCor database via the internet. This action is controlled by the MCPs operating system.

The wireless functionality built into the MCP should be exempt from testing for wireless coexistence given it has been issued an FCC certification (compliance to parts 15, 90, 95, and 97 of the FCC rules), Wi-Fi certification, etc. therefore passed all necessary compatibility, immunity, coexistence tests that would be related to this question. The *AliveCor Heart Monitor* components (hardware and App) produced by AliveCor do not alter or affect the wireless communication methods on the MCP, it simply utilizes them to transfer data as any other cell phone or Smartphone does under normal operating conditions.

8.1. Acoustic Data Transmission

The other “wireless” communication is real-time acoustic data transmission from the *AliveCor Heart Monitor* to the MCP microphone. Specifically, wireless coexistence does not apply to the acoustic data transmission techniques used by the *AliveCor Heart Monitor*. Wireless coexistence only applies to radio frequency (RF) data transmission.

Nearly identical to the data transmission techniques used for trans-telephonic ECG event monitors that typically operate with an acoustic center frequency of 1.9kHz, the *AliveCor Heart Monitor* operates at 19kHz. Trans-telephonic data transmission is a well established method with over 25 years of industry use. The majority of manmade equipment operates outside of this ultrasonic frequency range giving the *AliveCor Heart Monitor* a very quiet spectrum to work within. AliveCor has conducted proof of concept evaluations and have shown that 19kHz is approximately 30dB quieter than the 1.9kHz range in “bad” case scenarios as you can see below.

Acoustic spectrum over wing in a 737 airliner directly over wing/engine (note dB level at 1.9kHz is approximately 70dB while 19kHz is approximately 30dB):

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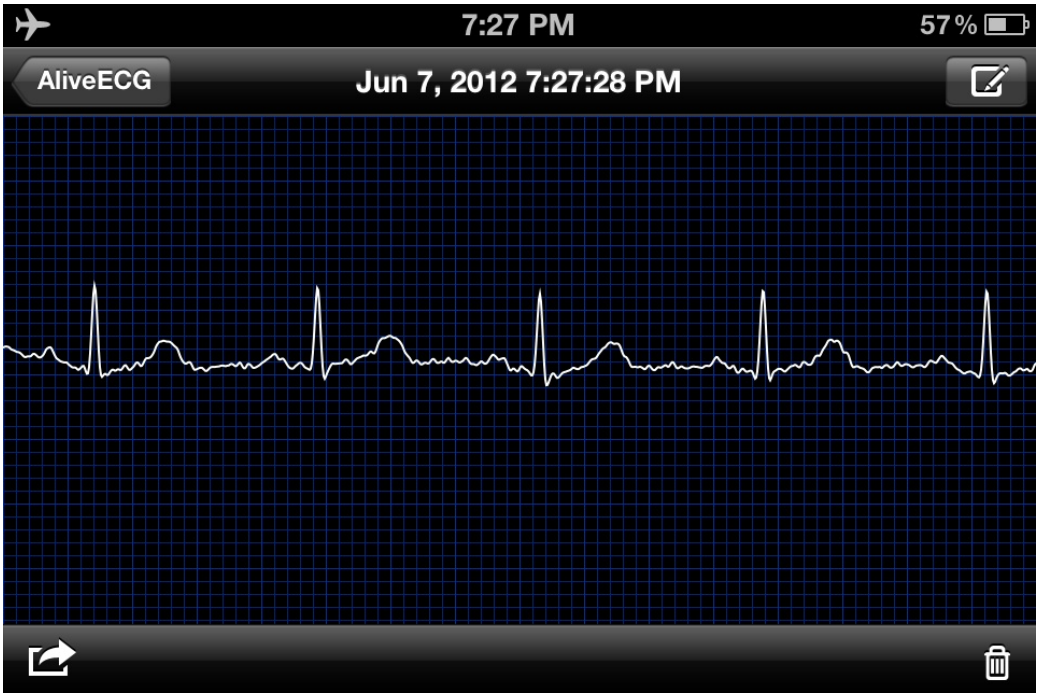
Acoustic spectrum over wing in a 737 airliner directly over wing/engine with the AliveCor device activated (note the dramatic spike at 19kHz indicating great signal-to-noise ratio):

Recording using the *AliveCor Heart Monitor* over wing in a 737 airliner directly over the wing/engine:



As you can see above in the example recording of the *AliveCor Heart Monitor* working in a 737 airliner located directly over the wing/engine, a clean signal can be obtained in contrast to a device with center frequency at 1.9kHz that does not work at all in this noisy location.

The low power acoustic waves that are emitted by the *AliveCor Heart Monitor* travel a very short distance, empirically measured at approximately 1-2 meters, depending on the acoustic environment. It is not likely that the *AliveCor Heart Monitor* will interfere with other equipment operating at that range.

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It is more likely that other equipment emit ultrasonic frequencies that may interfere with the Heart Monitor. Experimentation has shown that emission from interfering equipment is typically an unintended consequence of the equipment actions such as high speed motors or pneumatic systems. To mitigate the risk associated with other equipment that emit ultrasonic frequencies in the range of 19kHz, a software function during the Audio Acquisition phase analyzes for "noisy" signals, will notify the user of "excessive noise" and will not allow data acquisition. It is unlikely that two or more of the *AliveCor Heart Monitor* would be used in the same vicinity, but this upon this event, the same user notification appears.

The probability of ultrasonic frequency interference risk is at least two orders of magnitude lower than traditional trans-telephonic data transmission techniques used with event monitors today. The *AliveCor Heart Monitor* has a distinct advantage that it will work in the majority of human occupied spaces including airplanes, factories, outdoors, etc. where normal trans-telephonic devices fail to accurately acquire data.

8.2. Interactions with Other Devices on a Wireless Network

As with any device that uses a Smartphone or similar mobile computing platform as a component of a medical device (e.g. IBGstar, CellScope, Withings Blood Pressure Monitor, etc.), there are one or more methods of data communication available (e.g. Wi-Fi, cellular, Bluetooth, Zigbee). Data communication may occur as a result the medical device system, or independent of the medical device such as cellular telecommunications.

Obviously other devices (medical or non-medical) can use the same network as the MCP when it is transmitting data over a Wi-Fi or cellular network. Advancements in technology have mitigated many coexistence and security problems with these network types. AliveCor believes that Wi-Fi and Cellular network data communications are both safe and effective for transmitting data files to the AliveCor database.

8.3. Wireless Communication Restrictions

Another factor associated with using the MCP as a component of the medical device is related to cellular or Wi-Fi restricted environments such as airplanes or other "radio-silent" areas. Unlike other medical devices that rely on RF wireless communications as part of the primary functionality of the device, the *AliveCor Heart Monitor* and MCP as a system do not need RF wireless communications to function. Since the *AliveCor Heart Monitor* does not utilize RF wireless communications as part of its primary functionality, the device still works in the MCP's "Airplane Mode" setting, therefore safe and legal to use in locations where cell phones and other electronic equipment must be deactivated such as on an airplane or in an ICU. Since the microphone still works in Airplane Mode, the App can be used to collect data for upload at another time when Airplane Mode is deactivated. This is an example of the medical device system fully functional without RF wireless communication.

8.4. Wireless Coexistence Testing

No standardized test method has been published, although IEEE1900.2-2008 (Recommended Practice for the Analysis of In-Band and Adjacent Band Interference and Coexistence Between Radio Systems) is commonly referenced as a starting point for coexistence testing and suggests the structure for a coexistence report.

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AliveCor is not in a position to provide comprehensive coexistence testing for third party hardware that is a component of the medical device system, therefore, we do not have coexistence testing planned for design verification. If we performed any formalized coexistence testing according to recommendations in IEEE1900.2-2008, it would be far too narrow of a scope to be useful for industry or evaluation of safety and efficacy.

We intend on relying on industry experts, standards organizations (IEEE), and Smartphone manufacturers (e.g. Apple, Samsung) to maintain wireless compatibility and coexistence protocols and testing. We believe this is a safe assumption given that without proper design and testing of MCPs, a manufacturer's product would not be adopted by the market.

8.5. **Labeling**

AliveCor provides the following precaution in the user manual, "Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording." Additionally, if interference occurs, the in-App notifications (discussed above) end the recording to reduce the risk of erroneous recordings and notify the user.

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9. *ALIVECOR HEART MONITOR* SPECIFICATIONS (TYP.):

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	Lithium Manganese-Dioxide 3V Coin Cell
Battery life	100 Hours Operational Time, 12 months typical use

Physical Characteristics

Dimensions	118 x 62 x 16.5 mm
Weight	approximately 40 grams

Environmental Specifications

Operational Temperature	+10 to +45 degrees C
Operational Humidity	10% to 95% (non-condensing)
Operational Altitude	Based on mobile computing platform specifications
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 *AliveCor Heart Monitor*, which are either placed on the patient's chest or connected from left to right hand.

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510(k) PREMARKET NOTIFICATION

SUBSTANTIAL EQUIVALENCE DISCUSSION

1. SUBSTANTIAL EQUIVALENCE STRATEGY

To demonstrate substantial equivalence, two types of analysis are described herein:

- Standards test compliance
- A detailed predicate device comparison based on indications for use, electrical, mechanical and environmental specifications.

Note: The column for the *AliveCor Heart Monitor for iPhone* was retained to describe the changes made between the previously cleared device and the new device intended for use on any mobile computing platform (MCP). Basis for substantial equivalence is still in comparison to the original predicate device (*HeartCheck Pen*). "Same as previous" means there is no difference between the *AliveCor Heart Monitor for iPhone* and the more generic or encompassing *AliveCor Heart Monitor.*

2. CHOICE OF PREDICATE DEVICE

The options for choosing a predicate device for the *AliveCor Heart Monitor* (device) are plentiful. For well over 20 years, ECG event recorders, of both the post event and looping variety, have transmitted real-time and stored ECGs as frequency modulated (FM) audio signals (e.g. Instromedix, Inc. King of Hearts - K880626)

More recently, due to advancements in technology, ambulatory ECG monitors have been iterating to reduce cost and size (e.g. iRhythm Technologies, Inc. Event Card - K081471) while some have increased in complexity an features (CardioNet, Inc. Ambulatory ECG Monitor with Arrhythmia Detection - K093288). A few have tried to simplify the use model for Over-the-Counter use (e.g. Card Guard Scientific Survival, LTD. King of Hearts Express + AF Monitor).

AliveCor, Inc. (AliveCor) chose the *HeartCheck Pen* Handheld Heart Rhythm with GEMS Home (K121009) marketed by CardioComm, Inc. for several reasons.

- The *HeartCheck Pen* has an Over-the-Counter (OTC) indication for use, of which AliveCor believes, after proper validation studies and user interface modifications, our device may be resubmitted to obtain clearance for OTC.
- The *HeartCheck Pen* uses the identical product code (DPS) as the proposed device from AliveCor. This element was not a major factor in this decision, but
- The form factor and use model of the *HeartCheck Pen* is nearly identical to the proposed *AliveCor Heart Monitor*.

Since the original submission, an exceptionally *similar* device from Cardiac Design LLC called the *ECG Check* was cleared for OTC use (K122184), but for simplicity and continuity, the *HeartCheck* Pen remains as the predicated comparison.

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3. STANDARDS COMPLIANCE

In this 510(k) submission, we have shown that proposed device is compliant to AAMI/ANSI EC38:2007. Via compliance with that recognized standard, we claim substantial equivalence by inference, as other devices in this classification should also comply with this standard, or an equivalent, and in particular the predicated device. Although we did not explicitly test the predicate device to EC-38 standards, we can infer substantial equivalence because the predicate device, in order to receive premarket approval, would have to have demonstrated equivalent performance. The same can be said for IEC60601-1 series tests for general safety and particular safety for ambulatory ECG monitors. The predicate device, to have received premarket clearance would have to have shown that it was in compliance with certain safety and electromagnetic compatibility standards.

AliveCor's product requirements specification and verification protocols with associated acceptance criteria require compliance to the stated standards. Each mechanical configuration of the *AliveCor Heart Monitor* will be tested for standards compliance according to the individual design and development plan.

4. PREDICATE DEVICE SPECIFICATION COMPARISONS

The following comparison table delineates the incremental difference between the cleared *HeartCheck Pen* device, and any differences between the original *AliveCor Heart Monitor* ***for iPhone*** and *AliveCor Heart Monitor* devices. The table includes comparisons of the features and specifications of all devices, including electrical, mechanical, anatomical, and environmental characteristics. Any differences between the two designs have been marked with bold.

The discussion below the chart covers the areas in Table 1 where the designs diverge.

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Table 1: Predicate Device Comparison

Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor for iPhone***	***AliveCor Heart Monitor (OTC)***
Indications for Use:	The HeartCheck™ Pen Handheld with GEMS Home software is an **over-the-counter** device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor Heart Monitor **for iPhone** is intended for **use by licensed medical professionals** or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.	The AliveCor Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.
Standards: Essential Performance AECG Safety General Safety EMC Safety	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	Same	Same as previous
Data Acquisition: Frequency Response ECG channels Resolution Sample Rate	 **1 Hz** – 40Hz Single Channel Unknown **250** Samples/Second	 **0.5 Hz** – 40 Hz Single Channel 16 bit **300** Samples/Second	Same as previous

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Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor for iPhone***	***AliveCor Heart Monitor (OTC)***
Memory Capacity:	**20** recordings	Essentially **unlimited** due to real-time transmission to iPhone memory	Same as previous
Device Classification:	DPS: Electrocardiograph	Same	Same as previous
Power Supply: Battery Battery Life (typical)	 **2 AAA batteries** Unknown	 **1 Lithium Manganese Dioxide Coin Cells** 100 hours operational	Same as previous
User Interface: Primary Lead Data upload Software interface	 Lead I, Left to Right Hand **USB** **PC based software**	 Lead I, Left to Right **Ultrasonic acoustics** **iPhone OS based software**	 Same as previous Same as previous **Mobile Computing Platform OS**
Physical Specs: Dimensions, inches Weight	 **130 x 30 x 20 mm** **110 grams**	 **118 x 62 x 16.5 mm** **40 grams**	 **Insignificant variability due to different MCP form factors**
Electrodes: Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel	Same as previous
Lead Wires:	None	None	Same as previous
Where used:	Ambulatory outpatient use	Ambulatory outpatient use	Same as previous
Prescribed:	Over-the-Counter	**Prescription Only**	Over-the-Counter
Environmental: Operating Temp Storage Temp	 **5 to 40 degrees C** **-20 to 55 degrees C**	 **10 to 40 degrees C** **-20 to 60 degrees C**	Same as previous

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4.1. Indications For Use

The modification to the indications for use does not imply a change to the actual indication, but merely clarifies the predicate device indication. Most of the verbiage in the indications for the *HeartCheck Pen* is in AliveCor's opinion warnings/cautions that should be defined elsewhere as it is defined in our product labeling (See Section 13: Proposed Labeling).

4.2. Data Acquisition

The only difference among this group of specifications is that the predicate device has higher bandwidth cutoff at 1 Hz, versus 0.5 Hz for the *AliveCor Heart Monitor*. The *AliveCor Heart Monitor*, along with the majority of ambulatory ECG monitors follow the AAMI low-end bandwidth cutoff of 0.5 Hz. This has proven over the years to be adequate for quality ECG acquisition.

The sampling rate of the *AliveCor Heart Monitor* (300 Hz) is faster than the *HeartCheck Pen* (250 Hz). Faster sampling can potentially provide finer detail in the ECG rhythm strip, therefore the *AliveCor Heart Monitor* is substantially equivalent if not better than the predicate.

4.3. Memory Capacity

The *AliveCor Heart Monitor* transmits ECG data in real-time for storage on the iPhone non-volatile flash memory. Storing data on any handheld device is limited by the size of the on-board memory. The *HeartCheck Pen* uses onboard memory whereas the *AliveCor Heart Monitor* utilizes the vast memory capacity of the MCP. This is essentially the same function, although the *AliveCor Heart Monitor* transmits to the MCP before it stores, while the *HeartCheck Pen* stores before it transmits (via USB) only to store the data again on the PC.

4.4. Power Supply

The *AliveCor Heart Monitor* uses a single coin cell type battery, while the *Heart Check Pen* uses 2 AAA type batteries. Both of these batteries and battery chemistries are consumer off-the-shelf type batteries. Essentially there is no difference in power type. Lithium coin cell batteries are widely used in a variety of technologies and do not pose any significant safety hazards.

4.5. User Interface

4.5.1. General

The *HeartCheck Pen* device use a USB cable and PC based software (GEMS Home) to upload, while the *AliveCor Heart Monitor* uses ultrasonic transmission and the MCP Operating System.

The only signification change from the *AliveCor Heart Monitor* ***for iPhone*** to the more general device *AliveCor Heart Monitor* is the inclusion of additional mobile computing platforms. The iPhone 5 is a perfect example of an additional MCP that AliveCor can support with the *AliveCor Heart Monitor* with insignificant changes to the form factor.

The change from a USB cable to real-time acoustic data transmission is logical for this type of device. For well over 20 years, the industry has been sending acoustic ECGs by means of trans-telephonic data transmission (Instromedix, Inc. King of Hearts, iRhythm Technologies, Inc. Event Card, etc.). The *AliveCor Heart Monitor* is essentially performing the same action, but at an inaudible frequency range that the MCP's microphone can receive.

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The GEMS Home software package is comparable to the *AliveECG* mobile application (App). GEMS runs on a PC/Windows based operating system while the App runs on the MCP Operating System (OS). The difference in hardware platform (PC versus MCP) and operating system is not significant as long as the software has been validated for use with the MCP OS, and those elements of the operating system that are utilized for the software are validated for their particular purpose. AliveCor has a strong software V&V protocols for the *AliveECG* App, which is easily ported to test additional operating systems running on the applicable MCP.

Changes in the *AliveCor Heart Monitor* as a system include the addition of AliveCor WebApp functionality to allow the user to login to their account on-line to make changes to metadata associated with the ECG recording. This is in response to a general user need since using the keyboard functionality on the relatively small screen of an MCP is less convenient than a PC keyboard. This is very similar to the functionality of the GEMS Home software bundled with the *HeartCheck Pen*.

Moving the functionality from PC/Windows/software to the *AliveECG* App on a MCP is a logical move to consolidate data handling and transmission. The entire package is in the palm of the user's hand thereby potentially improving efficacy and controlled access to data. AliveCor believes that this logical shift of software platform does not negatively affect the safety or efficacy of ambulatory ECG monitoring in general, and we believe it is substantially equivalent to the predicate device.

4.5.2. Medical Professional and Prescribed Patient

The *AliveECG* App essentially performs the same actions as GEMS Home to upload ECG Data, store it for future access by a medical professional, and generate clinical quality ECG strip reports. As would a physician view the ECG with GEMS software, they can use the App to view recorded ECG rhythms. A significant advantage to the App compared to GEMS is that you do not have to go to a PC station to upload the data to view it. Additionally, the *HeartCheck Pen* can display the ECG data in real-time on a small OLED screen, but the *AliveECG* App allows the ECG to be viewed by a physician directly on the MCP in real-time or retrospectively on a high resolution display.

4.5.3. Health Conscious Individual (Use Over-the-Counter)

Similar to the *HeartCheck Pen*, the *AliveECG* App hides the ECG acquisition screen and the ECG report for consumer use. Additionally, similar to the *HeartCheck Pen*, the *AliveECG* App can be unlocked for a physician or when an OTC user becomes under the guidance of a physician such as in prescription/clinical service use.

4.6. Physical Specs

Construction materials, size and weight differ slightly between the compared devices, although the general category of materials, size and weight are very comparable. The *AliveCor Heart Monitor* device takes on additional size to function as a MCP case, but significantly reduces the weight due to the lack of hardware technology and batteries needed. Biocompatibility testing of all patient-contact materials has been performed and passed (see Appendix B: Biocompatibility Testing). All further mechanical configurations of the *AliveCor Heart Monitor* family of devices use the exact same materials tested. There are no additional risks associated with the difference in physical specifications that affect the safety or efficacy of the device.

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4.7. Operating Temp / Storage Temp

The upper and lower limits of the operational and storage temperature range are slightly different between devices. This is simply due to a difference in an option selected during the thermal conditioning used during the test. There are no safety or efficacy issues related to this difference in specification.

5. PERFORMANCE EQUIVALENCE TESTING

In addition to Standards test compliance comparison and the detailed specifications comparison, AliveCor has conducted bench testing with the Omron HGC-801 Portable, cordless, single-channel ECG Monitor (K060766). The *HeartCheck Pen* was not available for side-by-side comparison, so the Omron device was used as a qualitative performance comparison. Detailed test data is on file at AliveCor and described in Section 18: Bench Testing.

6. CONCLUSION

Based on the qualitative and quantitative comparative analysis provided here, the proposed *AliveCor Heart Monitor* is found to be substantially equivalent to the predicate device, HeartCheck Pen Handheld Heart Rhythm with GEMS Home marketed by CardioComm, Inc.

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510(k) PREMARKET NOTIFICATION

PROPOSED LABELING

(In accordance with 21 CFR 807.87e)

1. ALIVECOR HEART MONITOR LABELING

This section contains the AliveCor Heart Monitor labeling. Included in this section are the following.

- AliveCor Heart Monitor User Manual (OTC)
- AliveCor Heart Monitor Quick Start Guide (OTC)
- AliveCor Heart Monitor Product Box for iPhone 5 (Artwork)
- AliveCor Heart Monitor Product Label for iPhone 5

The included AliveCor Heart Monitor Product Label for iPhone 5 is presented as an example of the typical changes necessary for the different mechanical configurations of the AliveCor Heart Monitor. Both examples omit the Rx Only symbol due to the change in indications for use to Over-the-Counter.

Typically the Quick Start Guide and User Manual will be updated with the addition of mechanical configurations as presented in this section (iPhone 4/4S and iPhone 5 compatible hardware labeling combined). It is not anticipated that any warnings or precautions will change with the addition of mechanical configurations of the AliveCor Heart Monitor.

Over-The-Counter considerations according to 21CFR Part 801.60-62 (Principle Display Panel, Statement of Identity, and Net Quantity of Contents Statement) are incorporated into the above listed labeling.

2. PREDICATE DEVICE LABELING

For comparison purposes, product labeling describing the predicate device is included:

- HeartCheck Pen Handheld ECG Product Brochure
- HeartCheck Pen Product Sell Sheet

Questions? Contact FDA/CDRH/OCE/Director at CDRH-REGSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

AliveCor Heart Monitor

User Manual

iPhone® 4/4S/5

OTC

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

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iPhone is a trademark of Apple, Inc., registered in the U.S. and other countries. App Store is a service mark of Apple, Inc.

08LB01 Revision (A) | March 2013

Questions? Contact FDA/CDRH/OCE/Device CDRH-RIGHTSTATUS@fda.hhs.gov or 301-796-8118

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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 Heart Monitor is intended to record, display, 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.
- 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.

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- 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.

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- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PMSTATUS@fda.hhs.gov or 301-796-8118

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- **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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRAISTATUS@fda.hhs.gov or 301-796-8118

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12. 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: • 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 *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 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 *AliveECG* App on your phone. Launch the *AliveECG* 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).

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAGEINFO-STATUS@fda.hhs.gov or 301-796-8118

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Problem	Solution
I forgot my password and I'm unable to reset it.	Ensure that you've downloaded the *AliveECG* App on your phone. Similarly, ensure that you are logging into www.alivecor.com (not www.alivecorvet.com). 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.

Questions? Contact FDA/CDRH/OCE Section at CDRH-PAGIS-STATUS@fda.hhs.gov or 301-796-8118

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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	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	iPhone® 4/4S CR2016, iPhone® 5 CR2025 3V Coin Cell
Battery life	100 Hours 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	

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.

Questions? Contact FDA/CDRH/OCE Section at CDRH-EAGLE-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

14. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

www.alivecor.com

15. EUROPEAN AUTHORIZED REPRESENTATIVE

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAGIS-STATUS@fda.hhs.gov or 301-796-8118

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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	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	

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118

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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.			

Questions? Contact FDA/CDRH/OCE Section at CDRH-EASTATUS@fda.hhs.gov or 301-796-8118

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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** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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.			

Questions? Contact FDA/CDRH/OCE Section at CDRH-AGENDASTATUS@fda.hhs.gov or 301-796-8118

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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.

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118

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17. 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

Questions? Contact FDA/CDRH/OCE Section at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

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TITLE: ECG for iPhone 5 Quick Start Guide, OTC
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Change History

Revision	Date	Description of Change	Author
A	March 26, 2013	Initial Release, modifications to 08LB02 for OTC	Michael Righter

Note: The following body of text may be translated, reformatted or otherwise adjusted to meet the needs of the particular application displaying the information (*e.g.* website, mobile application, etc.). The text (copy) should not be modified upon adjustment. Only numbers of headings, bullets, hyperlinks, color and other non-content related format may change.

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AliveCor

Heart Monitor

Quick Start Guide

for iPhone® 4/4S or 5

NOTE: For the most up-to-date information on your product please visit www.alivecor.com/manuals

For more info visit AliveCor.com or follow us on Facebook at Facebook.com/AliveCor or Twitter @AliveCor

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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.

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

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- Request analysis by a medical professional.

1.1. Indications for Use

The Heart Monitor is intended to record, display, 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.
- 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,

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- 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.

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-PMOI-STATUS@fda.hhs.gov or 301-796-8118

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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.

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

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. LIMITED WARRANTY AND RETURNS POLICY

This Limited Warranty and Returns Policy ("Limited Warranty") applies to AliveCor Heart Monitor (the "Product") and is given by AliveCor, Inc., to the individual or entity (the "Owner") who purchased the Product from AliveCor or an AliveCor authorized dealer. This Limited Warranty applies only within the United States, European Union and within countries of the European Free Trade Association where the products are available for sale to customers located in such countries, and is not transferable.

14-DAY RETURN POLICY

If you purchased the Product directly from AliveCor or an AliveCor authorized dealer, you may return the Product within 14 days of receiving it. In order for a refund under this Returns Policy to be granted, you must request a Return Merchandise Authorization (RMA) number from AliveCor during the 14-day period following the date you received the Product from AliveCor or an authorized dealer. You may request an RMA number by submitting a request at https://support.alivecor.com. If the Product is returned in accordance with this Returns Policy, AliveCor will credit the account you used to make the original purchase with the full purchase price

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

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you paid for the Product and any applicable taxes minus any shipping and handling charges you paid when you purchased the Product. The time to credit your account may vary, depending on processing time. Please allow a minimum of 4 weeks for AliveCor to credit the account used to make the original purchase. If you received a damaged Product directly from AliveCor, please contact AliveCor's Customer Service at https://support.alivecor.com. If you purchased the Product from a retailer or distributor other than AliveCor, please contact that retailer or distributor regarding non-warranty returns.

MANUFACTURER'S LIMITED WARRANTY

AliveCor warrants to the Owner that the Product will materially conform to its published specifications and be free from defects in materials and workmanship under normal use for a period of ONE YEAR commencing on the date of delivery (the "Warranty Period"). If the Product proves defective during the Warranty Period, we would ask you to follow the instructions set out below for returning the Product, and AliveCor will take one of the following actions: (i) replace the Product with a product that is the same or equivalent to the Product you purchased: (ii) repair the Product; or (iii) refund to you the whole or part of the purchase price of the Product. A repaired or replacement Product or part assumes the remaining warranty of the original Product, or 30 days from the date of replacement or repair, whichever is longer. If AliveCor determines that a returned Product is irreparable, AliveCor will not return that Product to Owner and that Product becomes the property of AliveCor. AliveCor reserves the right to either replace any discontinued Product with a new product of comparable value and function, or to refund the purchase price paid for the Product by Owner.

HOW TO OBTAIN WARRANTY SERVICE

To obtain warranty service, please follow the instructions found at http://www.alivecor.com/warranty. If AliveCor determines that a Product is eligible for warranty service, AliveCor shall bear the costs associated with returning a Product for warranty service. AliveCor is not responsible for items damaged or lost in transit. A replacement Product provided under this Limited Warranty will only be dispatched to addresses within the United States, European Union and addresses within countries of the European Free Trade Association where the Product is available for sale to customers in such countries.

WHAT IS NOT COVERED?

This Limited Warranty will be void if the Product: (a) is used in any manner that is inconsistent with the intended purpose or design of the Product as described in AliveCor's published documentation for the Product, (b) is altered in any way, (c) the Product is used or maintained in any manner that is inconsistent with AliveCor's instructions or warnings included with the Product or (d) the Product is subjected to any other misuse, abuse, neglect, accident, or external forces. This Limited Warranty does not cover normal wear and tear (including, without limitation wear and tear of the display screen). AliveCor does not warrant that the operation of the Product will be uninterrupted or error-free. To the greatest extent permitted by applicable law, the warranties set forth in this Limited Warranty are exclusive and in lieu of all other warranties, express or implied.

LIMITATION OF REMEDIES

Resellers, agents, or employees of AliveCor are not authorized to make any modification, extension, or addition to this Limited Warranty. This Limited Warranty replaces all other AliveCor warranties and liabilities whether oral, written, (non-mandatory) statutory, contractual in tort or

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otherwise, including without limitation, and where permitted by applicable law, any implied conditions, warranties or other terms as to satisfactory quality or fitness for purpose. To the extent permitted by applicable law, AliveCor does not assume any liability for loss of or damage to or corruption of data, for any loss of profit, loss of use of Products or functionality, loss of business, loss of contracts, loss of revenues or loss of anticipated savings, increased costs or expenses or for any indirect loss or damage, consequential loss or damage or special loss or damage. To the extent permitted by applicable law, AliveCor's liability shall be limited to the purchase value of the Product.

OTHER IMPORTANT NOTICES

The rights provided to you under this Limited Warranty are provided in addition to all rights and remedies conveyed to you by consumer protection laws and do not affect your legal (statutory) rights under your applicable national law. This Limited Warranty is offered subject to AliveCor's Heart Monitor Terms and Conditions, which may change from time to time. You can find the latest version on our website at: http://www.alivecor.com/tos or by contacting us directly at support@alivecor.com. In the case of any inconsistencies between the Terms and Conditions and this Limited Warranty, this Limited Warranty will prevail. This Limited Warranty does not apply to any Apple iPhone or the cellular and/or other network or system on which the Product operates. Therefore, AliveCor will not accept any responsibility under this Limited Warranty for the operation, availability, coverage, services or range of the cellular or other network or system. Always completely follow safety, use, operation, and maintenance instructions for the Product or any other AliveCor product. Please remember to make back-up copies or keep written records of all important content and data stored in your Product, because content and data may be lost during repair or replacement of the Product. AliveCor, shall not under any circumstance be liable either expressly or impliedly, for any damages or losses of any kind whatsoever resulting from loss of, damage to, or corruption of, content or data during repair or replacement of the Product.

European Authorised Representative:

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

Manufactured for:

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

08LB04 Revision A | March 2013

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-510(K)STATUS@fda.hhs.gov or 301-796-8118

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AliveCor™

AliveCor™

Heart Monitor

ECG EVENT RECORDER

AliveCor.com
Compatible With iPhone® 5

iPhone not included.

AliveCor™

Heart Monitor

ECG EVENT RECORDER

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AliveCor™

AliveCor.com

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App Store is a service mark of Apple, Inc.

Contents: (1) Heart Monitor and (1) Quick Start Guide

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Questions? Contact FDA/CDRH/OCE/Section 510(k) STATUS@fda.hhs.gov or 301-796-8118

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Heart Check™

New to the consumer market: The HeartCheck™

PEN Handheld ECG

with Smart Monitoring ~ Powered by CardioComm Solutions, Inc.

Recommended by the FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH

*Unlocked view

Putting your heart health in your hands

Research has shown that regular ECG-based heart screening significantly reduces the risk of sudden cardiac death. Source: JAMA 2006 and Circulation 2012.

Using the HeartCheck™ PEN ECG device, you can now take heart readings the moment a symptom is felt. Whether at home, the gym, or at the office, the HeartCheck™ PEN is portable, easy to use, and takes accurate heart readings that can later be shared with a physician or HeartCheck™ ECG Coordinating Centre. Until now, monitoring this comprehensive would usually require a lengthy visit to a family physician or hospital.

With HeartCheck™ SMART Monitoring, you can enjoy the peace of mind of having your heart rhythm analyzed and interpreted by a physician, HeartCheck™ ECG Coordinating Centre, or both, at any time from anywhere in the world with an internet connection*

* The free GEMSTM Home software will need to be installed in order to upload your heart rhythm files containing your ECGs.

The first FDA-Cleared device that can be unlocked to allow consumers and patients to view and print their own ECGs.*

With the HeartCheck™ PEN device, it only takes 30 seconds to take a heart reading and the device can store up to 20 heart rhythms. Using a USB cable, simply connect the device to your PC and run the free GEMS™ Home software to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, can instantly view and analyze the results of your ECG and heart rhythm. This allows the physician or Coordinating Centre to identify any potential issues and provide the appropriate response.

for more information contact us today at

1 (877) 977.9425 or visit www.theheartcheck.com

how it works:

step 1 Using the HeartCheck™ PEN device, simply take heart readings the moment you feel any symptoms.

step 2 Using the USB cable provided, connect the device to your PC and run GEMS™ Home to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

step 3 Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, will view and analyze the results of your ECG and heart rhythms.

step 4 The HeartCheck™ ECG Coordinating Centre or physician will create an ECG report on your heart analysis identifying any potential issues.

The report will be made available on your PC through the GEMS™ Home application.

HeartCheck™ PEN Device

- ✓ *Cleared by the Food and Drug Administration (FDA)*
- ✓ *Easy to use*
- ✓ *Accurate heart readings in only 30 seconds*
- ✓ *Store up to 20 heart rhythms*
- ✓ ***Unlock the PEN to view and print your own ECGs****
- ✓ ***With SMART Monitoring, ECGs can be monitored remotely by a physician, clinic, or ECG coordinating centre****

* The HeartCheck PEN Handheld ECG can be unlocked to display your ECG waveform by CardioComm Solutions, Inc. under the direction of a physician.

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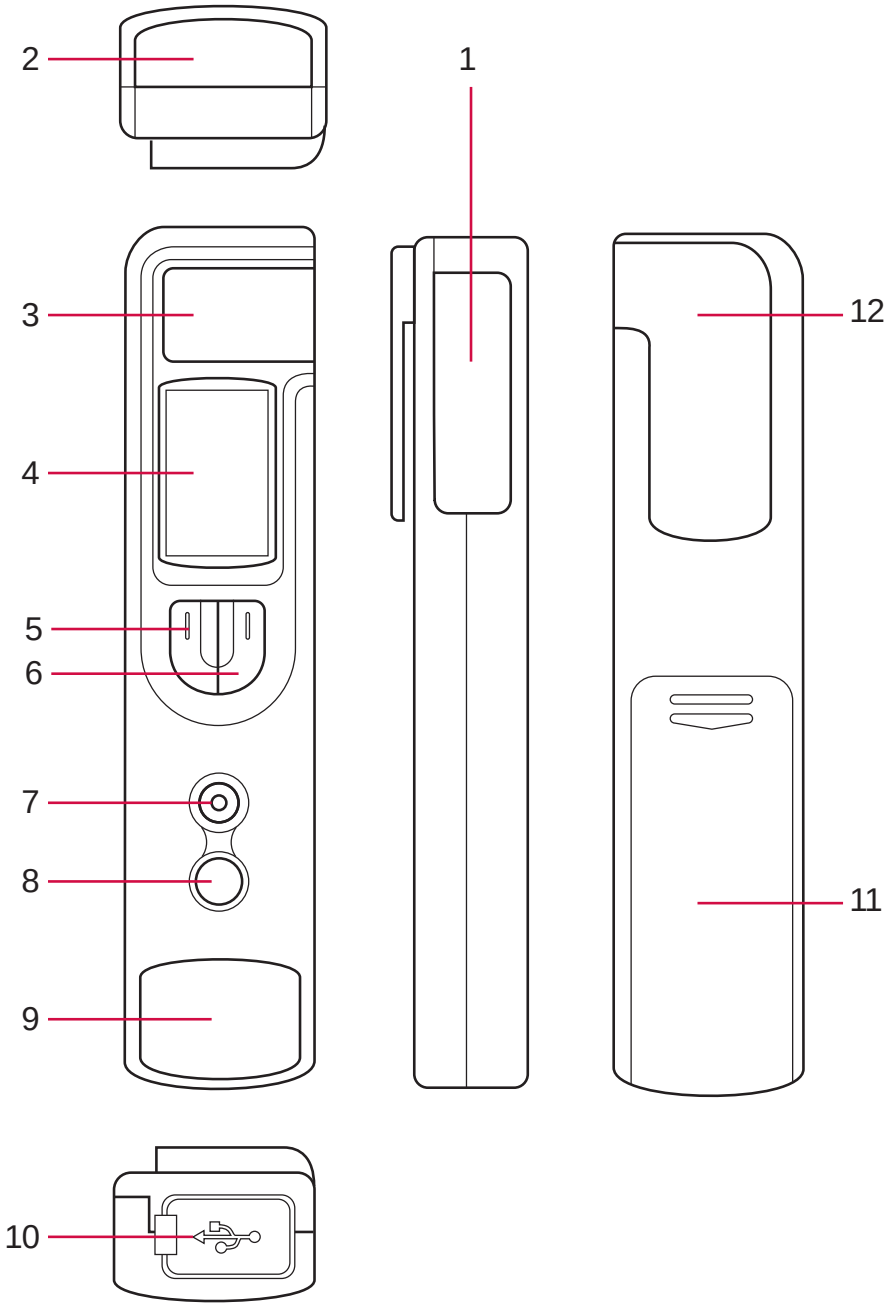
Heart Check™

The HeartCheck™ Pen Device

Specifications

Powered by CardioComm Solutions, Inc.



* The HeartCheck heart rhythm monitor can be unlocked by CardioComm Solutions, Inc under the direction of a physician. Visit www.theheartcheck.com for details.

1. Right index finger electrode
2. Left index finger electrode
3. Right thumb electrode
4. Display screen
5. Scroll right button
6. Scroll left button
7. Power / Select button: Use this button to power on the device and/or select a menu item from the display screen
8. Start button: Use this button to start taking a heart measurement
9. Left thumb electrode
10. USB Port: Plug USB cable into this port to connect device to PC
11. Battery cover
12. Clip

Mechanical Specfications

Lenght:	130mm
Width:	30mm
Height:	20mm
Weight:	110g (with batteries)

Technical Specfications

Lead Position:	Lead I - Hand lead only
Sampling Rate:	250Hz
Measuring Range:	30bpm - 240 bpm
Heart Rhythm Bandwidth:	1Hz - 40 Hz
Measuring Accuracy:	30 - 100bpm: ± 2bpm
	101 - 240bpm: ± 4bpm

Display

Display screen type:	OLED
Parameter:	Heart Rate
	* ECG option available when unlocked

Environmental Requirements

Operating temperature:	5°C - 40°C
Storage temperature:	-20°C - 55°C
Operating humidity:	≤80%, no condensation
Storage humidity:	≤90%, no condensation
Atmospheric pressure:	80kPa - 106kPa

Power Supply

Batteries:	2 AAA Alkaline batteries
Protection type:	Internally powered equipment
Degree of protection:	CF Type
Safety:	IEC 60601-1

Accessories

Standard Accessories:	2 x AAA Alkaline batteries
	1 x Instruction Manual
	1 x Quick Operation Guide
	1 x Warranty Card
	1 x USB cable
	Data Management Software

for more information contact us today at

1 (877) 977.9425

or visit www.theheartcheck.com

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the all new

Heart Check Pen 10

CardioComm Solution's new handheld Heart Check™ Pen gives you the benefit of quickly measuring your heart rhythm in just 30 seconds

- ✓ Very compact, portable and easy to operate
- ✓ Simply place your thumbs and index finger on the Heart Check™ Pen to see your heart rhythm
- ✓ 5 inches/130 mm in length and weighs only 3.8 oz/110 grams
- ✓ Saves 20 recordings of heart rate, data analysis and ECG
- ✓ Fast measurements in just 30 seconds
- ✓ Measure, record, and save or delete ECG waveform and Heart Rate
- ✓ Completely cable free
- ✓ Auto power-off
- ✓ Powered by two AAA batteries
- ✓ Transmit data to management software by USB cable

Heart Check

handheld ECG monitors

For more information contact:

CardioComm Solutions, Inc.

259 Yorkland Road, Suite 200
North York, Ontario M2J 0B5

Toll Free **1 (877) 977.9425**
Fax **1 (866) 576.4493**

email: **sales@cardiocommsolutions.com**

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

STERILIZATION AND SHELF LIFE

The *AliveCor Heart Monitor* is provided non-sterile but assembled and packaged in a clean environment to eliminate particulate contamination. AliveCor's Quality System and supplier management system ensure adherence to proper manufacturing conditions for the device. The *AliveCor Heart Monitor* has no sterilization requirements.

Officially, verification testing was performed at time-zero product with fresh batteries. Verification testing has been completed following standard environmental preconditioning and transit testing. This evaluation yielded passing results and showed the *AliveCor Heart Monitor* meets and exceeds all stated product requirements and that it conforms to applicable industry standards.

Additionally, battery testing and analysis was performed and proved that the device has a minimum operating time of 100 hours per the device specifications as defined in the Section 11 – Device Description. There are no critical device functions that deteriorate over time other than the battery life. The battery is a lithium coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries. AliveCor has retention samples that are planned for use for real-time shelf life testing.

Note: At this time AliveCor does not believe there is a reasonable shelf life limitation for the device. If a shelf life limitation is identified, AliveCor has unit level traceability that will allow us to retrieve expiring product. Subsequently, all further shipped product would be assigned an expiration date.

All results related to shelf life testing for the *AliveCor Heart Monitor* can be found in the *ECG for iPhone Human Test Protocol, Systems Integration* (02VEP2) and associated report (02VER2), on file at AliveCor.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

BIOCOMPATIBILITY ASSESSMENT

1. INTRODUCTION:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the device or the stainless-steel electrodes.

The biocompatibility assessment for the *AliveCor Heart Monitor* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the device for its utility purpose (as an iPhone case), and using the device for its medical purpose. All testing was performed by a certified laboratory, using ISO-10993 guidelines.

2. DEVICE MATERIALS TESTED:

Primarily two components of the device may contact skin: the plastic housing, and more significantly the stainless-steel electrodes. Currently all mechanical configurations of the *AliveCor Heart Monitor* are constructed differently than the predicate device; however, the primary patient-contact materials, are generally the same.

- The plastic housing components consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages attached). **(continuous contact)**

  Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products including a primary use for Smartphone cases.

- The electrodes are made from 304SS which is a medical grade stainless-steel. **(continuous contact)**

Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

Samples were constructed to include all materials from all parts of the device that may contact the patient, including incidental contact. The *AliveCor Heart Monitor* Biocompatibility Test Sample drawings and specifications for material composition used in these test samples can be found in Appendix B – Biocompatibility Reports.

Questions? Contact FDA/CDRH/OCE/Director CDRH-PRGSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

3. TEST METHODS:

To assess biocompatibility, the proposed patient-contact materials were subjected to the three standard tests for biocompatibility of medical devices for non-invasive long term wear (up to 30 days) on skin, as outlined in ISO 10993-1. These three tests were Cytotoxicity (MTT Method), Irritation (Animal intracutaneous reactivity test by means of polar extract), and Sensitization (GPMT), and were conducted by the Testing Center of Sanitation & Environment Technology Institute, Soochow University.

All three tests passed. See Appendix B – Biocompatibility Reports for the full test reports.

- The MTT Method Cytotoxicity test passed with a viability reduced to 81.7% minimum of all the samples where a passing viability is 70% or more. Under the conditions of this study, the test article did not show toxicity to L-929 cells.
- The Skin Irritation Test, conducted per ISO 10993-10:2010, passed with a Primary Irritation index of 0.0, where a score of 2 or greater is considered failing. The irritation response category for the test article was classified as slight.
- The Guinea pig maximization test (GPMT) Hypersensitivity, conducted per ISO 10993-10:2010, passed with the conclusion that no sensitization potential was observed.

AliveCor believes that the patient-contact materials proposed for use in the *AliveCor Heart Monitor* meet the requirements for biocompatibility and can therefore be safely used in the proposed application.

4. SCOPE:

All additional mechanical constructs of the *AliveCor Heart Monitor* intended to fit different form factors of various mobile computing platforms use the same materials tested in the reports listed above. According to FDA 510(k) memorandum #K97-1 (*Deciding when to Submit a 510(k) for a Change to an Existing Device*), any change to materials that requires retesting per ISO 10993-1 would require a new 510(k) and is not covered under the scope of this 510(k). AliveCor will not commercialize any mechanical construct without proper biocompatibility testing and clearance by FDA.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PRA-STATUS@fda.hhs.gov or 301-796-8118

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PRODUCT DATA SHEET

304/304L STAINLESS STEEL

UNS S30400/UNS S30403

AK Steel

AK Steel Type 304 is a variation of the basic 18-8 grade, Type 302, with a higher chromium and lower carbon content. Lower carbon minimizes chromium carbide precipitation due to welding and its susceptibility to intergranular corrosion. In many instances, it can be used in the "as-welded" condition, while Type 302 must be annealed in order to retain adequate corrosion resistance.

Type 304L is an extra low-carbon variation of Type 304 with a 0.03% maximum carbon content that eliminates carbide precipitation due to welding. As a result, this alloy can be used in the "as-welded" condition, even in severe corrosive conditions. It often eliminates the necessity of annealing weldments except for applications specifying stress relief. It has slightly lower mechanical properties than Type 304.

Typical uses include architectural mouldings and trim, kitchen equipment, welded components of chemical, textile, paper, pharmaceutical and chemical industry processing equipment.

AVAILABLE FORMS

AK Steel produces Type 304 Stainless Steel in thicknesses from 0.01" to 0.25" (0.025 to 6.35 mm) max. and widths up to 48" (1219 mm). For other thicknesses and widths, inquire.

COMPOSITION

	Type 304 %	Type 304L %
Carbon	0.08 max.	0.03 max.
Manganese	2.00 max.	2.00 max.
Phosphorus	0.045 max.	0.045 max.
Sulfur	0.030 max.	0.030 max.
Silicon	0.75 max.	0.75 max.
Chromium	18.00-20.00	18.0-20.0
Nickel	8.00-12.00	8.0-12.0
Nitrogen	0.10 max.	0.10 max.
Iron	Balance	Balance

SPECIFICATIONS

AK Steel Types 304 and 304L Stainless Steels are covered by the following specifications:

Type 304	Type 304L
AMS 5513	AMS 5511
ASTM A 240	ASTM A 240
ASTM A 666	ASTM A 666

MECHANICAL PROPERTIES

Typical Room Temperature Mechanical Properties

	UTS ksi (MPa)	0.2% YS ksi (MPa)	Elongation % in 2" (50.8 mm)	Hardness Rockwell
Type 304L	85 (586)	35 (241)	55	B80
Type 304	90 (621)	42 (290)	55	B82

Questions? Contact FDA/CDRH/OCE/Document Control Section at CDRH-REGSTATUS@fda.hhs.gov or 301-796-8118

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AK STEEL 304/304L STAINLESS STEEL DATA SHEET

PHYSICAL PROPERTIES

Density, 0.29 lbs/in^3
8.03 g/cm^3

Electrical Resistivity, microhm-in (microhm-cm)
68°F (20°C) – 28.4 (72)
1200°F (659°C) – 45.8 (116)

Specific Heat, BTU/lb/°F (kJ/kg•K)
32 - 212°F (0 - 100°C) – 0.12 (0.50)

Thermal Conductivity, BTU/hr/ft^2/ft/°F (W/m•K)
at 212°F (100°C) – 9.4 (16.2)
at 932°F (500°C) – 12.4 (21.4)

Mean Coefficient of Thermal Expansion, in/in/°F (μm/m•K)
32- 212°F (0 - 100°C) – 9.4 x 10^{-6} (16.9)
32- 600°F (0 - 315°C) – 9.6 x 10^{-6} (17.3)
32-1000°F (0 - 538°C) –10.2 x 10^{-6} (18.4)
32-1200°F (0 - 649°C) –10.4 x 10^{-6} (18.7)

Magnetic Permeability, H = 200 Oersteds, Annealed - 1.02 max.

Modulus of Elasticity, ksi (MPa)
28.0 x 10^3 (193 x 10^3) in tension
11.2 x 10^3 (78 x 10^3) in torsion

Melting Range, °F (°C) – 2550 - 2650 (1399 - 1454)

CORROSION RESISTANCE

These steels exhibit excellent resistance to a wide range of atmospheric, chemical, textile, petroleum and food industry exposures.

OXIDATION RESISTANCE

The maximum temperature to which Types 304 and 304L can be exposed continuously without appreciable scaling is about 1650°F (899°C). For intermittent exposure, the maximum exposure temperature is about 1500°F (816°C).

HEAT TREATMENTS

Type 304 is non-hardenable by heat treatment. Annealing: Heat to 1900 - 2050°F (1038 - 1121°C), then cool rapidly. Thin strip sections may be air cooled, but heavy sections should be water quenched to minimize exposure in the carbide precipitation region.

Stress Relief Annealing: Cold worked parts should be stress relieved at 750°F (399°C) for 1/2 to 2 hours.

FORMABILITY

Types 304 and 304L have very good drawability. Their combination of low yield strength and high elongation permits successful forming of complex shapes. However, these grades work harden rapidly. To relieve stresses produced in severe forming or spinning, parts should be full annealed or stress-relief annealed as soon as possible after forming.

WELDABILITY

The austenitic class of stainless steels is generally considered to be weldable by the common fusion and resistance techniques. Special consideration is required to avoid weld "hot cracking" by assuring formation of ferrite in the weld deposit. Types 304 and 304L are generally considered to be the most common alloys of this stainless class. When a weld filler is needed, AWS E/ER 308, 308L or 347 are most often specified. Types 304 and 304L Stainless Steels are well known in reference literature and more information can be obtained in this way.

METRIC CONVERSION

Data in this publication are presented in U.S. customary units. Approximate metric equivalents may be obtained by performing the following calculations:

Length (inches to millimeters) – Multiply by 25.4

Strength (ksi to megapascals or meganewtons per square meter) – Multiply by 6.8948

Temperature (Fahrenheit to Celsius) – (°Fahrenheit - 32) Multiply by 0.5556

Density (pounds per cubic inch to kilograms per cubic meter) – Multiply by 27,670

The information and data in this product data sheet are accurate to the best of our knowledge and belief, but are intended for general information only. Applications suggested for the materials are described only to help readers make their own evaluations and decisions, and are neither guarantees nor to be construed as express or implied warranties of suitability for these or other applications.

Data referring to mechanical properties and chemical analyses are the result of tests performed on specimens obtained from specific locations with prescribed sampling procedures; any warranty thereof is limited to the values obtained at such locations and by such procedures. There is no warranty with respect to values of the materials at other locations.

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AK Steel

Customer Service 800-331-5050

AK Steel Corporation
9227 Centre Pointe Drive
West Chester, OH 45069

www.aksteel.com

Stainless Steel The Value Option

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7100-0096 7/07

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PRODUCT DATA

AVALON® 75 ABX

Thermoplastic Polyurethane

INTRODUCTION

AVALON 75 ABX is a high performance polyester based thermoplastic polyurethane for injection moulding.

AVALON 75 ABX is part of the AVALON Perform Range and offers a specially designed, flexible material with improved slip resistance and rubber-like properties, particularly suitable for TPU/PU applications.

The features offered include :

- Improved processing
- Lower density
- Excellent surface definition
- Abrasion resistance
- Flex resistance
- Phthalate free TPU

Table 1: Typical Physical Properties [(1)]

Property	Method	Unit	Value
Density	DIN 53479	g/cm^3	1.14
Hardness, Shore A	DIN 53505	A	75
Hardness, Shore D	DIN 53505	D	-
Tensile Strength	DIN 53504	MPa	>25
Elongation at Break	DIN 53504	%	>750
Tear Strength (Angle)	DIN 53507	kN/m	>35
Abrasion Resistance	DIN 53516	mm^3	<50
Flex. Life	DIN 53522 T3	k.cycles	>100

(1) : Test plates conditioned 20 hours at 100°C before testing.

HEALTH AND SAFETY ADVICE

Before undertaking any trials with this product it is essential that all personnel are aware of the necessary precautions that must be taken. These are detailed in the relevant Safety Data Sheet that will be provided by Huntsman Polyurethanes.

POLYMER SELECTION

Before selecting this product it is necessary that the user ensures its performance will meet all operational and end use requirements. Having satisfied these requirements, should changes be contemplated in method of application, materials, service conditions or any other change that could affect the ultimate performance of the end product, then further tests and trials should be carried out.

For assistance with particular problems and applications, please contact the AVALON TPU Technical Service Department.

PACKAGING & STORAGE

AVALON TPU is supplied in 20 or 25 kg moisture guarded sacks, 40 per pallet and shrink wrapped.

AVALON Thermoplastic Polyurethanes may be stored for 24 months from the date of manufacture, sealed in the manufacturers original packaging.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PMASTATUS@fda.hhs.gov or 301-796-8118

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PRODUCT DATA

AVALON® 75 ABX

Thermoplastic Polyurethane

MATERIAL PREPARATION

AVALON TPU grades are supplied pre dried in moisture guarded sacks.

To ensure trouble free processing and high quality injection moulded parts, it is preferable to dry AVALON TPU grades.

The recommended drying conditions are 2hrs at 80-90°C in a desiccant dryer.

For specific advice on colouring AVALON TPU grades, the use of additives and regrind, please contact the AVALON TPU Technical Service group.

SCREW DESIGN

Injection moulding machines with general purpose polyethylene type 3 stage screws are most suitable for processing AVALON TPU grades.

High shear screws with mixing pins, nylon type screws or short compression stage screws are not recommended.

The most suitable configuration is listed in Table 2.

MOULD CONSIDERATIONS

To avoid shear degradation the runner system should be as generous as possible with a full round / circular or trapezoid section offering the best results.

Gating should be as large as possible with a relatively short length to ensure maximum transference of holding pressure.

Most designs are appropriate with the exception of submarine and pin gating.

Mould cavities with a sand blasted finish will improve demoulding.

However polished moulds give best transparency properties.

Standard venting techniques should be employed to eliminate air trapping and burn marks.

Table 2: Typical Processing Parameters	
Typical Screw Diameter	40 – 120 mm
L/D Ratio	20 – 25 :1
Compression ratio	2.0 – 3.0 :1
3 Stage Design	
Feed Zone	0.4L
Compression Zone	0.3L
Metering Zone	0.3L
Screw rotation speed	20 – 80 rpm
Injection pressure	20 – 100 Bar
Secondary or holding pressure	10 – 50 Bar
Back pressure	0.3 – 3 Bar
Injection speed	As slow as possible
Mould temperature	25 – 50°C
Temperature profile:	
Feed Zone	25 – 35°C
Rear Zone	160 – 180°C
Centre Zone	165 – 185°C
Front Zone	165 – 190°C
Nozzle Tip	160 – 185°C

Enquiries should be addressed to the nearest Huntsman Sales Office or to:
Huntsman (Europe) BVBA, Everslaan 45, B-3078 Everberg, Belgium.
Tel: +32 2 758 98 74 Fax: +32 2 758 90 18

The address of your nearest technical centre is:
Huntsman (Europe) BVBA, Everslaan 45, B-3078 Everberg, Belgium.
Tel: +32 2 758 98 74 Fax: +32 2 758 90 18

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AVALON is a registered trademark of Huntsman International LLC in one or more countries, but not all countries.

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Bayblend® T65 and T85

- **(PC+ABS) blends**
- **Non-reinforced**
- **General-purpose injection molding grades**

Characterization

Bayblend® T65 and T85 are non-reinforced, amorphous thermoplastic polymer blends based on polycarbonate (PC) and acrylonitrile butadiene styrene copolymer (ABS). They are noted for their ideal combination of toughness, rigidity and flowability.

The Vicat softening temperature (VST/B 120) of T65 is in the region of 120 °C and that of T85 in the region of 131 °C.

Delivery form

Bayblend® T65 and T85 are available worldwide and supplied in the form of granules, packed in 25-kg polyethylene sacks, big bags, octatainer with a polyethylene inliner or in bulk. The products are available in their natural color or in a wide range of opaque shades.

The production plants for Bayblend® have been certificated to DIN ISO by the appropriate quality organizations.
The certificates can be found in the internet at
http://www.bayermaterialscience.com
(Customer Services / Certificates / Quality).

Applications

The main applications for Bayblend® T65 and T85 are in automotive interiors for parts requiring a high heat resistance in conjunction with very good low-temperature toughness, dimensional stability and suitability for secondary finishing.

Typical applications include trim components, such as instrument panels, central consoles, column trims, door sills, emblems, glove compartment lids, instrument frames, interior mirror housings, loudspeaker covers, steering column trims, ventilation systems, exterior mirror housings, grilles, headlamp housings, rear light chassis, side protection moldings, spoilers, wheel covers.
Because of their outstanding property profiles, Bayblend® T65 and T85 are also used in the production of safety components such as airbag covers.

Further areas of application are to be found in

- Telecommunications:
  Mobile telephone housings.
- Electrical/electronics industries:
  Sockets, switches, covers.
- Household:
  Top sections of irons, hairdryers, coffee machines, shaver housings, time-switch housings.

Properties (see also table)

Thanks to their exceptionally well-balanced and beneficial property profiles, components made from Bayblend® T65 and T85 can be produced cost-effectively and to a very high quality.

Mechanical properties

T65 and T85 display a very high impact and notched impact strength over a broad range of temperatures. The toughness at low temperatures is outstanding. The material demonstrates ductile fracture behavior in the notched flexural impact test at temperatures down to minus 35 °C.

The property values from the tensile test increase slightly from T65 to T85 (see stress-strain curves in the Appendix).

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Thermal properties

Bayblend® grades T65 and T85 differ primarily in terms of their heat resistance. T65 covers the medium heat resistance range with a Vicat temperature of about 120 °C while T85 covers the upper end of the range at about 131 °C.

When parts are subject to a low level of mechanical loading, short-term exposure to temperatures of up to 110 °C in the case of T65 and 120 °C in the case of T85 will not lead to any essential dimensional changes. The maximum continuous service temperature depends on the molded part geometry, the type of loading and the requirements.

The melting range begins at approx. 200 °C, with thermal decomposition setting in at approx. 300 °C.

The coefficient of linear thermal expansion (ISO 11359-1,-2, 23 °C – 55 °C) is only influenced to a small extent by the melt flow direction and is in the range of about 0.8 to 0.85×10^{-4}/K for T65 and in the range of about 0.75 to 0.8×10^{-4}/K for T85.

Rheological properties

Bayblend® T65 displays better flowability than Bayblend® T85 (see viscosity curves in the Appendix).

The melt volume-flow rate (MVR) is identical for both products and is thus not suitable for assessing the flow behavior of Bayblend®.

The favorable combination of good flowability and excellent mechanical properties means that Bayblend® grades T65 and T85 are also frequently used for the thin-wall technique.

Burning behaviour

Bayblend® T65 and T85 have a UL 94 HB recognition (all colors) at a wall thickness of 0.85 mm.

In addition, at a wall thickness of 1.0 mm or more, both products satisfy the requirements of FMVSS 302 with regard to the permissible burning rate (max. 101.6 mm/min).

Chemical resistance

At room temperature, Bayblend® molded parts are resistant to mineral acids, a large number of organic acids, and aqueous saline solutions. Bayblend® parts are not resistant to bases, aromatics, ketones, esters, chlorinated hydrocarbons and a number of greases and oils.

Their resistance to chemicals is determined by among other things the temperature, loading duration and the internal and external stress status of the molded part. In case of doubt, compatibility should be checked in a stress cracking test.

Weatherability

As with most thermoplastics, weathering leads to color changes and to an impairment of the product`s mechanical properties. This reduction in properties, however, is not so pronounced, and the release specifications of the automotive industry, for example, can still be met. For more demanding requirements, a UV-stabilized variant with the designation BBS910 is available. Painting is recommended for parts that are required to satisfy highly stringent demands.

Emissions characteristics

Bayblend® T65 and T85 have low emission values, which means that they generally satisfy the emissions requirements of the European automotive industry for components used in vehicle interiors. Since the automotive industry requires the emissions rating to be determined on the component rather than the material, it is important to remember that the emission characteristics are substantially influenced by the injection molding process and the design of the part and the mold (especially the gating system). In order to obtain the best possible emission values it is advisable to follow our design and processing recommendations.

Processing

Processing is generally performed by injection molding. All modern injection molding machines may be used.

Bayblend® T65 and T85 can basically be extruded. In the case of extrusion applications, version BBS904 of the products should be used where more stringent requirements are imposed on surface finish.

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Pre-treatment/drying

It is essential for Bayblend® T65 and T85 to be dried prior to processing. For injection molding, there must be less than 0.02 % residual moisture in the granules. Moisture in the plastic melt can lead to surface defects in the form of streaks and also to hydrolytic degradation (reduction in mechanical properties). Drying is best conducted in dry-air dryers.

Drying conditions: 2-4 h at 110 °C (dry-air dryer)

Excessively long drying times should be avoided, since color changes cannot otherwise be ruled out.

Melt temperature[1)] injection molding

The optimum processing temperature must be established as a function of the molded part and should be between 250 and 280 °C. It is advisable to check the actual melt temperature on the ejected press cake using a thermometer. Overheating, and also excessively long residence times for the melt in the barrel must be avoided, since this can lead to material damage, i.e. to a reduction in toughness, excessively high emission values or to surface defects in the form of streaks on the injection molded part.

Thermal decomposition of the material commences at around 300 °C.

1) see also disclaimer at the end of this Technical Information

Mold temperature control

The mold should be kept at a uniform temperature in the recommended range of between 70 and 100 °C. While lower temperatures result in shorter cycle times, they also lead to poorer molded part quality. The degree of orientation, inherent stress and post-shrinkage increases, while the surface finish deteriorates.

Screw speed

The screw speed should be controlled in such a way that the circumferential velocity of the screw is between 0.1 and 0.3 m/s.

Shrinkage

Molding shrinkage is virtually identical in all axes, in between a range of about 0.55 to 0.75 %. In addition to the geometry of the part, shrinkage is primarily dependent on the level of holding pressure and the time for which this acts, as well as on the temperature of the melt and the mold and on the cooling conditions prevailing in the mold.

Postshrinkage depends essentially on the storage temperature and time and is generally less than 0.1 %.

Further literature

Information on processing can also be found in the following technical publications:

"Processing Data for the Injection Molder",
"The Injection Molding of High-Quality Molded Parts".

Finishing

- Forming:
  hot-forming processes, such as thermoforming, bending, stamping.
- Machining:
  sawing, drilling, milling, filing, punching. The use of carbide-tipped tools is recommended.
- Joining:
  Screw connections, gluing, welding.
- Post-treatment:
  Painting, printing, foam-coating, metallization (high vacuum vapor metallization).

Safety Notice

The information given in Safety Data Sheet No. 112000008466 (for T65) and 112000008467 (for T85) must be observed.
The safety data sheets are available to registered customers on the internet at http://www.bayerone.bayer.com or can be sent out by request.
They contain details of labeling, handling and storage, as well as information on composition, product safety and toxicological/ecological profiles.

Recycling

Single-sort moldings made of Bayblend® T65 and T85 which do not contain any harmful substances can be mechanically recycled after use. Molded parts containing harmful substances can be chemically or thermally recycled.

Parts should be marked in accordance with DIN ISO 11469. The identification mark for parts made of Bayblend® T65 and T85 is as follows:

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>PC+ABS<

Further details can be found in our Technical Information brochure TI PCS1164en (Identification of Thermoplastics Parts for Recycling).

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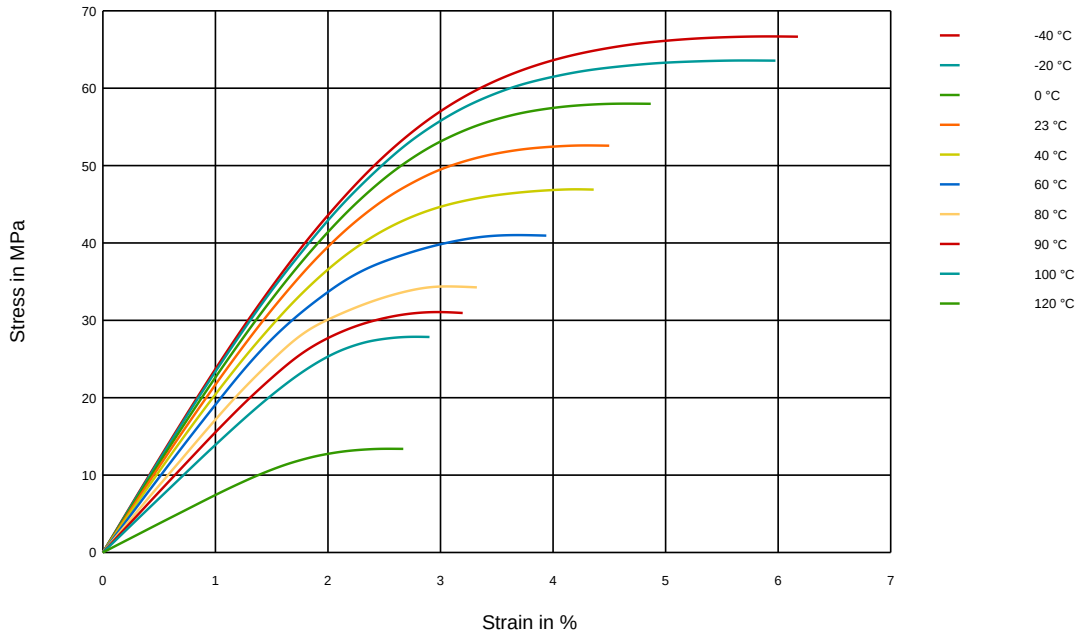

Figure 1: Isothermal stress-strain curves up to yield stress from the short-time tensile test to ISO 527-1,-2 of Bayblend® T65.

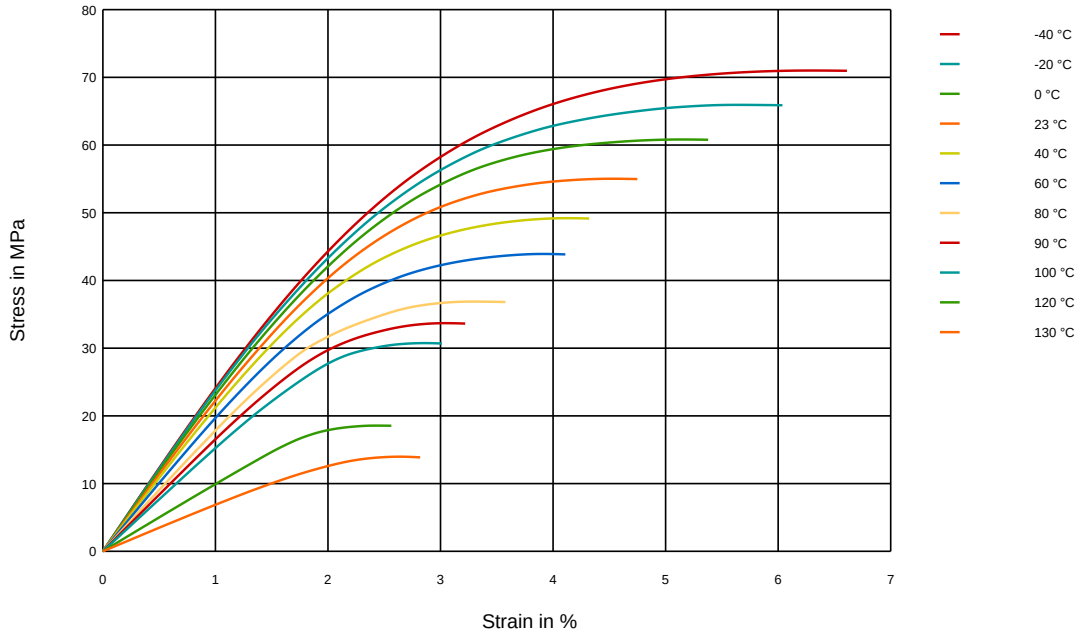

Figure 2: Isothermal stress-strain curves up to yield stress from the short-time tensile test to ISO 527-1,-2 of Bayblend® T85.

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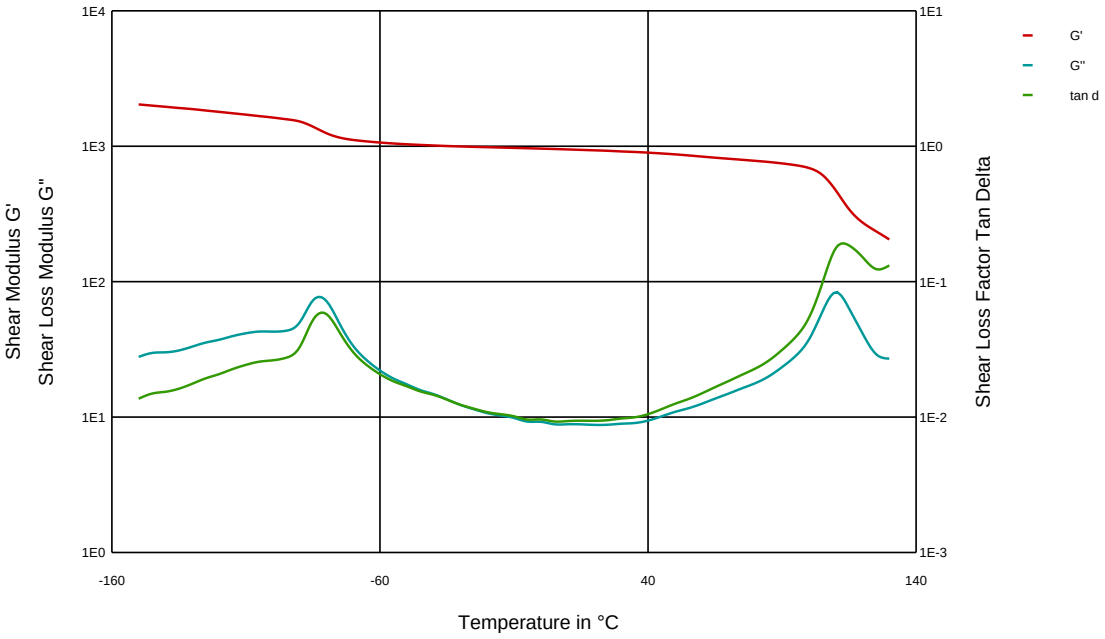

Figure 3: Shear modulus as a function of temperature to ISO 6721-7 of Bayblend® T65.

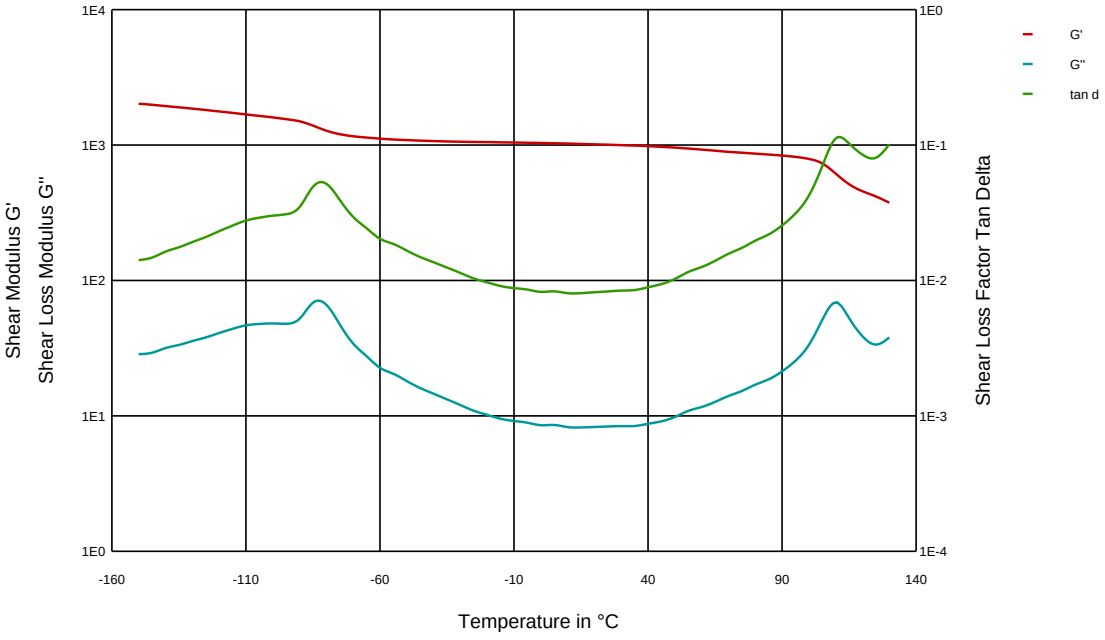

Figure 4: Shear modulus as a function of temperature to ISO 6721-7 of Bayblend® T85.

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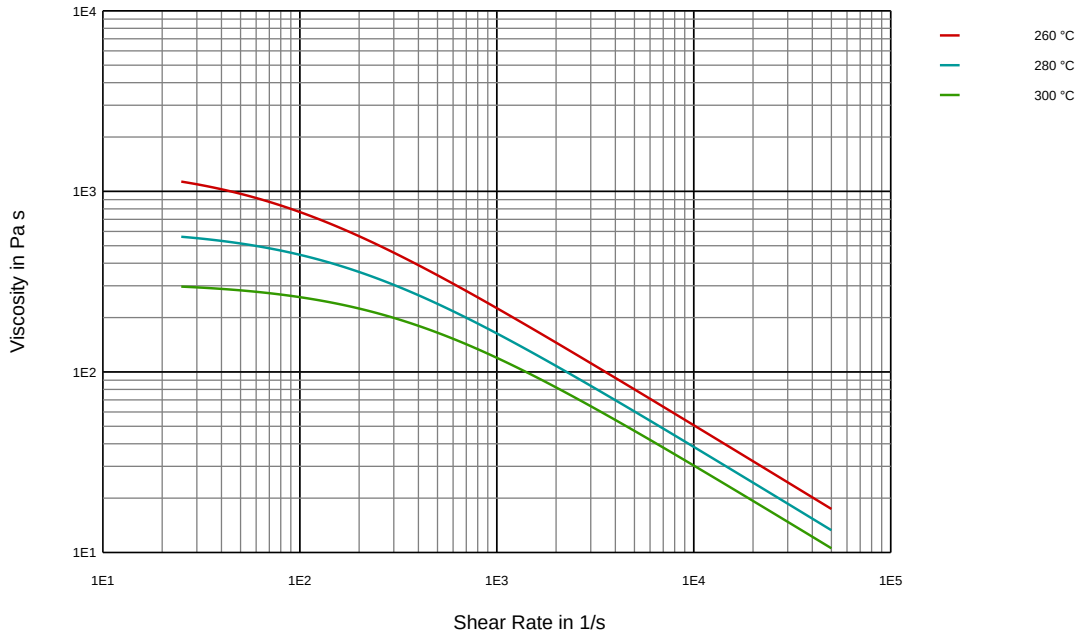

Figure 5: Melt viscosity as a function of shear rate b. o. ISO 11443-A of Bayblend® T65.

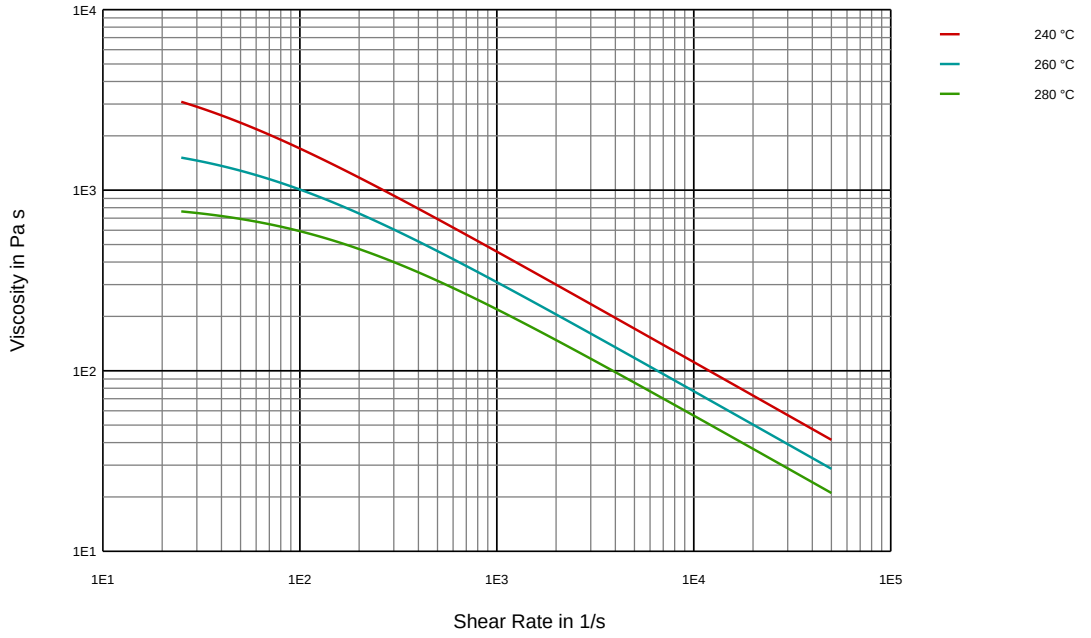

Figure 6: Melt viscosity as a function of shear rate b. o. ISO 11443-A of Bayblend® T85.

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Typical Values

	Property	Test Condition	Unit	Standard	Bayblend® T65	Bayblend® T85
Rheological properties						
C	Melt volume-flow rate	260 °C; 5 kg	cm³/10 min	ISO 1133	12	12
	Molding shrinkage, parallel	150x105x3 mm; 260 °C / MT 80 °C	%	b.o. ISO 2577	0.55 - 0.75	0.55 - 0.75
	Molding shrinkage, normal	150x105x3 mm; 260 °C / MT 80 °C	%	b.o. ISO 2577	0.55 - 0.75	0.55 - 0.75
	Melt viscosity	1000 s^-1^; 260 °C	Pa·s	b.o. ISO 11443-A	230	290
Mechanical properties (23 °C/50 % r. h.)						
C	Tensile modulus	1 mm/min	MPa	ISO 527-1,-2	2200	2300
C	Yield stress	50 mm/min	MPa	ISO 527-1,-2	52	55
C	Yield strain	50 mm/min	%	ISO 527-1,-2	4.2	4.7
	Stress at break	50 mm/min	MPa	ISO 527-1,-2	45	48
	Strain at break	50 mm/min	%	b.o. ISO 527-1,-2	> 50	> 50
	Izod impact strength	23 °C	kJ/m²	ISO 180-U	N	N
	Izod impact strength	-30 °C	kJ/m²	ISO 180-U	N	N
	Izod notched impact strength	23 °C	kJ/m²	ISO 180-A	45	48
	Izod notched impact strength	-30 °C	kJ/m²	ISO 180-A	41	38
Thermal properties						
C	Temperature of deflection under load	1.80 MPa	°C	ISO 75-1,-2	100	109
C	Temperature of deflection under load	0.45 MPa	°C	ISO 75-1,-2	122	127
C	Vicat softening temperature	50 N; 50 °C/h	°C	ISO 306	118	129
	Vicat softening temperature	50 N; 120 °C/h	°C	ISO 306	120	131
C	Coefficient of linear thermal expansion, parallel	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.8	0.75
C	Coefficient of linear thermal expansion, transverse	23 to 55 °C	10^{-4}/K	ISO 11359-1,-2	0.85	0.8
C	Burning behavior UL 94	0.85 mm	Class	UL 94	HB	HB
Electrical properties (23 °C/50 % r. h.)						
C	Relative permittivity	100 Hz	-	IEC 60250	3.1	3.1
C	Relative permittivity	1 MHz	-	IEC 60250	3.0	3.0
C	Dissipation factor	100 Hz	10^{-4}	IEC 60250	30	20
C	Dissipation factor	1 MHz	10^{-4}	IEC 60250	85	85
C	Volume resistivity		Ohm·m	IEC 60093	1E14	1E14
C	Surface resistivity		Ohm	IEC 60093	1E16	1E16
C	Electrical strength	1 mm	kV/mm	IEC 60243-1	35	35
C	Comparative tracking index CTI	Solution A	Rating	IEC 60112	250	225
Other properties (23 °C)						
C	Water absorption (saturation value)	Water at 23 °C	%	ISO 62	0.7	0.7
C	Water absorption (equilibrium value)	23 °C; 50 % r. h.	%	ISO 62	0.2	0.2
C	Density		kg/m³	ISO 1183-1	1130	1150
Processing conditions for test specimens						
C	Injection molding-Melt temperature		°C	ISO 294	260	260
C	Injection molding-Mold temperature		°C	ISO 294	80	80
C	Injection molding-Injection velocity		mm/s	ISO 294	240	240

C These property characteristics are taken from the CAMPUS plastics data bank and are based on the international catalogue of basic data for plastics according to ISO 10350.

Impact properties: N = non-break, P = partial break, C = complete break

colored fields = UL recognition

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Unless specified to the contrary, the values given have been established on standardized test specimens at room temperature. The figures should be regarded as guide values only and not as binding minimum values. Please note that, under certain conditions, the properties can be affected to a considerable extent by the design of the mold/die, the processing conditions and coloring.

Under the recommended processing conditions small quantities of decomposition product may be given off during processing.To preclude any risk to the health and well-being of the machine operatives, tolerance limits for the work environment must be ensured by the provision of efficient exhaust ventilation and fresh air at the workplace in accordance with the Safety Data Sheet. In order to prevent the partial decomposition of the polymer and the generation of volatile decomposition products, the prescribed processing temperatures should not be substantially exceeded.

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AliveCor

510(k) PREMARKET NOTIFICATION

SOFTWARE

1. SOFTWARE – LEVEL OF CONCERN

Using methods described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued by FDA on: May 11, 2005, AliveCor, Inc. (AliveCor) has made the determination from the decision tree and tables that the Level of Concern is Moderate because malfunction or latent design flaws could lead to erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury of the patient. See document 01DES1 - ECG for iPhone Design Description, Software, attached to this section.

The Moderate Level of Concern determination is consistent with our understanding of most if not all other ambulatory ECG Event Recorders on the market.

2. SOFTWARE REQUIREMENTS SPECIFICATION

Specific software requirements have been defined for the *AliveCor Heart Monitor*. Requirements are documented in 02REQ1 - ECG for iPhone Human Design Input-Output Matrix, on-file at AliveCor.

Note that "ECG for iPhone" is an internal project name while the "*AliveCor Heart Monitor*" is the proprietary product name. For all intents and purposes, these terms are equivalent.

3. SOFTWARE DESCRIPTION

An extensive description of the software written for the *AliveECG* App and applicable portions of the AliveCor Web Application (WebApp) can be found in the Software Design Description. See document 01DES1 - ECG for iPhone Design Description, Software, attached to this section.

Note that the majority of functionality of the WebApp is defined as a Medical Device Data System (MDDS) since it simply transfers and stores data on AliveCor servers. MDDS functionality is not described fully in the Software Design Description nor covered in this section since it is Class I medical device. The only elements of the WebApp covered here are those related to the *AliveCor Heart Monitor* as a system, e.g. the ability to modify metadata associated with an ECG recording just as the user can do on the AliveECG mobile application.

The description includes an architecture design chart, identifies key modules with description of functionality, security design, user interface, other design features and a discussion of the software development environment, and implementation/deployment methods. Although not required for Moderate Level concern software, AliveCor chose to provide this as it is meets many of the content requirements for this section.

4. SOFTWARE HAZARD ANALYSIS

Software Hazard Analysis is covered as part of the overall risk assessment. See Appendix A of this submission for the ECG for iPhone Risk Assessment and Hazard Analysis.

5. DESIGN VERIFICATION AND VALIDATION

The ECG for iPhone Design and Development Plan outlines and provides traceability for the necessary design verification and validation activities. These activities include evaluation of the

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device for its intended uses and validation of the end-to-end, manufacturing-to-patient flow. These protocols include validating elements of the software that cannot be verified. This process is part of Design Control and reviewed at scheduled Design Review Meetings. See Section 21 for conformance to Design Controls.

6. SOFTWARE VERIFICATION AND VALIDATION

In addition to the general verification activities for User Needs and System Level Requirements, specific protocols are in place for verifying elements of the software that can be demonstrated by test or inspection, on file at AliveCor and listed in Section 21.

Custom software is validated during design validation (system level evaluation) – refer to 02VAP1 - ECG for iPhone Human Validation Protocol and 02VAR1 - ECG for iPhone Human Validation Report noted in Section 21. Off-the-shelf software is validated independently of the design validation. Each software package/module used in the device, used during design verification, or used as a development tool have been validated according to AliveCor's Quality Management System requirements for Software Validation. Reports are on file at AliveCor.

7. TRACEABILITY ANALYSIS

Each software requirement in 02REQ1 - ECG for iPhone Human Design Input-Output Matrix correlates to a verification method and result listed within that document. See Section 21 for a complete list of related Design Control documents.

8. CHANGE CONTROL AND CONFIGURATION MANAGEMENT

AliveCor Inc. has established procedures for Design Control including software design and development. The Design Control Procedures follow a phased approach to development. The Software Design and Development procedure also defines the practices in place following commercialization under maintenance activities.

All design documents are considered controlled documents and thereby undergo review and approval prior to release. In the same way, software code is controlled and maintained in a code repository. Any changes made to the code during maintenance are evaluated and a test plan appropriate for the change is defined. Any software bugs or anomalies are logged and evaluate to determine the level of risk posed by the bug. Software releases are approved through technical review, and revision history is tracked and documented by AliveCor's Software Deployment procedures. As appropriate, risk assessment, hazard analysis, design requirements, verification plans and other necessary design control documentation will be revised with each software release.

Software releases are typically deployed with release notes describing necessary changes to the development environment that may necessitate revalidation of software. Regulatory and Quality sign-off on all official software releases. AliveCor has no control over iPhone Operation System (iOS) releases implemented by Apple for the iPhone, nor do we have much control over our users upgrading their iOS, but we believe we have a comprehensive test protocol to maintain seamless functionality of our software (02VEP1 - ECG for iPhone Human Verification Protocol, iOS Application in Section 21).

Since initial product release, we have responded to three iOS upgrades then justified and documented any changes to the software by means of a letter-to-file (LTF002, LTF003). AliveCor

Questions? Contact FDA/CDRH/OCE/Document Control Room at STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

believes that we have adequate response time to mitigate the risk of a user operating the device on unverified operating system. The severity of the risk does not necessitate mitigation but we are developing internal procedures to ensure prompt response to operating system upgrades.

Additionally, this period of time after initial product release allowed us to strengthen our verification protocol with product expansion in-mind. We now believe that our general protocol can easily be adapted to additional mobile computing platforms. The iPhone 5 is the first additional mobile computing platform to be added to the protocol along with other design control documents.

9. SUMMARY OF VERIFICATION RESULTS

The *AliveECG* App has been verified according to the verification plans contained in 02REQ1 - ECG for iPhone Human Design Input-Output Matrix. For a detailed description of verification results, refer to ECG for iPhone Human Verification Report, Systems Integration (02VER2), on file at AliveCor. All tests passed with zero deviations and the specifications have been fully verified. AliveCor believes the test methodology/protocol is strong enough to prove the safety and efficacy of the system.

10. UNRESOLVED ANOMALIES

There are zero open defects for the currently supported mobile computing platforms.

Upon addition of other compatible mobile computing platforms and their associated software operating systems into the *AliveCor Heart Monitor* device family, we expect to identify a multitude of bugs, defects or minor features that are necessary to accommodate the user experience or essential functionality. These cases are entered and tracked within AliveCor's bug tracking system and changes are reviewed and approved through AliveCor's change control system.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PAGESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

11. *ALIVEECG* APP REVISION HISTORY

The previous 510(k) (K122356) noted applicable *AliveECG* App revisions prior to production release.

The information below describes the production revision history for the *AliveECG* App software. These software releases have been subject to the change control processes described above.

Version: **1.1.0 (Build 8)**
Date: 18-Mar-2013
Location: US and UK App Stores
Web upload: app.alivecor.com
Requirements: Requires iOS5.0 or later
Changes:

- Support for EU server
- Allow user to identify as a non-professional
- Patient lookup and select for professional users
- New consumer profile and ECG fields (gender, weight, height, etc.)
- Many UI tweaks and changese

Version: **1.0.2 (Build 1)**
Date: 15-Jan-2013
Location: US App Store
Web upload: app.alivecor.com
Requirements: Requires iOS5.0 or later
Changes:

- Added Offline mode, not requiring user to log in to use app

Version: **1.0.1 (Build 1)**
Date: 3-Jan-2013
Location: US App Store
Web upload: app.alivecor.com
Requirements: Requires iOS5.0 or later
Changes:

- Changed Terms and Conditions

Version: **1.0.0 (Build 6)**
Date: 10-Dec-2012
Location: US App Store
Web upload: app.alivecor.com
Requirements: Requires iOS5.0 or later
Changes:

- Added full 2-way syncing
- Changed startup screens for new flow
- Added forgot password functionality
- Require user to be logged in to an account
- Added “How It Works” screens
- Added privacy notice to settings

Questions? Contact FDA/CDRH/OCE/Device CDRH-PAGESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

12. ALIVECOR WEBSITE (WEBAPP) REVISION HISTORY

The information below describes the engineering revision history for the AliveCor WebApp software. These software releases have been subject to change control processes described above. The below list includes all website releases. Only releases affecting MDDS or WebApp (functionality related to the medical device system according to the appropriate input-output matrix) have verification plans and reports assigned in the Quality System.

Release: v1.1.2.0
Date: 03/27/2013
Site: app.alivecor.com, eu.alivecor.com

- Refactored recording spec.
- Refactored demographic_profiles spec.
- Updated test gems.
- Refactored api users controller spec.
- WEB-186: Fix incorrect gender sync
- Refactored group controller spec.
- Refactored professional profile spec.
- Added unit tests for male. Some refactoring.

Release: v1.1.1.1
Date: 03/18/2013
Site: app.alivecor.com, eu.alivecor.com

- Updated simplecov gem.
- Fixed broken test.
- Change stats to reflect users with uploads

Release: v1.1.1.0
Date: unreleased
Site: app.alivecor.com

- WEB-176: Restructure realm settings
- merge
- add styles for realm redirect page
- WEB-177: Change medications to a text field
- WEB-175: Add multi-region password reset
- WEB-175: Add multi-region forgot password
- WEB-175: Add login unit tests
- WEB-175: Add multi-region redirect on login

Release: v1.1.0.0
Date: Unreleased
Site: app.alivecor.com

- Add S3 host to paperclip config
- Add realm configuration for staging
- Change error message for email used on other realm

Questions? Contact FDA/CDRH/OCE/Device CDRH-PMASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Remove trailing whitespace
- WEB-112: Add profile_type to user login
- WEB-175: Fix realm connector
- WEB-175: Multi realm configuration
- WEB-171 Fix consumer demographic updating
- WEB-174: Add units metric to professional profile
- Updating phantomjs gem.
- Added ALL_DATA scenario to test deletion.
- WEB-171, WEB-172: Add demographic fields
- Add paperclip secret for dev to fix cucumber tests
- WEB-173: 500 is returned when querying for app version without passing any arguments
- Added tests for ALL_DATA and REPORT user permissions.
- WEB-140: Add version check API
- Updating site_prism gem declaration in Gemfile.
- Reverting capybara, poltergeist and site_prism. Causing error in Jenkins.
- Change config for better multi environment support
- Updating capybara, phantomjs, poltergeist and site_prism.

Release: v1.0.1.6
Date: 02/06/2013
Site: app.alivecor.com

- Add new group for development and staging
- Remove jQuery arg in self executing function
- Move setTimeout to the "complete" callback.
- Ignore public/spree directory
- Update gen data to run in staging
- Fix dob in test data generation script

Release: v1.0.1.5
Date: 01/30/2013
Site: app.alivecor.com

- precompile stats.css
- add styles for large stats
- WEB-144: Add web stats page
- WEB-141: Fix view PDF button in IE8

Release: v1.0.1.4
Date: 01/24/2013
Site: app.alivecor.com

- Updating selenium-webdriver gem.
- WEB-138: Fix off by 1 and commit libs
- WEB-138: Add tools to for dev db population
- WEB-137: Add more data to weekly stats email
- WEB-136: Limit stats to web views only
- WEB-130: Status dialog appears before redirect

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PAGESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: v1.0.1.3
Date: 01/15/2013
Site: app.alivecor.com

- Setup dev environment to use mailcatcher
- Add rake task for weekly stats email
- Add weekly stats email
- WEB-134: Don't display delete ECGs in all
- Updated testrail id for recordings test.

Release: v1.0.1.2
Date: 01/11/2013
Site: app.alivecor.com

- WEB-132: Update rails to latest version
- WEB-131: Skip pdf creation on upload for long ecgs
- WEB-129: Change pagination theme to bootstrap
- WEB-128: Sort all recordings view by date
- WEB-127: Admin view and delete of all data users
- WEB-127: Allow all data user access to all ecgs
- WEB-127 Rename superuser to support_user
- WEB-127: Make support user permission more generic
- Updated phantomjs gem with specific ref.
- Downgrade aws and paperclip gems.
- Added pdf test for medical professional.
- Added testrail id to recordings test.
- Added pdf test for non medical professional.
- Added test for pdf footer.
- Added rake task to return emails of active users.
- Added recordings test for sort order.
- Updating poltergeist and phantomjs.
- Add reset password job

Release: v1.0.1.1
Date: 12/12/2012
Site: app.alivecor.com

- Upgrade new relic
- Register .atc mime type
- Add ability to download .atc file
- Added tests for WEB-98.
- WEB-98: Fix Invalid email error message does not appear during signup
- WEB-17: Adjust sizing on pdf header to match phone
- WEB-17: Don't wrap just truncate values
- Added unit tests for users api spec.
- Removed redundant test in users_controller_spec.
- Upgrade rails version to 3.2.9
- IOS-56: Replace server value when sync times match

Questions? Contact FDA/CDRH/OCE/Device CDRH-PMASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Removed redundant test in users_controller_spec.
- WEB-17: Fix truncation in PDF Header
- Add shop development environment config files
- Add verify environment config file
- Update start services instructions
- Add config for verify site
- Add config for verify environment
- WEB-105: Fix back button from PDF under IE
- Alter encrypted columns to text fields
- Change FDA and copyright notice
- Change redirect url to work with shop
- WEB-111 Correctly display duration and patient age
- WEB-109: Validate the length of attribute values
- WEB-104: Add name and institution to create API
- WEB-102: Add public id to account create
- WEB-101 Add API for forgot password
- Added recordings test for upload.
- WEB-100: Add user public id to API

Release: r20121126
Date: 11/26/2012
Site: app.alivecor.com

- Fixed broken recordings tests.
- Add error handling on pdf load
- Add foreman
- Remove newrelic config
- Set newrelic monitor true
- Move newrelic off heroku
- Fixed recordings test.
- Added recording_pdf factory instance. Fixed test for view action in audit logs.
- WEB-91 - Remove hover to view pdf button
- WEB-4: Change PDF to generate in offline process
- Adding audit log test for update action.
- Removed whitespace.
- Adding testrail ids to automated tests.
- Adding railroady rake tasks.
- New cucumber formatter that integrates with testrail api.
- Revert "Updating poltergeist gem." Premature.
- Updating poltergeist gem.
- Adding railroady to Gemfile.
- Refactored login tests. Added testcase id from testrail to scenario name.
- Adding faraday to Gemfile. Used for communicating with the testrail api.
- Updated scenario name for signup test.
- Change repo name from alivecorweb
- Text update in rake task.

Questions? Contact FDA/CDRH/OCE/Desk Officer CDRH-PAGESTATUS@fda.hhs.gov or 301-796-8118

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Release: r20121107
Date: 11/07/2012
Site: app.alivecor.com

- Added new rake task to calculate stats.
- Check for presence of values on PDF header.
- Added tests for view and create action in audit logs.
- Added patient name to recordings factory. Added function to find table row based on patient name in recordings page.
- Allow enter key to submit a log search
- Fix return value for an invalid public id
- Display user in audit log even on api
- Removed trailing whitespace
- Add internal tool page for viewing audit log
- Add auditing and logging

Release: r20121031
Date: 10/31/2012
Site: app.alivecor.com

- Add newrelic to staging
- Some minor changes to groups automation code.
- Removing youtube link from footer.
- Added automated test for group membership.

Release: r20121024
Date: 10/24/2012
Site: app.alivecor.com

- Fix typo in rake task
- Fixed delete groups element locator.
- Add tools for administrators to manage groups
- Fix server error when using and invalid group id
- Add public_id to users
- Added another group deletion verification.
- Added automated tests for admin groups page.
- Make support tool for creating groups
- Added tags for smoke.

Release: r20121017
Date: 10/17/2012
Site: app.alivecor.com

- Rename group permissions table to participants
- Use an authorization library for recording access
- Remove unused spec files
- Correct description of unit test
- Fix bug with syncing new user profiles.
- Fix raw ecg dowload when files are on S3
- Remove username and fix full name for users

Questions? Contact FDA/CDRH/OCE/Desk Officer at STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Add user information to sync.
- Add consumer and professional profile tables

Release: r20121010
Date: 10/10/2012
Site: app.alivecor.com

- Duration on PDF should display mins and seconds
- Minor update to user steps.

Release: r20121003
Date: 10/03/2012
Site: app.alivecor.com

- Clean up and rearrange unit tests
- Updated simplecov config.
- Updated code coverage configuration. Removed simplecov-rcov gem.
- Fix PDF generation with a nil patient dob
- Fix error when viewing PDF with nil DOB
- Remove unit test that called out to MailChimp
- Fix error that occurs when a patient DOB is empty
- Move raw_ecg files in dev to persist on VM reboot
- Add tests for rendering deleted PDFs
- Prevent user from viewing deleted recording as PDF
- Remove unused environment variable
- Fix invalid byte sequence and UTF8 string in tests
- Updated simplecov to support rcov output format.
- Removed user_sessions factory.
- Added cucumber test for deleted ecg.

Release: r20120926
Date: 09/26/2012
Site: app.alivecor.com

- Hide deleted recordings on View Recordings page
- Add ability to mark recordings as deleted
- Remove require junit.rb from spec_helper.
- Added junit output formatter for rspec.
- Updated cucumber ci profile to exclude vet specific tests.
- Change format of date fields for sync
- Fix sync request not returning any recordings
- Added recordings test.
- Add ability get fetch raw ecgs via api
- Fix wrong number of recordings returned on sync
- Add coverage directory to .gitignore
- Add ability to get updated recordings
- Added simplecov to Gemfile.
- Added more tests for password reset.

Questions? Contact FDA/CDRH/OCE/Section 510(k) STATUS@fda.hhs.gov or 301-796-8118

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Release: r20120919
Date: 09/19/2012
Site: app.alivecor.com

- Allow updating of metadata by phone
- Add sync fields to database

Release: r20120912
Date: 09/12/2012
Site: app.alivecor.com

- Change 200 to 201 to support the older app
- Add email address to fix dups task
- Add script to cleanup duplicate recordings
- Broke test in last commit. Fixed.
- Cleaned up some code.
- Added tests for superuser
- Allow updates to existing ECG recordings
- Added tests for admin page.

Release: r20120905
Date: 09/05/2012
Site: app.alivecor.com

- Fix default action mailer host
- Added cucumber profile for CI.
- Remove swap file
- Add link to manage superusers
- Add superuser tools framework

Release: r20120829
Date: 08/29/2012
Site: app.alivecor.com

- Add group tables.
- Add touch icon link.
- Add apple touch icon for mobile bookmarks
- Fix pdf generation error when dob is nil
- Improve documentation
- Fix remote auth when the first login fails
- Remove unused test file
- Caculate patient age based on recording date
- Calculate patient age based on recording date.
- Specify ruby version for heroku

Release: r20120822
Date: 08/22/2012
Site: app.alivecor.com

- Launch

Questions? Contact FDA/CDRH/OCE/Section 510(k) STATUS@fda.hhs.gov or 301-796-8118

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TITLE:	ECG for iPhone Design Description, Software

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Change History

Revision	Date	Description of Change	Author
(b)(4)			

(b) (4) Software Design

(b) (4) Software Design

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AliveCor

510(k) PREMARKET NOTIFICATION

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The original *AliveCor Heart Monitor* (for the iPhone 4/4S) was evaluated for electromagnetic compatibility (EMC), including both emissions and immunity. We tested the device according to ANSI/AAMI/IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests to demonstrate the EMC characteristics of the device. The device was tested according to IEC 60601-1, ANSI/AAMI EC38 and ANSI/AAMI/IEC 60601-1-2 for patient safety.

Standard	Description
IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
ANSI/AAMI/IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests
ANSI/AAMI EC38	Medical Electrical Equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

All subsequent mechanical configurations will comply with the above safety standards and test methodologies. Some renditions of the *AliveCor Heart Monitor* may not require retesting under these protocols due to the scope of the change. For example, following the progression of iPhone hardware, the iPhone 5 compatible device has nearly the same form factor, allowing us to use the same printed circuit board assembly (PCBA) in a new mechanical construct. Essentially the design remains the same while the iPhone case portion of the design is lengthened to accommodate the larger iPhone 5.

In the event of a PCBA redesign, it is likely that the change will justify retesting according to the above standards. AliveCor will have these protocols and reports published and available upon commercialization of any additional mobile computing platform compatibility.

The *AliveCor Heart Monitor* has been designed to meet the set requirements of the above standards, and has been tested against those standards to assure compliance. Each applicable requirement from the individual standard has been translated to a specific requirement in design control documentation. Each of the requirements has been verified. A list of the verification activities are described in Section 21 and are on file at AliveCor. The majority of requirements related to EMC and Electrical Safety are tested within the ECG for iPhone Human Test Protocol, Systems Integration (02VEP2).

The Electrical Safety and Compatibility Information is in compliance with ANSI/AAMI/IEC 60601-1-2 is contained in the device labeling (see Section 13).

The Extent of Standard Compliance to each of these standards can be found in Section 9 of this submission.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING - BENCH

The following bench testing was performed on the *AliveCor Heart Monitor*.

Full test protocols, results and conclusions are provided in the report location specified below, or on-file at AliveCor.

Description of Test	Standard	Test Report Located
System Integration Verification Testing	02VEP2.A On-file at AliveCor	02VER2.A On-file at AliveCor
General Safety	IEC 60601-1	Appendix C On-file at AliveCor
EMC Testing	ANSI/AAMI EC38, and 60601-1-2	Appendix D On-file at AliveCor
Environmental Testing	ANSI/AAMI EC38	Appendix D On-file at AliveCor
Biocompatibility Testing	ISO 10993-1	Appendix B On-file at AliveCor
Ambulatory ECG Safety Testing	ANSI/AAMI EC38 60601-2-47	Appendix E On-file at AliveCor
Real Life Radio Interference	N/A	Technical Report On-file at AliveCor
iPhone 4 GSM, 4 CDMA, 4S Hardware Compatibility	N/A	Technical Report On-file at AliveCor
Battery Capacity Evaluation	N/A	Technical Report On-file at AliveCor
Amplitude and Time Base Accuracy	N/A	Technical Report On-file at AliveCor
Performance Comparison to Omron HGC-801 Portable ECG Monitor	N/A	Technical Report On-file at AliveCor

All additional bench testing resulted in confidence that the *AliveCor Heart Monitor* performs to the development team's expectations. No additional concerns related to safety and effectiveness resulted from the above testing.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING – ANIMAL

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PRGSTATUS@fda.hhs.gov or 301-796-8118

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510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING – CLINICAL

This section **does not apply**.

The previous submission for the *AliveCor Heart Monitor for iPhone* (K122356) included clinical testing that was performed using prototype devices under IRB approval that provides some indication of design efficacy. Those studies are still valid but not applicable directly to this submission, therefore omitted.

After clearance of the original 510(k) submission (K122356) AliveCor conducted formal design validation testing to support the clinical data submitted in the previous submission. Similar design validation testing will be performed on additional mechanical configurations of the AliveCor Heart Monitor that AliveCor deems necessary by our Design Control process and Design Development Plan(s).

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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510(k) PREMARKET NOTIFICATION

Declaration of Conformity with Design Control Activities

All design control activities have been performed per the AliveCor, Inc. Quality System Procedures and in compliance with Title 21 CFR part 820.30.

The following is a summary of the design control activities completed for the *AliveCor Heart Monitor* design history file:

- 01RSK1 – ECG for iPhone Hazard Analysis
- 01RSK2 – ECG for iPhone Risk Assessment
- 01DES1 – ECG for iPhone Design Description, Software
- 02DDP1 – ECG for iPhone Human Design and Development Plan
- 02REQ2 – ECG for iPhone Human Design Input-Output Matrix, Hardware
- 02REQ3 – ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
- 02VAP1 – ECG for iPhone Human Validation Protocol
- 02VAR1 – ECG for iPhone Human Validation Report
- 02VEP1 – ECG for iPhone Human Verification Protocol, iOS Application
- 02VER1 – ECG for iPhone Human Verification Report, iOS Application
- 02VEP2 – ECG for iPhone Human Verification Protocol, System Integration
- 02VER2 – ECG for iPhone Human Verification Report, System Integration
- 04REQ1 – ECG Website Human Design Input-Output Matrix
- 04VEP1 – ECG Website Human Verification Protocol, Web Application
- 04VER1 – ECG Website Human Verification Report, Web Application
- 09REQ1 – ECG Universal Module Design Input-Output Matrix, Hardware
- 09REQ2 – ECG Universal Module Design Input-Output Matrix, Mobile Software for Android OS

Note that the titles of the above referenced documents are specific for the first mechanical configuration of the *AliveCor Heart Monitor* released for the iPhone 4/4S, hence the project name "*ECG for iPhone*". It was natural for us to add the iPhone 5 mechanical configuration hardware into the scope of these documents rather than create a duplicate set of design control documentation. Very few changes were necessary due to the similarity of products for the iPhone 4/4S and iPhone 5 devices.

It is expected to create an additional design control documentation set for other additional mechanical configurations such as the Android compatible device (e.g. 09DDP1 – ECG for Android Design and Development Plan). Completion of this documentation is pending FDA clearance for commercialization. Items will be completed and filed in the respective Design History File (DHF) prior to marketing the device. The DHF will be complete prior to commercial launch.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

Declaration of Conformity with Design Controls

All design control activities including verification activities, as required by the design and development plan, and risk assessment for the additional mechanical configurations of the *AliveCor Heart Monitor* and necessary software (*AliveECG* App) changes shall be performed by the designated individual(s) and the results shall demonstrate that the predetermined acceptance criteria were met.

The manufacturing facility, IDT Technology Ltd. is in conformance with the design control requirements as specified in 21 CFR part 820.30. Records will be available for review for each mechanical configuration of the *AliveCor Heart Monitor* family of products.

_____

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Director, Regulatory Affairs

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AliveCor

510(k) PREMARKET NOTIFICATION

RISK ASSESSMENT

This section contains the following reports:

- 01RSK2 – ECG for iPhone Risk Assessment
- 01RSK1 – ECG for iPhone Hazard Analysis

AliveCor, Inc. considers Risk Management to be a continual process and each of the documents contained in this section to be 'living' documents. These documents will be updated upon future device/system verification and validation, product surveillance, and other activities as described in AliveCor's Quality Management System procedures.

Upon the initiation of a design development plan for a new mechanical configuration of the *AliveCor Heart Monitor* to fit additional mobile computing platform units (such as Android phones or next generation of iPhone), AliveCor will either update the Hazard Analysis and Risk Assessment above to include the new mobile computing platforms in the scope of the document. Both the Risk Assessment and Hazard analysis show an example of this methodology with the addition of the iPhone 5 compatible mechanical configuration.

Risk management methods have been applied to accommodate the new use model for the Health Conscious Individual (HCI) using the device Over-the-counter according to:

- ISO14971 - Medical devices. Application of risk management to medical devices
- FDA Draft Guidance: Design Considerations for Devices Intended for Home Use (December 12, 2012)
- FDA Draft Guidance: Applying Human Factors and Usability Engineering to Optimize Medical Device Design (June 22, 2011)
- IEC 60601-1-6 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366 – Medical devices -- Application of usability engineering to medical devices

As a result of the additional process considerations and use model, the most notable newly identified hazard is for the health conscious individual that does not have the required specialty knowledge (or ability to consult a medical professional) to properly view the ECG leading to misguided concerns/reactions. AliveCor chose to mitigate that risk by hiding the ECG waveform from the health conscious individual. To accommodate our current prescription only user base of physicians and patients, and if a health conscious individual becomes a patient under the care and guidance of a physician, AliveCor has the ability to unlock the app to show the ECG waveform if there is a clinical need.

Other additional areas of risk identified include some more in-depth analysis of how the device may be used in ways that are not anticipated and other user-centric design considerations especially those related to the devices graphical user interface.

Questions? Contact FDA/CDRH/OCE/DAE at CDRH-510(K)STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

As a result of the additional compliance to the guidance documents and standards listed above, a significant improvement AliveCor has made to our validation plans is the initiation of Human Factors Validation testing to support many of the mitigations identified in the hazard analysis. The scope of that protocol and report are growing as we better understand our user groups since we did not have the opportunity to perform formative research early on in the design process. We feel that the robustness of our verification and validation activities are building a great foundation for future development of mechanical configurations that fit into the *AliveCor Heart Monitor* family of products.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE:	ECG for iPhone Risk Assessment

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Change History

Revision	Date	Description of Change	Author
(b)(4)			

(b) (4) Hazard and Risk Analysis Tests and Results

(b) (4) Hazard and Risk Analysis Tests and Results

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG for iPhone Hazard Analysis

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AliveCor

510(k) PREMARKET NOTIFICATION

Biocompatibility Testing

This section contains the following reports:

1. **ALIVECOR HEART MONITOR BIOCOMPATIBILITY TESTING PER ISO 10993-1**

(b) (4) Third Party Test Sites and Results

[redacted]

2. **SCOPE**

All additional mechanical constructs of the *AliveCor Heart Monitor* intended to fit different form factors of various mobile computing platforms use the same materials tested in the reports listed above. According to FDA 510(k) memorandum #K97-1 (*Deciding when to Submit a 510(k) for a Change to an Existing Device*), any change to materials that requires retesting per ISO 10993-1 would require a new 510(k) and is not covered under the scope of this 510(k). AliveCor will not commercialize any mechanical construct without proper biocompatibility testing and clearance by FDA.

Questions? Contact FDA/CDRH/OCE/DHT4 at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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COVER SHEET MEMORANDUM

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics and
Radiological Health

NOTE: This form is REQUIRED for holds and for final decisions.

Reviewer Name Stephen Browning

510(k) Number K130921

Please list CTS decision code: SE - Substantially Equivalent

☐ Hold (Additional Information or Telephone Hold) Hold Date

☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.)

☐ Incomplete Response - Convert Supplement to Amendment (attach email sent to firm)

☐ Add to File

(review staff should follow the instructions and complete the memo/routing sheet at: http://eroom.fda.gov/eRoom/CDRH3/CDRHPremarketNotification510kProgram/0_3bba7. DCC should refer to that documentation for the close-out code and mail any provided letter.)

The remainder of this form must be filled out for close-outs only

Class:	II
Regulation Number:	21 CFR 870.2340
Product Code:	DPS
Additional Product Codes:	

Please complete the following for a final clearance decision (i.e, SE, SE with Limitations, etc.)	YES	NO
Indications for Use Page *(Attach IFU)*	X	
510(k) Summary or 510(k) Statement *(Attach Summary)*	X	
Truthful and Accurate Statement *(Must be present for a Final Decision)*	X	
Is the device Class III?		X
Is this a combination product?		X
Is this device intended for pediatric use only?		X
Is this a prescription device? (If both prescription & OTC, check both boxes.)	X	X
Is clinical data necessary to support the review of this 510(k)?		X
For United States based clinical studies only, did the application include a completed Form FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If study was conducted in the United States and Form FDA 3674 was not included or was incomplete, then applicant must be contacted to obtain completed form.)		X
Does this device include an Animal Tissue Source?		X
All Pediatric Patients age <= 21		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.

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Neonate/Newborn (Birth to 28 days)		
Infant (29 days to < 2 years)		
Child (2 years to <12 years)		
Adolescent (12 years to <18 years)		
Transitional Adolescent A (18 years to <21 years); Special considerations are being given to this group, different from adults age >= 21 (different device design or tesating, different protocol procedures, etc.)		
Transitional Adolescent B (18 years to <21 years); No special considerations compared to adults >= 21 years)		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance)		

Digital Signature Concurrence Table
(Not all signatures may be required)

Branch Chief Sign-Off	Linda J. Ricci -S 2014.02.06 13:19:14 -05'00'
Division Sign-Off	Digitally signed by Owen P. Faris -S Date: 2014.02.06 16:25:05 -05'00'

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118.

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

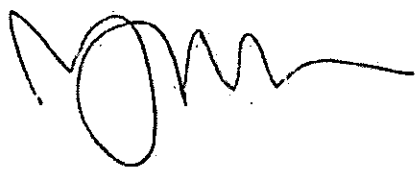
AliveCor

510(k) PREMARKET NOTIFICATION

510(k) STATEMENT

(as required by 21 CFR 807.93)

I certify that, in my capacity as *Director, Regulatory Affairs* of *AliveCor, Inc.*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.



(Signature of Certifier)

Michael S. Righter

(Typed Name)

April 1, 2013

(Date)

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

K130921/S001

AliveCor

510(k) PREMARKET NOTIFICATION

Response to Notification: "K130921 was Refused"

October 8th, 2013

FDA CDRH DMC
OCT 15 2013
Received

Stephen Browning
U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Control Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Mr. Browning,

We received notification of refusal for premarket notification K130921. I agree with the determination that the submission was incomplete as I unintentionally omitted the requirements specification and traceability document "input-output matrix" from the submission. I apologize for overlooking this detail and any inefficiency I caused. On the other hand, it is reassuring to see the pre-review program is working well, and I commend FDA for making the 510(k) process more industry friendly.

Previous submissions (K122356 and K130409) for the AliveCor Heart Monitor listed document number 02REQ1 which included all requirements (system, mechanical, hardware, software and web). In between K130409 and this submission K130921, AliveCor chose to split the requirements into a more organized and manageable documentation set therefore the Software Section 16 now includes the documents listed below:

- 02REQ3 – ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
- 09REQ2 – ECG Universal Module Design Input-Output Matrix, Mobile Software for Android OS
- 04REQ1 – ECG Website Human Design Input-Output Matrix

These documents are related to the software associated with the AliveCor Heart Monitor as a system. More changes have been made according to the additional information request for K130409 to limit the scope of clearance to iOS and Android OS mobile devices. This submission reflects those changes.

Rather than organizing and resubmitting edited sections, the attached documentation is intended to replace the original K130921 submission in its entirety.

Michael S. Righter
Director, Regulatory Affairs
AliveCor, Inc.
email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor™

510(k) PREMARKET NOTIFICATION

ELECTRONIC COPY CERTIFICATION

An electronic copy (eCopy) is supplied with this premarket notification [510(k)] submission in accordance with Section 745A(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), added by section 1136 of the Food and Drug Administration Safety and Innovation Act (FDASIA).

The eCopy is an exact duplicate of the paper copy.

Source files are included under the "Misc Files" directory for the convenience of the reviewer.

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94103

email: mike@alivecor.com
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor™

AliveCor, Inc.

AliveCor Heart Monitor (OTC)

Traditional 510(k) Submission

Electronic

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

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Appendix E: IEC 60601-2-47, ANSI/AAMI EC38 Report Universal Module	29

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Form Approved: OMB No. 0910-511 Expiration Date: February 28, 2013. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: (b) (4) [redacted] Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
ALIVECOR INC 30 Maiden Lane, 6th Floor San Francisco CA 94108 US	Michael Righter
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****1679	2.1 E-MAIL ADDRESS mike@alivecor.com 2.2 TELEPHONE NUMBER (include Area code) 415-7959812 2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA

[X] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates

[ ] The sole purpose of the application is to support conditions of use for a pediatric population

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only

[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b) (4) [redacted]

08-Mar-2013

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/01/2013	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
AliveCor, Inc.	3009715978		
Division Name *(if applicable)*	Phone Number *(including area code)*		
San Francisco	415.795.9812		
Street Address	FAX Number *(including area code)*		
30 Maiden Lane, 6th Floor	415.397.0440		
City	State / Province	ZIP/Postal Code	Country
San Francisco	CA	94108	USA
Contact Name			
Michael Righter			
Contact Title	Contact E-mail Address		
Director, Regulatory Affairs	mike@alivecor.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Street Address	FAX Number *(including area code)*		
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title	Contact E-mail Address		

FORM FDA 3514 (12/10)

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Response to FDA correspondence:

- ☐ Change in design, component, or specification:
  - ☐ Software/Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify)*:

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent/Applicant
  - ☐ Design/Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify)*:

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify)*:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DPS	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- ☐ 510 (k) summary attached
- ☒ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K121009	1	HeartCheck Pen Handheld Heart Rhythm with GEMS Home	1	CardioComm Solutions, Inc.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrocardiograph

	Trade or Proprietary or Model Name for This Device		Model Number
1	AliveCor Heart Monitor OTC	1	AC-00X
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

- ☒ Laboratory Testing
- ☐ Animal Trials
- ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DPS	870.2340	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The AliveCor Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City		State / Province	ZIP Code / Country
Contact Name	Contact Title	Contact E-mail Address	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment - Part 1: General requirements for safety	2005	10/31/2005
2	60601-1-2	AAMI/ANSI/IEC	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests	2007	06/10/2010
3	60601-2-47	IEC	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	1.0	07/10/2001
4	EC38	ANSI/AAMI	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems	2007	09/09/2008
5	10993-1	ISO	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process	2009	10/04/2010
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 2-28-2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
   AliveCor, Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   04/01/2013

3. ADDRESS *(Number, Street, State, and ZIP Code)*
   30 Maiden Lane, 6th Floor
   San Francisco, CA 94108

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
   (Tel.) 415.795.9812
   (Fax) 415.397.0440

PRODUCT INFORMATION

5. FOR DRUGS/BIOLOGICS: Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
   FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
   (Attach extra pages as necessary)

   Common Name: ECG Event Recorder

   Classification Name: Electrocardiograph

   Proprietary Name: AliveCor Heart Monitor

   Model: AC-00X

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
   ☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☑ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

   ☑ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

   ☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

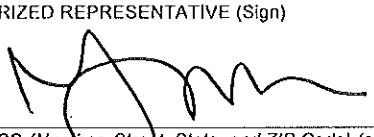
   ☐ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*

    NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)



12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
    (Name) Michael S. Righter
    (Title) Director, Regulatory Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
    30 Maiden Lane, 6th Floor
    San Francisco, CA 94108

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
    (Tel.) 415.795.9812
    (Fax) 415.697.0440

15. DATE OF CERTIFICATION
    04/01/2013

PSC Publishing Services (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Instructions for Completion of Form FDA 3674

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter** - This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.
2. **Date** - This is the date of the application/submission which the certification accompanies.
3. & 4. - Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.
5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.
6. **Type of Application/Submission** - Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."
7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number** - If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.
8. **Serial Number** - In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field. If there is no such number, leave this field blank.
9. **Certification** - This section contains three different check-off boxes.

   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission of the certification to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, even though some or all of the clinical trials included, relied upon, or otherwise referred to in the application/submission may be "applicable clinical trials" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, on the date the certification is signed, 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, does not require that any information be submitted to the ClinicalTrials.gov Data Bank with respect to those clinical trials.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply, on the date the certification is signed, to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, as of the date the certification is signed, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.
10. **National Clinical Trial (NCT) Numbers** - If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as the term "NCT" will be added automatically before number. Include any and all NCT numbers that, as of the date the certification is signed, have been assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Leave this field blank if you have checked Box 9.C but, at the time the certification is completed, you have not yet received any NCT numbers for the "applicable clinical trial(s)" included, relied upon, or otherwise referred to in the application/ submission.
11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative** - The person signing the certification must sign in this field.
12. **Name and Title of Person Who Signed in number 11** - Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.
13. & 14. - Provide the full address, telephone and fax numbers of the person who is identified in number 11 and signs the certification in number 11.
15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

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Rockville, MD 20850

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Form FDA 3674 (3/12) (BACK)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

Response to Notification: "K130921 was Refused"

October 8th, 2013

Stephen Browning
U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Control Center (WO66-G609)
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Mr. Browning,

We received notification of refusal for premarket notification K130921. I agree with the determination that the submission was incomplete as I unintentionally omitted the requirements specification and traceability document "input-output matrix" from the submission. I apologize for overlooking this detail and any inefficiency I caused. On the other hand, it is reassuring to see the pre-review program is working well, and I commend FDA for making the 510(k) process more industry friendly.

Previous submissions (K122356 and K130409) for the AliveCor Heart Monitor listed document number 02REQ1 which included all requirements (system, mechanical, hardware, software and web). In between K130409 and this submission K130921, AliveCor chose to split the requirements into a more organized and manageable documentation set therefore the Software Section 16 now includes the documents listed below:

- 02REQ3 – ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
- 09REQ2 – ECG Universal Module Design Input-Output Matrix, Mobile Software for Android OS
- 04REQ1 – ECG Website Human Design Input-Output Matrix

These documents are related to the software associated with the AliveCor Heart Monitor as a system. More changes have been made according to the additional information request for K130409 to limit the scope of clearance to iOS and Android OS mobile devices. This submission reflects those changes.

Rather than organizing and resubmitting edited sections, the attached documentation is intended to replace the original K130921 submission in its entirety.

_____

Michael S. Righter
Director, Regulatory Affairs
AliveCor, Inc.
email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DECA/CDRH-RQIS STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

TRADITIONAL 510(k) COVER LETTER

April 1st, 2013

Frank Lacy; Orlando Lopez, PhD
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

To Whom It May Concern;

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market a software revision of our previously cleared medical device (K122356) for Over-The-Counter (OTC) use. As mentioned in the previous submission, AliveCor chose the CardioComm, Inc. *HeartCheck Pen* as the predicate device because it has clearance for OTC use and we anticipated there was going to be some level of demand for the *AliveCor Heart Monitor* for OTC. Since the original submission, an exceptionally *similar* device from Cardiac Design LLC called the *ECG Check* was cleared for OTC use (K122184), but for simplicity and continuity, the *HeartCheck* Pen remains as the predicated comparison.

Currently known with the proprietary name of *AliveCor Heart Monitor for iPhone*, AliveCor submitted an addition to the indications for use (K130409 cleared on September 6th, 2013) with the intent to remove "*for iPhone*" from the product name and expanded the scope of use to other Mobile Computing Platforms (MCPs) that AliveCor verifies and validates as compatible with the applicable mechanical configuration of the *AliveCor Heart Monitor* and associated *AliveECG* mobile application. In response to an additional information request, AliveCor limited the scope of the clearance to MCPs operating with Apple iOS and Android operating systems only.

This 510(k) submission is essentially a carbon copy of K130409 with two changes:

1. Indications for use to include OTC designation:

   After successful FDA clearance, marketing and design validation of the AliveCor Heart Monitor (K122356), we have received a great deal of feedback from medical professionals, patients and health conscious individuals related to the availability of our device for Over-The-Counter use. We believe with minor changes to the software and labeling we can support OTC users and provide a product that encourages a healthcare system that promotes preventive medicine practices.

2. *AliveECG* App modification to hide ECG waveform:

   In response to this market need, AliveCor commenced work on a modification to the *AliveECG* app that hides the ECG waveform from a 'consumer' while still providing an informative user interface (similar to a heart-rate-monitor) that allows the user to send their recording to a medical professional for review and interpretation. The proposed change allows the app to be reconfigured to view the ECG waveform for physicians, and patients under the guidance of a physician.

Questions? Contact FDA/CDRH/OCE/DECAL/RAPIDSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

By following Memorandum K97-1 to determine if a new 510(k) application is necessary for the change, AliveCor determined that due to the expanded indications for use, a Traditional 510(k) was necessary.

Submission Content, in accordance to 21 CFR 807.92:

Submitter's Name: ..... AliveCor, Inc.
Submitter's Address: ..... 30 Maiden Lane, 6th Floor, San Francisco, CA 94108
Facility Registration Number: 3009715978
Contact Person: ..... Michael S. Righter
Contact Person Title: ..... Director, Regulatory Affairs
Telephone: 415.795.9812
Fax: 415.397.0440
Email: ..... mike@alivecor.com
510(k) Submission Type: ..... Traditional 510(k)
Date Prepared: ..... February 1, 2013
Classification Name: ..... Electrocardiograph
Common Name: ..... ECG Event Recorder
Proprietary Name: ..... AliveCor Heart Monitor
Model Number: AC-00X
Product Code: ..... DPS
C.F.R. Section: 870.2340
Recommended Classification: ..... Class II
Classification Panel: ..... Cardiovascular
Reason for Submission: ..... Additional Indications (OTC)

Confidentiality Statement, in accordance to 21 CFR 807.95

We consider our intent to market this device as confidential information and request that it be considered as such by the FDA during the evaluation process, in accordance with (21 CFR 807.95).

Design and Use of the Device

The following table summarizes the principal factors about the design and use of the devices

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device intended for single use?		X
Is the device a reprocessed single use device?		X
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?	X	
Does the submission include clinical information?		X
Is the device implanted?		X

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AliveCor

Michael S. Righter
Director, Regulatory Affairs

AliveCor, Inc.
30 Maiden Lane, 6th Floor
San Francisco, CA 94103

email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DECA/CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

Indications for Use:

The *AliveCor Heart Monitor* is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.

Prescription Use _____X_____ AND/OR Over-The-Counter Use _____X____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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AliveCor

510(k) PREMARKET NOTIFICATION

510(k) STATEMENT

(as required by 21 CFR 807.93)

I certify that, in my capacity as *Director, Regulatory Affairs* of *AliveCor, Inc.*, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

_____

(Signature of Certifier)

Michael S. Righter

(Typed Name)

April 1, 2013

(Date)

_____

*(Premarket Notification [510(k)] Number)

*For a new submission, leave the 510(k) number blank

Questions? Contact FDA/CDRH/OCE/DECAD at 510(K)STATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as *Director, Regulatory Affairs* of *AliveCor, Inc.*, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

_____
(Signature)

Michael S. Righter
(Typed Name)

April 1, 2013
(Date)

_____
*(Premarket Notification [510(k)] Number)
*For a new submission, leave the 510(k) number blank.

Must be signed by a responsible person of the firm required to submit the premarket notification [e.g., not a consultant for the 510(k) submitter].

30 Maiden Lane, 6th Floor | San Francisco, CA 94108 | 415.795.9804 | www.alivecor.com

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

CLASS III CERTIFICATION AND SUMMARY

(As Required by 21 CFR 807.94)

(To be submitted when claiming equivalence to a Class III device)

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

Financial Certification or Disclosure Statement

(As Required by 21 CFR 54)

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

DECLARATIONS OF CONFORMITY TO INDUSTRY STANDARDS

The following table is a list of the FDA recognized standards used to evaluate the *AliveCor Heart Monitor* device.

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

A declaration of conformity is provided below for each of the standards in the table above.

Questions? Contact FDA/CDRH/OCE/DHE at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

Declaration of Conformance

IEC 60601-1 (2005)

The *AliveCor Heart Monitor* is in compliance with IEC 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1.

IEC 60601-1-2 (2007)

The *AliveCor Heart Monitor* is in compliance with IEC 60601-1-2: Medical Electrical Equipment – Part 1: General Requirements for Safety, Collateral Standard: Electromagnetic compatibility – Requirements and Tests. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for IEC 60601-1-2.

ANSI/AAMI EC38 (2007)

The *AliveCor Heart Monitor* is in compliance with ANSI/AAMI EC38: Ambulatory Electrocardiographs. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for EC38.

ISO 10993-1 (2009)

The *AliveCor Heart Monitor* is in compliance with ISO 10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process. The *AliveCor Heart Monitor* has been verified to meet all applicable requirements in the standard. A detailed list of any deviations or exceptions from the standard can be found in the Summary Report Table for ISO 10993-1.

Questions? Contact FDA/CDRH/OCE/DECAL/CDRH-RECALLSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

THIRD PARTY LABORATORIES USED FOR TESTING CONFORMANCE TO STANDARDS

Biocompatibility:

(b)(4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DHE and CDRH-PRE-STATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1: Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (2005)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	#5-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

Questions? Contact FDA/CDRH/OCE/Device CDRH Page STATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Department of Health and Human Services
Food and Drug Administration

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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-2: Med. Elec. Equip. - Gen. Req. for Safety; Electromagnetic Compatibility - Reqs. and Tests (2007)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-54	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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Questions? Contact FDA/CDRH/OCE/Document Control Section at STATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Rockville, MD 20850

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Questions? Contact FDA/CDRH/OCE/DECAD at STATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI EC38: Part 2-47: Particular req's for the safety, including essential perf., of ambulatory electrocardiographic systems (2007)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-65	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

◆ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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Form Approved: OMB No. 0910-0120; Expiration Date: 12/31/13

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☒	☐
If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: #G95-1: Use of International Standard ISO-10993, 'Biological ... Testing'

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISO10993-1: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process (2009)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 5	Part 5: Tests for in vitro cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Cytotoxicity tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Part 10	Part 10: Tests for irritation and skin sensitization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION
The AliveCor Heart Monitor for iPhone passes Irritation and Sensitization tests.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
ALL OTHER		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED ◆

DESCRIPTION

JUSTIFICATION
All other parts not applicable to the he AliveCor Heart Monitor for iPhone according to the standard

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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AliveCor

510(k) PREMARKET NOTIFICATION

EXECUTIVE SUMMARY

1. INTRODUCTION

AliveCor, Inc. (AliveCor) has developed and plans to market the *AliveCor Heart Monitor* for Over-The-Counter (OTC) use. The device hardware and mechanical components are identical to the previously cleared *AliveCor Heart Monitor for iPhone.* The *HeartCheck Pen Handheld Heart Rhythm with GEMS Home* device (*HeartCheck Pen* or predicate device) manufactured for CardioComm Solutions, Inc. intended for OTC remains as the predicate device. We believe that the *AliveCor Heart Monitor* is substantially equivalent to the *HeartCheck Pen Handheld Heart Rhythm with GEMS Home* (K121009).

This 510(k) submission is essentially a carbon copy of K130409 (pending clearance) with two changes:

1.1. Indications for use to include Over-The-Counter

We believe with minor changes to the software we can support OTC use of the device. This change requires modifications to the appropriate labeling.

1.2. *AliveECG* App modification to hide ECG waveform:

A modification to the *AliveECG* app is required that hides the ECG waveform from a 'consumer' while still providing an informative user interface (similar to a consumer heart-rate-monitor) that allows the user to send their recording to a medical professional for review and interpretation. The proposed change allows the app to be reconfigured to view the ECG waveform for physicians, and patients under the guidance of a physician.

2. BACKGROUND

This Traditional 510(k) is intended to notify the FDA CDRH that AliveCor, Inc. of San Francisco, California, intends to market a revision of our previously cleared medical device (K122356) for Over-The-Counter (OTC) use. Currently known with the proprietary name of *AliveCor Heart Monitor for iPhone*, AliveCor submitted an addition to the indications for use (K130409) with the intent to remove "*for iPhone*" from the product name and expanded the scope of use to other Mobile Computing Platforms (MCPs) that AliveCor verifies and validates as compatible with the applicable mechanical configuration of the *AliveCor Heart Monitor* and associated *AliveECG* mobile application. This submission outlines the additional changes necessary for OTC use.

3. INTENDED USE

The *AliveCor Heart Monitor* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (*e.g.* physician, nurse, EMT) with the ability to perform an immediate assessment of a user's ECG rhythm. Additionally, the simple user interface allows a user to directly acquire a recording from their body for transmission-to and assessment-by a medical professional.

4. CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS:

The *AliveCor Heart Monitor* has no known contraindications; however, the device should be used in accordance with the instructions as indicated in the User Manual and as directed by a physician.

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Refer to Section 13: Proposed Labeling for additional warnings and precautions.

5. DEVICE DESCRIPTION

The *AliveCor Heart Monitor* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the computing power of a MCP while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the user's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor* uses acoustic waves in the non-audible ultrasonic wavelength. The medical device consists of the combination of the *AliveCor Heart Monitor* (electro-mechanical assembly), the *AliveECG* mobile application (App), a compatible MCP, and the auxiliary AliveCor Database WebApp for editing metadata online.

6. SUBSTANTIAL EQUIVALENCE

Legally marketed predicate device:

510(k) Number: K121009

Product: *HeartCheck Pen Handheld Heart Rhythm with GEMS Home*

Manufacturer: CardioComm Solutions, Inc.

The major differences between the currently marketed *HeartCheck Pen* and the *AliveCor Heart Monitor* are summarized below and detailed in Section 12: Substantial Equivalence discussion.

Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor***
Indications for Use:	The *HeartCheck™ Pen Handheld with GEMS Home* software is an over-the-counter device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The *HeartCheck™ Pen Handheld device along with GEMS Home* software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The *AliveCor Heart Monitor* is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.
Standards: Essential Performance AECG Safety General Safety EMC Safety	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2

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Specification	*HeartCheck Pen* Handheld Heart Rhythm with GEMS Home	*AliveCor Heart Monitor*
Data Acquisition: Frequency Response ECG channels Resolution Sample Rate	 **1 Hz** – 40Hz Single Channel Unknown **250** Samples/Second	(b) (4)
Memory Capacity:	**20** recordings	
Device Classification:	DPS: Electrocardiograph	
Power Supply: Battery Battery Life (typical)	 2 AAA batteries Unknown	
User Interface: Primary Lead Data upload Software platform	 Lead I, Left to Right Hand **USB** **PC based software**	
Physical Specs: Dimensions, inches Weight	 **130 x 30 x 20 mm** **110 grams**	
Electrodes: Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	
Lead Wires:	None	
Where used:	Ambulatory outpatient use	
Prescribed:	Over-the-Counter	
Environmental: (minimum) Operating Temp Storage Temp	 **5 to 40 degrees C** **-20 to 55 degrees C**	

None of the above differences in specification affect the safety or efficacy of the *AliveCor Heart Monitor* compared to the *HeartCheck Pen* system as discussed in Section 12: Substantial Equivalence Discussion.

In addition to Section 12: Substantial Equivalence Discussion, additional testing was performed to demonstrate the safety and efficacy of the device in Sections 16: Software, Section 17: Electromagnetic Compatibility and Electrical Safety and Section 18: Performance Testing – Bench. The results of performance, safety and bench testing suggest that the main functional characteristics of the *HeartCheck Pen* and *AliveCor Heart Monitor* are comparable for key metrics, thus confirming their substantial equivalence.

7. COMPLIANCE TESTING

The *AliveCor Heart Monitor* was evaluated for conformity to the following list of standards. The *AliveCor Heart Monitor* demonstrated compliance with all applicable tests. Greater detail is discussed in Section 9: Declaration of Conformity, Industry Standards.

Safety and Compliance Standards and Guidelines:

Standard	Recognized Standard #	Description
IEC 60601-1 (2005)	[FDA# 5-4]	Medical electrical equipment - Part 1: General requirements for basic safety and

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		essential performance
IEC 60601-1-2 (2007)	[FDA# 5-54]	Medical Electrical Equipment – Part 1: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
ANSI/AAMI EC38 (2007)	[FDA# 3-65]	Medical electrical equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems
ISO 10993-1 (2009)	[FDA# 2-156]	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

8. CONCLUSION:

The *AliveCor Heart Monitor for Over-The-Counter use* represents a logical modification to the technology of the predicate device and an obvious extension of the previously cleared *AliveCor Heart Monitor for iPhone*. The extension of the *AliveCor Heart Monitor* product line to include OTC use is in response to user requests/needs. The clinical use of the device remains identical to the predicate device. AliveCor has concluded that the *AliveCor Heart Monitor* is substantially equivalent to the predicate device and the differences between them do not adversely affect safety and effectiveness of the device.

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AliveCor™

510(k) PREMARKET NOTIFICATION

DEVICE DESCRIPTION

Figure 1: User Interface

Figure 2: *AliveCor Heart Monitor*

1. BASIC DESCRIPTION:

The *AliveCor Heart Monitor* (the device) is the next generation of trans-telephonic (transmission by telephone) ECG (electrocardiogram) event recorders. The device utilizes the processing power of a *mobile computing platform* (MCP) while reducing the complexity of the electronics hardware associated with data acquisition and transmission. The device is placed on the chest or held by the user's hands to provide a single-channel ECG rhythm strip. Similar to many other devices that use telephone data transmission, the *AliveCor Heart Monitor* uses a proprietary method of data transmission using acoustic waves. Unlike other devices, the *AliveCor Heart Monitor* uses acoustic waves in the non-audible ultrasonic wavelength. The device consists of the combination of the *AliveCor Heart Monitor*, *AliveECG* mobile App (App), and a MCP such as a Smartphone.

Auxiliary functionality on the AliveCor website (WebApp) allows users to access their ECG data and any data shared with them that is stored on the AliveCor Database. The majority of the functionality associated with these features are MDDS (Medical Device Data System), although editing of the metadata (Patient Name, Date of Birth, measurement position, comments, symptoms, etc.) is considered a component of the medical device.

2. INTENDED USE:

The *AliveCor Heart Monitor* is a single-channel ECG acquisition, display and transmission device that provides a medical professional (*e.g.* physician, nurse, EMT) with the ability to perform an immediate assessment of a patient's ECG rhythm. Additionally, the simple user interface allows a user to directly acquire a recording from their body for transmission-to and assessment-by a medical professional.

3. PATIENT BENEFITS:

Traditional ECG monitors that use telephone transmission techniques require the user to record their ECG then at some later time, use a phone (typically a land-line) to transmit the data to a service center. The *AliveCor Heart Monitor* simplifies the process for the user by removing the need to manually transmit the data. The device automatically records the data on the MCP and the associated App uploads the data with minimal user interaction.

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AliveCor, Inc. (AliveCor) believes that by removing the complexity of electronics hardware from the device, we can improve accessibility to care. In other words, reducing the cost of the medical device, strategic use of the computing horsepower within MCPs, and prevalent accessibility to MCPs such as Smartphones will allow improved patient compliance and efficacy of the device as compared to other ECG event recorders currently on the market. Patients can perform an ECG recording almost anywhere and during normal daily activities without major interruption to their lives.

4. CLINICAL USE MODEL:

The *AliveCor Heart Monitor* is both a Real-Time ECG display device and an ECG Post-Event Recorder depending on the type of user (medical professional, patient or consumer).

4.1. Users:

In the hands of a medical professional, the *AliveCor Heart Monitor* is a real-time ECG recording and display device, which allows real-time viewing, storage, reviewing and printing of a single-channel ECG rhythm strip.

In the hands of a patient using the device under the prescription of a physician, the *AliveCor Heart Monitor* is an ECG Post-Event Recorder, allowing the recording of a single-channel ECG rhythm strip from the hands or the chest during a symptomatic event or during a period without symptoms. In this clinical application, the ECG rhythm strip is transmitted wirelessly via WiFi or cellular data for review by a medical professional on the AliveCor Database. Unlike traditional trans-telephonic ECG Event Recorders, the device does not rely on call centers and receiving stations to upload the data. It allows the wireless (via WiFi or cellular data) transfer/upload of recorded ECGs for web storage and review by a medical professional on the AliveCor Database.

In the hands of a consumer, the AliveCor Heart Monitor is a real-time heart rate monitor that collects the same clinical quality ECG as in the physician or patient modes, but the ECG data is hidden from the consumer. The ECG is uploaded to the AliveCor website for review by a trained professional.

4.2. User Interaction:

The most common method of using the *AliveCor Heart Monitor* is to hold the device such that the users left and right hands are in contact with the left and right electrodes on the back of the device, see Figure 3. The equivalent ECG lead detected and displayed is normal Lead I (left hand minus right hand). By viewing the real-time scrolling ECG display, the physician or patient can experiment to minimize muscle noise and maximize the ECG signal quality. Alternatively, the device may be held directly to the chest for data acquisition, See Figure 4.

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Figure 3: Handheld monitoring

Figure 4: Chest Placement on sternum

For Over-the-Counter consumer, the *AliveECG* app functionality is limited to restrict the user's ability to see the ECG waveform while still providing a tactical and useful experience such as providing a signal quality metric to help ensure a clean signal, visualization of proper ECG acquisition and a BPM measurement as shown below in Figures 5 and 6.

Figure 5: User Interface

Figure 6: ECG Visualization (hiding waveform)

5. OPERATING PRINCIPLE AND DETAILED DESIGN DESCRIPTION:

In layman's terms, the *AliveCor Heart Monitor* wirelessly communicates to the MCP with human-silent, ultra-low power data transmission protocol. It has extremely accurate front end electronics with high resolution analog-to-digital conversion processed by the *AliveECG* App. The MCP provides the computing horsepower for the App to digitally filter the data and process it to create a high resolution human readable ECG strip. The website (AliveCor WebApp) allows access to user data and the ability to edit metadata such as patient name, date-of-birth, comments, etc.

5.1. AliveCor Heart Monitor

5.1.1. Mechanical Configurations

The *AliveCor Heart Monitor's electronics are* configured into several different mechanical constructs or configurations to adapt to different form factors of many MCPs. Each mechanical configuration has identical hardware performance characteristics and they utilize the same materials as defined below.

Figure 7 and 8 show two such mechanical configurations of the *AliveCor Heart Monitor*.

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Figure 7: *AliveCor Heart Monitor* for iPhone 4/4S

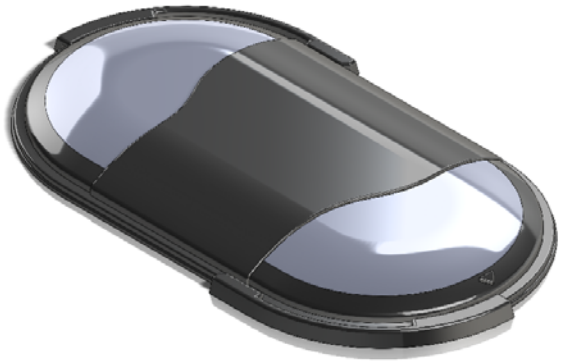

Figure 8: *AliveCor Heart Monitor* for Android

5.1.2. Hardware Functionality

The following is applicable to any mechanical configuration:

There are just two modes of operation for the device, STANDBY and ON. In the STANDBY mode, the electronic circuitry is actively looking for a connection between the electrodes (impedance). When the device detects presence of a conductive path between the electrodes (hands or skin contact), it turns ON and begins to emanate a modulated ultrasonic frequency (inaudible pressure wave) with a piezo oscillator, see Figures 9 and 10. After the electrodes are removed from the conductive path, the device returns to the STANDBY mode.

5.1.3. Hardware Design

(b) (4)

[redacted]

The battery used in each configuration may change due to size restrictions or excess space in a particular mechanical construct, but the battery chemistry will remain as a lithium coin cell, typical of a wrist watch battery. The *AliveCor Heart Monitor* circuit has an “OFF” current drain of less than 1 microamp and an “ON” current drain of 600 microamps. This provides an operating battery life for the ECG acquisition and transmission circuit of no less than 100 hours (6,000 minutes) of use for any mechanical/hardware configuration. At a model of 5 minutes per day of use, the operational battery life (to 83% of capacity) is 1200 days. We conservatively estimate a battery life of 1 years and recommend that the battery be changed at that interval which will provide a large margin of safety.

When the MCP is attached to the *AliveCor Heart Monitor*, the ultrasonic signal level from the device will be much greater than the signal from another reasonably powered acoustic emitter in the same vicinity and the effect on the demodulated ECG signal is negligible. The piezo is specifically located close to the microphone when the MCP is attached the device so that the Signal-to-Noise Ratio (SNR) is high.

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The *AliveCor Heart Monitor* occupies an ambient acoustic environment (18-20 kHz) at least 20-30 dB quieter at than the typical 1500-2000 Hz spectra. This superior signal-to-noise environment holds true in quiet rooms, noisy indoor urban places and inside jets at 35,000 feet while next to a wing-mounted engine.

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(b) (4)

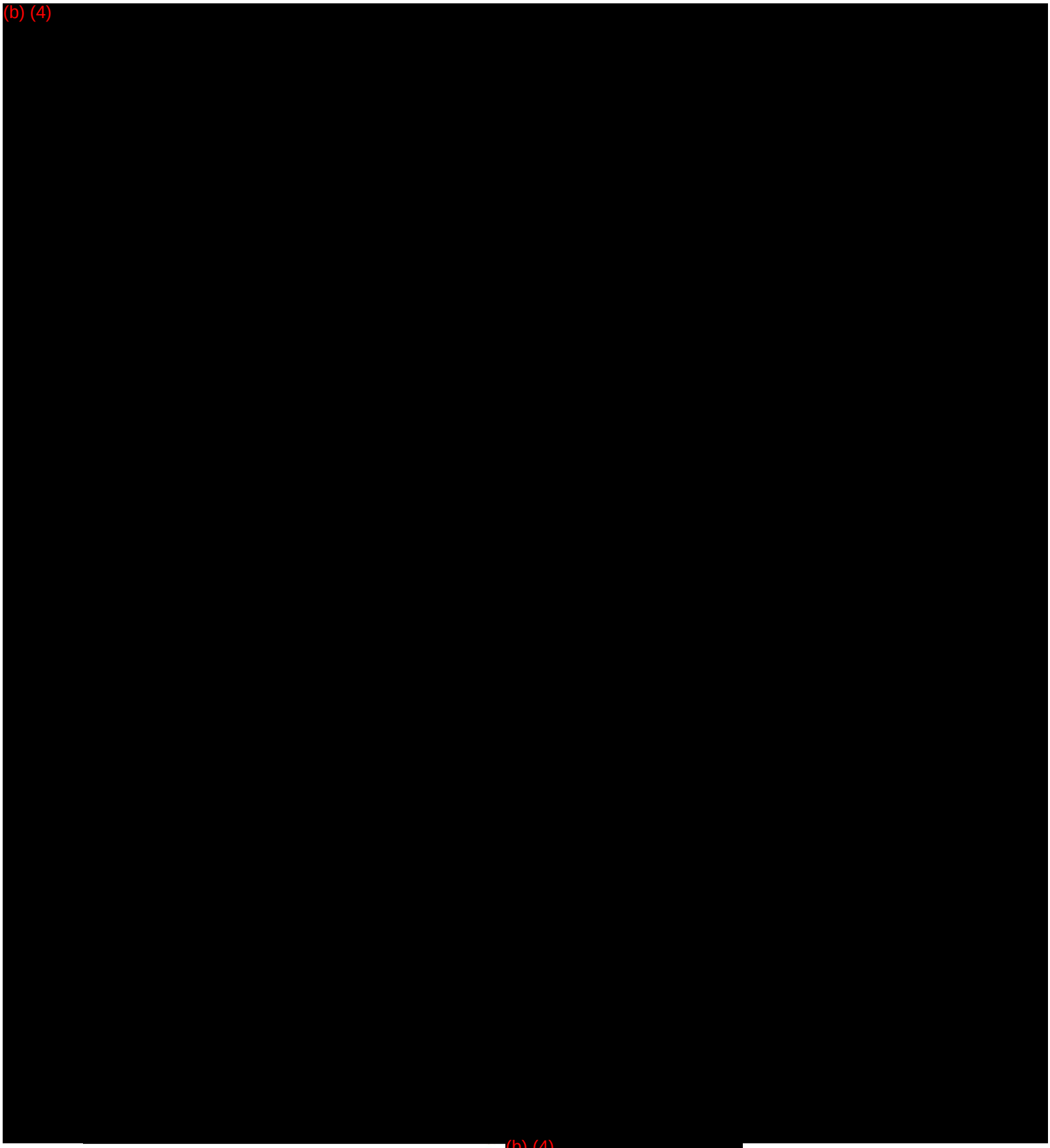

Figure 9: Typical exploded view of the device (b) (4)

Questions? Contact FDA/CDRH/OCE/Director CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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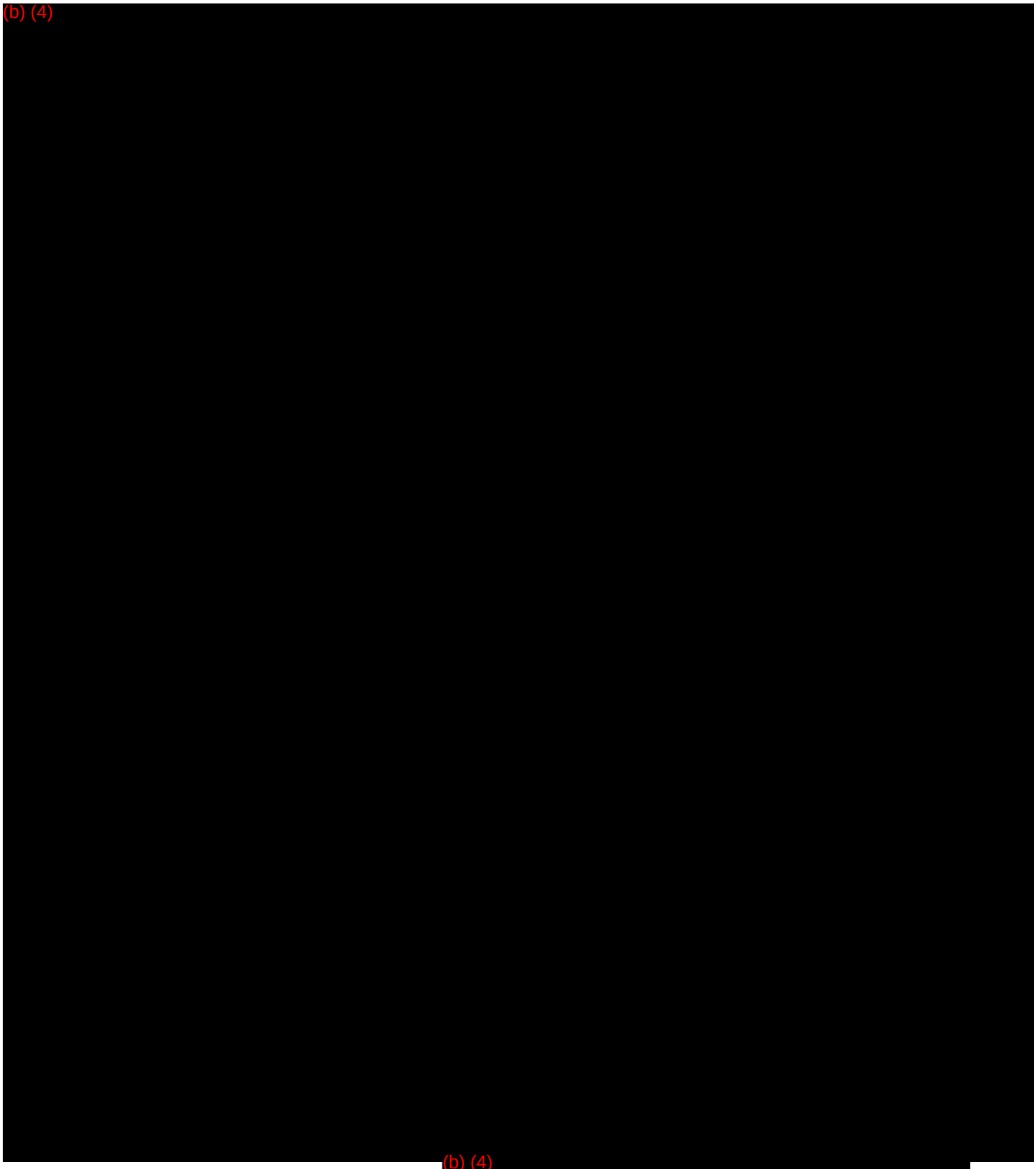
(b) (4)



(b) (4)

Figure 10: Typical exploded view of the device

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AliveCor™

5.2. Mobile Computing Platform (MCP)

The frequency modulated ultrasonic ECG signal is acquired by the built-in microphone on the MCP. The MCP provides the ability to process the data as requested by the App.

Only compatible MCPs may be used with the *AliveCor Heart Monitor* as defined by AliveCor's Mobile Computing Platform Compatibility Chart shown below. Compatible MCPs are state-of-the art, touch interface, typically handheld devices with wireless connectivity to 2G, 3G, 4G, WiFi, Bluetooth and/or GPS radio systems.

5.3. Software Design of the *AliveECG* App

(b) (4)

5.4. AliveCor ECG WebApp

As opposed to entering information on the typically small screens of MCPs, users may find it more useful to enter metadata on any personal computer with web access. Authenticated with a valid login and password, users have the ability to edit existing metadata such as Patient Name, Date of Birth, measurement position, comments, symptoms, etc. that are associated with individual ECG recordings. Additionally, sharing functionality allows physicians to access and view their patients ECG data at any time from a PC terminal.

6. MATERIALS:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the device, touching the stainless steel-electrodes, or replacing the battery.

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Primarily two components of the device may contact skin: the top housing, and more significantly the stainless-steel electrodes. The required biocompatibility tests according to ISO10993-1 were performed to ensure user safety while handling the device for its utility purpose (as an accessory to a MCP), and using the device for its medical purpose.

*The biocompatibility studies are presented in Appendix B and are summarized in Section 15.

The housing material consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages available). Besides passing Biocompatibility testing as required, these materials are commonly used in consumer products that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products.

The electrodes are made from 304SS which is a medical grade stainless-steel. Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

7. MOBILE COMPUTING PLATFORM COMPATIBILITY

In a previous 510(k) submission, we noted:

> *"Future test protocol improvements are underway to expand the potential use of the device to other Smartphone platforms or iOS versions. Deployment of software for other Smartphone platforms will not be launched for commercial distribution until review and clearance by FDA. AliveCor has plans for future regulatory filings that may include specific Android devices, or future iPhone devices that meet necessary acoustic reception requirements for proper functionality with AliveCor's data transmission technology."*

To date, the test methodology/protocol described above has been deployed on the following MCP hardware and operating system (MCP/OS) combinations:

AliveCor's Mobile Computing Platform Compatibility Chart

MCP Version	iOS 5.1	iOS 6.X	Android OS: TBD
iPhone 4 (GSM)	S	S	X
iPhone 4 (CDMA)	S	S	X
iPhone 4S	S	S	X
iPhone 5 (GSM)	X	S	X
iPhone 5 (GSM + CDMA)	X	S	X
iPod touch 4th gen	O	O	X
iPod touch 5th gen	X	O	X
iPad 2	X	O	X
The New iPad (all versions)	X	O	X
Various Android devices: TBD	X	X	O

S = Currently supported MCP/OS by verification and validation testing on file at AliveCor
O = Pending supported MCP/OS
X = Will not be supported or MCP is incompatible with OS

AliveCor intends on providing this compatibility matrix to its users (through our website and other means deemed necessary). Commercialization of the additional MCP/OS combinations will occur

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only after our design control process concludes that the MCP/OS is covered under the scope of this 510(k) and it has passed all applicable verification and validation testing as necessary.

We anticipate that there will be some MCP/OS combinations that will not be compatible with the *AliveCor Heart Monitor*, e.g. the MCP does not have the ability to receive the ultrasonic transmission from the device. To determine this, minimum hardware and software requirements have been defined for the *AliveCor Heart Monitor* family of products.

7.1. Minimum Hardware Requirements:

The MCP must have a built-in microphone capable of receiving ultrasonic acoustics up to 20 kHz. ECG signal is acquired by the built-in microphone on the MCP. The MCP provides the ability to process the data as requested by the App.

Only compatible MCPs may be used with the *AliveCor Heart Monitor* as defined by AliveCor's Mobile Computing Platform Compatibility Chart. Compatible MCPs are state-of-the art, touch interface, typically handheld devices with wireless connectivity to 2G, 3G, WiFi, Bluetooth and/or GPS radio systems.

7.2. Minimum Software Requirements:

To date, we have completed verification testing with our device in conjunction with the iPhone Operation System (iOS) version 5.1 and greater. Additionally, we have verified the Android Operating System version 4.0 and greater. All validated MCP/OS combinations are listed in AliveCor's Mobile Computing Platform Compatibility Chart.

We have verified compatibility and/or modified the *AliveECG* App supported by a letter-to-file within about 10 days of operating system release. We believe this is a sustainable engineering practice and our reaction time will only decrease as we further improve our software V&V and deployment procedures. If we cannot meet those timelines, we believe that sufficient precautions in our labeling (and/or notification within the *AliveECG* App) will appropriately notify our users of the risk of incompatibility with OS upgrades, but we do not feel it is necessary to promote that mitigation at this time based on the severity of the risk.

8. WIRELESS COEXISTENCE

The *AliveCor Heart Monitor* uses non-RF, wireless communication between the hardware and the MCP which allows ECG recording in RF-sensitive environments like in-flight airplanes and ICUs when the MCP is in airplane mode with all radios turned off. Due to the ambulatory nature of the *AliveCor Heart Monitor*, it is highly likely that it will be exposed to wireless communication frequencies and networks. While being exposed to those energies, it is likely that the MCP component of the *AliveCor Heart Monitor* system will attempt data communication, thereby performing a task within the same wireless communication bandwidth. This suggests that evaluation of wireless coexistence is necessary to prove safety and efficacy of the medical device, but it is important to note that the MCP is a component of the *AliveCor Heart Monitor* medical device system and works independently of the medical device hardware produced by AliveCor. The AliveCor hardware does not use RF transmission technology and the *AliveCor Heart Monitor* system works independently of the wireless RF communications on the MCP. The MCP is constantly

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performing wireless communication duties with or without the *AliveCor Heart Monitor* as an attachment. The only wireless function that the MCP performs is data upload to the AliveCor database via the internet. This action is controlled by the MCPs operating system.

The wireless functionality built into the MCP should be exempt from testing for wireless coexistence given it has been issued an FCC certification (compliance to parts 15, 90, 95, and 97 of the FCC rules), Wi-Fi certification, etc. therefore passed all necessary compatibility, immunity, coexistence tests that would be related to this question. The *AliveCor Heart Monitor* components (hardware and App) produced by AliveCor do not alter or affect the wireless communication methods on the MCP, it simply utilizes them to transfer data as any other cell phone or Smartphone does under normal operating conditions.

8.1. Acoustic Data Transmission

The other "wireless" communication is real-time acoustic data transmission from the *AliveCor Heart Monitor* to the MCP microphone. Specifically, wireless coexistence does not apply to the acoustic data transmission techniques used by the *AliveCor Heart Monitor*. Wireless coexistence only applies to radio frequency (RF) data transmission.

Nearly identical to the data transmission techniques used for trans-telephonic ECG event monitors that typically operate with an acoustic center frequency of 1.9kHz, the *AliveCor Heart Monitor* operates at 19kHz. Trans-telephonic data transmission is a well established method with over 25 years of industry use. The majority of manmade equipment operates outside of this ultrasonic frequency range giving the *AliveCor Heart Monitor* a very quiet spectrum to work within. AliveCor has conducted proof of concept evaluations and have shown that 19kHz is approximately 30dB quieter than the 1.9kHz range in "bad" case scenarios as you can see below.

Acoustic spectrum over wing in a 737 airliner directly over wing/engine (note dB level at 1.9kHz is approximately 70dB while 19kHz is approximately 30dB):

Acoustic spectrum over wing in a 737 airliner directly over wing/engine with the AliveCor device activated (note the dramatic spike at 19kHz indicating great signal-to-noise ratio):

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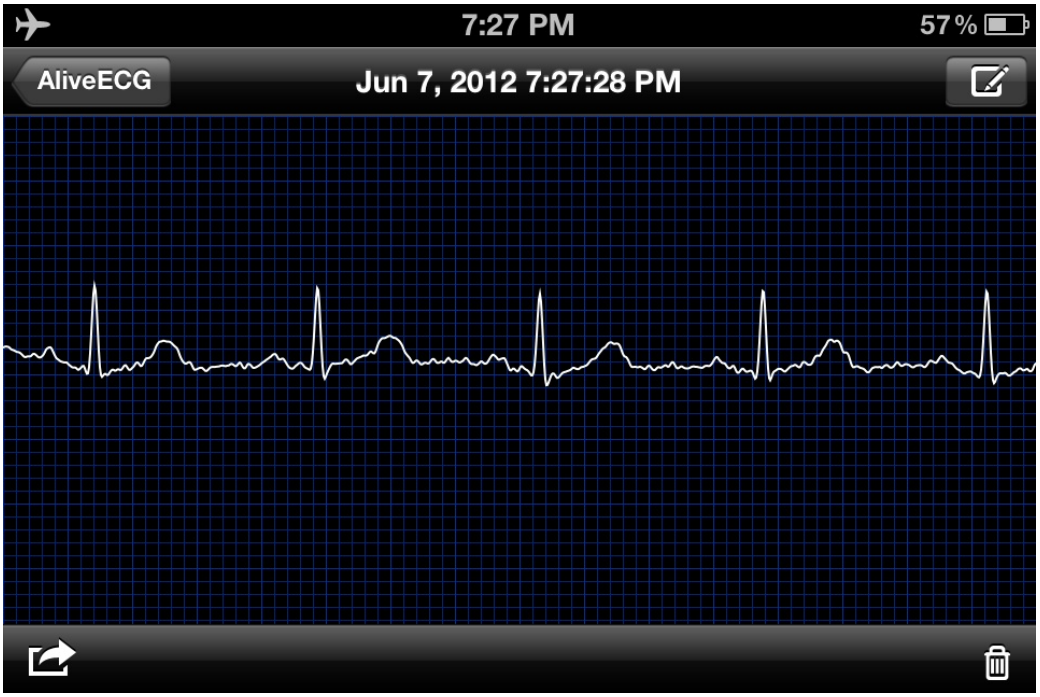
Recording using the *AliveCor Heart Monitor* over wing in a 737 airliner directly over the wing/engine:



As you can see above in the example recording of the *AliveCor Heart Monitor* working in a 737 airliner located directly over the wing/engine, a clean signal can be obtained in contrast to a device with center frequency at 1.9kHz that does not work at all in this noisy location.

The low power acoustic waves that are emitted by the *AliveCor Heart Monitor* travel a very short distance, empirically measured at approximately 1-2 meters, depending on the acoustic environment. It is not likely that the *AliveCor Heart Monitor* will interfere with other equipment operating at that range.

It is more likely that other equipment emit ultrasonic frequencies that may interfere with the Heart Monitor. Experimentation has shown that emission from interfering equipment is typically an unintended consequence of the equipment actions such as high speed motors or pneumatic systems. To mitigate the risk associated with other equipment that emit ultrasonic frequencies in

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the range of 19kHz, a software function during the Audio Acquisition phase analyzes for "noisy" signals, will notify the user of "excessive noise" and will not allow data acquisition. It is unlikely that two or more of the *AliveCor Heart Monitor* would be used in the same vicinity, but this upon this event, the same user notification appears.

The probability of ultrasonic frequency interference risk is at least two orders of magnitude lower than traditional trans-telephonic data transmission techniques used with event monitors today. The *AliveCor Heart Monitor* has a distinct advantage that it will work in the majority of human occupied spaces including airplanes, factories, outdoors, etc. where normal trans-telephonic devices fail to accurately acquire data.

8.2. Interactions with Other Devices on a Wireless Network

As with any device that uses a Smartphone or similar mobile computing platform as a component of a medical device (e.g. IBGstar, CellScope, Withings Blood Pressure Monitor, etc.), there are one or more methods of data communication available (e.g. Wi-Fi, cellular, Bluetooth, Zigbee). Data communication may occur as a result the medical device system, or independent of the medical device such as cellular telecommunications.

Obviously other devices (medical or non-medical) can use the same network as the MCP when it is transmitting data over a Wi-Fi or cellular network. Advancements in technology have mitigated many coexistence and security problems with these network types. AliveCor believes that Wi-Fi and Cellular network data communications are both safe and effective for transmitting data files to the AliveCor database.

8.3. Wireless Communication Restrictions

Another factor associated with using the MCP as a component of the medical device is related to cellular or Wi-Fi restricted environments such as airplanes or other "radio-silent" areas. Unlike other medical devices that rely on RF wireless communications as part of the primary functionality of the device, the *AliveCor Heart Monitor* and MCP as a system do not need RF wireless communications to function. Since the *AliveCor Heart Monitor* does not utilize RF wireless communications as part of its primary functionality, the device still works in the MCP's "Airplane Mode" setting, therefore safe and legal to use in locations where cell phones and other electronic equipment must be deactivated such as on an airplane or in an ICU. Since the microphone still works in Airplane Mode, the App can be used to collect data for upload at another time when Airplane Mode is deactivated. This is an example of the medical device system fully functional without RF wireless communication.

8.4. Wireless Coexistence Testing

No standardized test method has been published, although IEEE1900.2-2008 (Recommended Practice for the Analysis of In-Band and Adjacent Band Interference and Coexistence Between Radio Systems) is commonly referenced as a starting point for coexistence testing and suggests the structure for a coexistence report.

AliveCor is not in a position to provide comprehensive coexistence testing for third party hardware that is a component of the medical device system, therefore, we do not have coexistence testing planned for design verification. If we performed any formalized coexistence testing according to recommendations in IEEE1900.2-2008, it would be far too narrow of a scope to be useful for industry or evaluation of safety and efficacy.

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We intend on relying on industry experts, standards organizations (IEEE), and Smartphone manufacturers (e.g. Apple, Samsung) to maintain wireless compatibility and coexistence protocols and testing. We believe this is a safe assumption given that without proper design and testing of MCPs, a manufacturer's product would not be adopted by the market.

8.5. **Labeling**

AliveCor provides the following precaution in the user manual, "Audio and video products and similar equipment may cause interference. Please stay away from such equipment when you are recording." Additionally, if interference occurs, the in-App notifications (discussed above) end the recording to reduce the risk of erroneous recordings and notify the user.

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9. *ALIVECOR HEART MONITOR* SPECIFICATIONS (TYP.):

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	Lithium Manganese-Dioxide 3V Coin Cell
Battery life	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)	41 grams	128 x 62 x 15 mm
AC-004 with Attachment Plate	27 grams	89 x 50 x 7 mm
AC-004 with Galaxy S4 Case	34 grams	137 x 72 x 16 mm

Environmental Specifications

Operational Temperature	+10 to +45 degrees C
Operational Humidity	10% to 95% (non-condensing)
Operational Altitude	Based on mobile computing platform specifications
Storage Temperature	-20 to +60 degrees C
Storage Humidity	10% to 95% (non-condensing)

Standards Compliance

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

Patient Interface

Two stainless-steel electrodes are exposed on the back of the *AliveCor Heart Monitor*, which are either placed on the patient's chest or connected from left to right hand.

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510(k) PREMARKET NOTIFICATION

SUBSTANTIAL EQUIVALENCE DISCUSSION

1. SUBSTANTIAL EQUIVALENCE STRATEGY

To demonstrate substantial equivalence, two types of analysis are described herein:

- Standards test compliance
- A detailed predicate device comparison based on indications for use, electrical, mechanical and environmental specifications.

Note: The column for the *AliveCor Heart Monitor for iPhone* was retained to describe the changes made between the previously cleared device and the new device intended for use on any mobile computing platform (MCP). Basis for substantial equivalence is still in comparison to the original predicate device (*HeartCheck Pen*). "Same as previous" means there is no difference between the *AliveCor Heart Monitor for iPhone* and the more generic or encompassing *AliveCor Heart Monitor.*

2. CHOICE OF PREDICATE DEVICE

The options for choosing a predicate device for the *AliveCor Heart Monitor* (device) are plentiful. For well over 20 years, ECG event recorders, of both the post event and looping variety, have transmitted real-time and stored ECGs as frequency modulated (FM) audio signals (e.g. Instromedix, Inc. King of Hearts - K880626)

More recently, due to advancements in technology, ambulatory ECG monitors have been iterating to reduce cost and size (e.g. iRhythm Technologies, Inc. Event Card - K081471) while some have increased in complexity an features (CardioNet, Inc. Ambulatory ECG Monitor with Arrhythmia Detection - K093288). A few have tried to simplify the use model for Over-the-Counter use (e.g. Card Guard Scientific Survival, LTD. King of Hearts Express + AF Monitor).

AliveCor, Inc. (AliveCor) chose the *HeartCheck Pen* Handheld Heart Rhythm with GEMS Home (K121009) marketed by CardioComm, Inc. for several reasons.

- The *HeartCheck Pen* has an Over-the-Counter (OTC) indication for use, of which AliveCor believes, after proper validation studies and user interface modifications, our device may be resubmitted to obtain clearance for OTC.
- The *HeartCheck Pen* uses the identical product code (DPS) as the proposed device from AliveCor. This element was not a major factor in this decision, but
- The form factor and use model of the *HeartCheck Pen* is nearly identical to the proposed *AliveCor Heart Monitor*.

Since the original submission, an exceptionally *similar* device from Cardiac Design LLC called the *ECG Check* was cleared for OTC use (K122184), but for simplicity and continuity, the *HeartCheck* Pen remains as the predicated comparison.

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3. STANDARDS COMPLIANCE

In this 510(k) submission, we have shown that proposed device is compliant to AAMI/ANSI EC38:2007. Via compliance with that recognized standard, we claim substantial equivalence by inference, as other devices in this classification should also comply with this standard, or an equivalent, and in particular the predicated device. Although we did not explicitly test the predicate device to EC-38 standards, we can infer substantial equivalence because the predicate device, in order to receive premarket approval, would have to have demonstrated equivalent performance. The same can be said for IEC60601-1 series tests for general safety and particular safety for ambulatory ECG monitors. The predicate device, to have received premarket clearance would have to have shown that it was in compliance with certain safety and electromagnetic compatibility standards.

AliveCor's product requirements specification and verification protocols with associated acceptance criteria require compliance to the stated standards. Each mechanical configuration of the *AliveCor Heart Monitor* will be tested for standards compliance according to the individual design and development plan.

4. PREDICATE DEVICE SPECIFICATION COMPARISONS

The following comparison table delineates the incremental difference between the cleared *HeartCheck Pen* device, and any differences between the original *AliveCor Heart Monitor* ***for iPhone*** and *AliveCor Heart Monitor* devices. The table includes comparisons of the features and specifications of all devices, including electrical, mechanical, anatomical, and environmental characteristics. Any differences between the two designs have been marked with bold.

The discussion below the chart covers the areas in Table 1 where the designs diverge.

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Table 1: Predicate Device Comparison

Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor for iPhone***	***AliveCor Heart Monitor (OTC)***
Indications for Use:	The HeartCheck™ Pen Handheld with GEMS Home software is an **over-the-counter** device intended to record, store, transfer single channel Heart Rhythm signals and, for users under a physician's care, display Heart Rhythm waveforms. The HeartCheck™ Pen Handheld device along with GEMS Home software is not intended to substitute a hospital diagnostic ECG device. The device is not intended for simultaneously recording and transmitting a user's Heart Rhythm. Users with an implanted pacemaker or a defibrillator are not recommended to use this device. GEMS Home is a simple software user interface for managing Heart Rhythm recordings and associated data.	The AliveCor Heart Monitor **for iPhone** is intended for **use by licensed medical professionals** or patients to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.	The AliveCor Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.
Standards: Essential Performance AECG Safety General Safety EMC Safety	 AAMI/ANSI EC38 AAMI/ANSI EC38 IEC 60601-1 IEC 60601-1-2	Same	Same as previous
Data Acquisition: Frequency Response ECG channels Resolution Sample Rate	 **1 Hz** – 40Hz Single Channel Unknown **250** Samples/Second	 **0.5 Hz** – 40 Hz Single Channel 16 bit **300** Samples/Second	Same as previous

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Specification	***HeartCheck Pen* Handheld Heart Rhythm with GEMS Home**	***AliveCor Heart Monitor for iPhone***	***AliveCor Heart Monitor (OTC)***
Memory Capacity:	**20** recordings	Essentially **unlimited** due to real-time transmission to iPhone memory	Same as previous
Device Classification:	DPS: Electrocardiograph	Same	Same as previous
Power Supply: Battery Battery Life (typical)	 **2 AAA batteries** Unknown	 **1 Lithium Manganese Dioxide Coin Cells** 100 hours operational	Same as previous
User Interface: Primary Lead Data upload Software interface	 Lead I, Left to Right Hand **USB** **PC based software**	 Lead I, Left to Right **Ultrasonic acoustics** **iPhone OS based software**	 Same as previous Same as previous **Mobile Computing Platform OS**
Physical Specs: Dimensions, inches Weight	 **130 x 30 x 20 mm** **110 grams**	 **118 x 62 x 16.5 mm** **40 grams**	 **Insignificant variability due to different MCP form factors**
Electrodes: Skin Contact Material	Integrated into device Thumbs (left and right) Stainless Steel	Integrated into device Any part of hand (left to right) Stainless Steel	Same as previous
Lead Wires:	None	None	Same as previous
Where used:	Ambulatory outpatient use	Ambulatory outpatient use	Same as previous
Prescribed:	Over-the-Counter	**Prescription Only**	Over-the-Counter
Environmental: Operating Temp Storage Temp	 **5 to 40 degrees C** **-20 to 55 degrees C**	 **10 to 40 degrees C** **-20 to 60 degrees C**	Same as previous

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4.1. Indications For Use

The modification to the indications for use does not imply a change to the actual indication, but merely clarifies the predicate device indication. Most of the verbiage in the indications for the *HeartCheck Pen* is in AliveCor's opinion warnings/cautions that should be defined elsewhere as it is defined in our product labeling (See Section 13: Proposed Labeling).

4.2. Data Acquisition

The only difference among this group of specifications is that the predicate device has higher bandwidth cutoff at 1 Hz, versus 0.5 Hz for the *AliveCor Heart Monitor*. The *AliveCor Heart Monitor*, along with the majority of ambulatory ECG monitors follow the AAMI low-end bandwidth cutoff of 0.5 Hz. This has proven over the years to be adequate for quality ECG acquisition.

The sampling rate of the *AliveCor Heart Monitor* (300 Hz) is faster than the *HeartCheck Pen* (250 Hz). Faster sampling can potentially provide finer detail in the ECG rhythm strip, therefore the *AliveCor Heart Monitor* is substantially equivalent if not better than the predicate.

4.3. Memory Capacity

The *AliveCor Heart Monitor* transmits ECG data in real-time for storage on the MCP non-volatile flash memory. Storing data on any handheld device is limited by the size of the on-board memory. The *HeartCheck Pen* uses onboard memory whereas the *AliveCor Heart Monitor* utilizes the vast memory capacity of the MCP. This is essentially the same function, although the *AliveCor Heart Monitor* transmits to the MCP before it stores, while the *HeartCheck Pen* stores before it transmits (via USB) only to store the data again on the PC.

4.4. Power Supply

The *AliveCor Heart Monitor* uses a single coin cell type battery, while the *Heart Check Pen* uses 2 AAA type batteries. Both of these batteries and battery chemistries are consumer off-the-shelf type batteries. Essentially there is no difference in power type. Lithium coin cell batteries are widely used in a variety of technologies and do not pose any significant safety hazards.

4.5. User Interface

4.5.1. General

The *HeartCheck Pen* device use a USB cable and PC based software (GEMS Home) to upload, while the *AliveCor Heart Monitor* uses ultrasonic transmission and the MCP Operating System.

The only signification change from the *AliveCor Heart Monitor* ***for iPhone*** to the more general device *AliveCor Heart Monitor* is the inclusion of additional mobile computing platforms. The iPhone 5 is a perfect example of an additional MCP that AliveCor can support with the *AliveCor Heart Monitor* with insignificant changes to the form factor.

The change from a USB cable to real-time acoustic data transmission is logical for this type of device. For well over 20 years, the industry has been sending acoustic ECGs by means of trans-telephonic data transmission (Instromedix, Inc. King of Hearts, iRhythm Technologies, Inc. Event Card, etc.). The *AliveCor Heart Monitor* is essentially performing the same action, but at an inaudible frequency range that the MCP's microphone can receive.

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The GEMS Home software package is comparable to the *AliveECG* mobile application (App). GEMS runs on a PC/Windows based operating system while the App runs on the MCP Operating System (OS). The difference in hardware platform (PC versus MCP) and operating system is not significant as long as the software has been validated for use with the MCP OS, and those elements of the operating system that are utilized for the software are validated for their particular purpose. AliveCor has a strong software V&V protocols for the *AliveECG* App, which is easily ported to test additional operating systems running on the applicable MCP.

Changes in the *AliveCor Heart Monitor* as a system include the addition of AliveCor WebApp functionality to allow the user to login to their account on-line to make changes to metadata associated with the ECG recording. This is in response to a general user need since using the keyboard functionality on the relatively small screen of an MCP is less convenient than a PC keyboard. This is very similar to the functionality of the GEMS Home software bundled with the *HeartCheck Pen*.

Moving the functionality from PC/Windows/software to the *AliveECG* App on a MCP is a logical move to consolidate data handling and transmission. The entire package is in the palm of the user's hand thereby potentially improving efficacy and controlled access to data. AliveCor believes that this logical shift of software platform does not negatively affect the safety or efficacy of ambulatory ECG monitoring in general, and we believe it is substantially equivalent to the predicate device.

4.5.2. Medical Professional and Prescribed Patient

The *AliveECG* App essentially performs the same actions as GEMS Home to upload ECG Data, store it for future access by a medical professional, and generate clinical quality ECG strip reports. As would a physician view the ECG with GEMS software, they can use the App to view recorded ECG rhythms. A significant advantage to the App compared to GEMS is that you do not have to go to a PC station to upload the data to view it. Additionally, the *HeartCheck Pen* can display the ECG data in real-time on a small OLED screen, but the *AliveECG* App allows the ECG to be viewed by a physician directly on the MCP in real-time or retrospectively on a high resolution display.

4.5.3. Health Conscious Individual (Use Over-the-Counter)

Similar to the *HeartCheck Pen*, the *AliveECG* App hides the ECG acquisition screen and the ECG report for consumer use. Additionally, similar to the *HeartCheck Pen*, the *AliveECG* App can be reconfigured for a physician or when an OTC user becomes under the guidance of a physician such as in prescription/clinical service use.

4.6. Physical Specs

Construction materials, size and weight differ slightly between the compared devices, although the general category of materials, size and weight are very comparable. The *AliveCor Heart Monitor* device takes on additional size to function as a MCP case, but significantly reduces the weight due to the lack of hardware technology and batteries needed. Biocompatibility testing of all patient-contact materials has been performed and passed (see Appendix B: Biocompatibility Testing). All further mechanical configurations of the *AliveCor Heart Monitor* family of devices use the exact same materials tested. There are no additional risks associated with the difference in physical specifications that affect the safety or efficacy of the device.

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4.7. Operating Temp / Storage Temp

The upper and lower limits of the operational and storage temperature range are slightly different between devices. This is simply due to a difference in an option selected during the thermal conditioning used during the test. There are no safety or efficacy issues related to this difference in specification.

5. PERFORMANCE EQUIVALENCE TESTING

In addition to Standards test compliance comparison and the detailed specifications comparison, AliveCor has conducted bench testing with the Omron HGC-801 Portable, cordless, single-channel ECG Monitor (K060766). The *HeartCheck Pen* was not available for side-by-side comparison, so the Omron device was used as a qualitative performance comparison. Detailed test data is on file at AliveCor and described in Section 18: Bench Testing.

6. CONCLUSION

Based on the qualitative and quantitative comparative analysis provided here, the proposed *AliveCor Heart Monitor* is found to be substantially equivalent to the predicate device, HeartCheck Pen Handheld Heart Rhythm with GEMS Home marketed by CardioComm, Inc.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PGHSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

PROPOSED LABELING

(In accordance with 21 CFR 807.87e)

1. ALIVECOR HEART MONITOR LABELING

This section contains the AliveCor Heart Monitor labeling for the proposed Over-the-Counter (OTC) indication for use. Included in this section are the following:

- AliveCor Heart Monitor User Manual (OTC)
- AliveCor Heart Monitor Quick Start Guide (OTC)
- AliveCor Heart Monitor Product Box for iPhone 5 (Artwork)
- AliveCor Heart Monitor Product Label for iPhone 5

Typically the Quick Start Guide and User Manual will be updated with the addition of mechanical configurations as presented in this section (iPhone 4/4S and iPhone 5 compatible hardware labeling are combined into a single Quick Start Guide and single User Manual). It is not anticipated that any warnings or precautions will change with the addition of mechanical configurations of the *AliveCor Heart Monitor*. When it makes sense to separate these documents such as with the Universal Module configuration which can be used with either the Apple iOS or Android Operating Systems, the User Manuals will be split to accommodate the inherent differences in the Operating System and its interaction with the *AliveECG* app.

The included *AliveCor Heart Monitor* Product Label for iPhone 5 is presented as an example of the typical changes necessary for the different mechanical configurations of the AliveCor Heart Monitor used for OTC. This example omits the 'Rx Only' symbol due to the change in indications for use to Over-the-Counter.

Over-The-Counter considerations according to 21CFR Part 801.60-62 (Principle Display Panel, Statement of Identity, and Net Quantity of Contents Statement) are incorporated into the above listed labeling.

2. PREDICATE DEVICE LABELING

For comparison purposes, product labeling describing the predicate device is included:

- HeartCheck Pen Handheld ECG Product Brochure
- HeartCheck Pen Product Sell Sheet

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

AliveCor Heart Monitor

User Manual

iPhone® 4/4S/5

OTC

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

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iPhone is a trademark of Apple, Inc., registered in the U.S. and other countries. App Store is a service mark of Apple, Inc.

08LB01 Revision (A) | March 2013

Questions? Contact FDA/CDRH/OCE/Device CDRH-RIGHTSTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/Device CDRH-RGHSTATUS@fda.hhs.gov or 301-796-8118

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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 Heart Monitor is intended to record, display, 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.
- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRAISTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRAISTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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- **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.

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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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PSGSTATUS@fda.hhs.gov or 301-796-8118

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- 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.

Questions? Contact FDA/CDRH/OCE/Device CDRH-PRAISTATUS@fda.hhs.gov or 301-796-8118

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12. 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: • 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 *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 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 *AliveECG* App on your phone. Launch the *AliveECG* 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).

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAGEINSTATUS@fda.hhs.gov or 301-796-8118

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Problem	Solution
I forgot my password and I'm unable to reset it.	Ensure that you've downloaded the *AliveECG* App on your phone. Similarly, ensure that you are logging into www.alivecor.com (not www.alivecorvet.com). 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.

Questions? Contact FDA/CDRH/OCE Section at CDRH-PAGIS-STATUS@fda.hhs.gov or 301-796-8118

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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 ..... 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 ..... iPhone® 4/4S CR2016, iPhone® 5 CR2025 3V Coin Cell
Battery life ..... 100 Hours 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	

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.

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAGE1STATUS@fda.hhs.gov or 301-796-8118

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14. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

www.alivecor.com

15. EUROPEAN AUTHORIZED REPRESENTATIVE

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAGIS-STATUS@fda.hhs.gov or 301-796-8118

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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	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	

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118

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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.			

Questions? Contact FDA/CDRH/OCE Section at CDRH-EASTATUS@fda.hhs.gov or 301-796-8118

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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** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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.			

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EUA-STATUS@fda.hhs.gov or 301-796-8118

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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.

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EUSTATUS@fda.hhs.gov or 301-796-8118

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17. 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

Questions? Contact FDA/CDRH/OCE Section at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG for iPhone 5 Quick Start Guide, OTC
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Change History

Revision	Date	Description of Change	Author
A	March 26, 2013	Initial Release, modifications to 08LB02 for OTC	Michael Righter

Note: The following body of text may be translated, reformatted or otherwise adjusted to meet the needs of the particular application displaying the information (*e.g.* website, mobile application, etc.). The text (copy) should not be modified upon adjustment. Only numbers of headings, bullets, hyperlinks, color and other non-content related format may change.

Questions? Contact FDA/CDRH/OCE/Section 513 at 301-796-5500 or DEVICESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

Heart Monitor

Quick Start Guide

for iPhone® 4/4S or 5

NOTE: For the most up-to-date information on your product please visit www.alivecor.com/manuals

For more info visit AliveCor.com or follow us on Facebook at Facebook.com/AliveCor or Twitter @AliveCor

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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.

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- Request analysis by a medical professional.

1.1. Indications for Use

The Heart Monitor is intended to record, display, 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.
- 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,

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- 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.

Questions? Contact FDA/CDRH/OCE/Section 513 at 301-796-5640 or STATUS@fda.hhs.gov or 301-796-8118

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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.

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

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. LIMITED WARRANTY AND RETURNS POLICY

This Limited Warranty and Returns Policy ("Limited Warranty") applies to AliveCor Heart Monitor (the "Product") and is given by AliveCor, Inc., to the individual or entity (the "Owner") who purchased the Product from AliveCor or an AliveCor authorized dealer. This Limited Warranty applies only within the United States, European Union and within countries of the European Free Trade Association where the products are available for sale to customers located in such countries, and is not transferable.

14-DAY RETURN POLICY

If you purchased the Product directly from AliveCor or an AliveCor authorized dealer, you may return the Product within 14 days of receiving it. In order for a refund under this Returns Policy to be granted, you must request a Return Merchandise Authorization (RMA) number from AliveCor during the 14-day period following the date you received the Product from AliveCor or an authorized dealer. You may request an RMA number by submitting a request at https://support.alivecor.com. If the Product is returned in accordance with this Returns Policy, AliveCor will credit the account you used to make the original purchase with the full purchase price

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you paid for the Product and any applicable taxes minus any shipping and handling charges you paid when you purchased the Product. The time to credit your account may vary, depending on processing time. Please allow a minimum of 4 weeks for AliveCor to credit the account used to make the original purchase. If you received a damaged Product directly from AliveCor, please contact AliveCor's Customer Service at https://support.alivecor.com. If you purchased the Product from a retailer or distributor other than AliveCor, please contact that retailer or distributor regarding non-warranty returns.

MANUFACTURER'S LIMITED WARRANTY

AliveCor warrants to the Owner that the Product will materially conform to its published specifications and be free from defects in materials and workmanship under normal use for a period of ONE YEAR commencing on the date of delivery (the "Warranty Period"). If the Product proves defective during the Warranty Period, we would ask you to follow the instructions set out below for returning the Product, and AliveCor will take one of the following actions: (i) replace the Product with a product that is the same or equivalent to the Product you purchased: (ii) repair the Product; or (iii) refund to you the whole or part of the purchase price of the Product. A repaired or replacement Product or part assumes the remaining warranty of the original Product, or 30 days from the date of replacement or repair, whichever is longer. If AliveCor determines that a returned Product is irreparable, AliveCor will not return that Product to Owner and that Product becomes the property of AliveCor. AliveCor reserves the right to either replace any discontinued Product with a new product of comparable value and function, or to refund the purchase price paid for the Product by Owner.

HOW TO OBTAIN WARRANTY SERVICE

To obtain warranty service, please follow the instructions found at http://www.alivecor.com/warranty. If AliveCor determines that a Product is eligible for warranty service, AliveCor shall bear the costs associated with returning a Product for warranty service. AliveCor is not responsible for items damaged or lost in transit. A replacement Product provided under this Limited Warranty will only be dispatched to addresses within the United States, European Union and addresses within countries of the European Free Trade Association where the Product is available for sale to customers in such countries.

WHAT IS NOT COVERED?

This Limited Warranty will be void if the Product: (a) is used in any manner that is inconsistent with the intended purpose or design of the Product as described in AliveCor's published documentation for the Product, (b) is altered in any way, (c) the Product is used or maintained in any manner that is inconsistent with AliveCor's instructions or warnings included with the Product or (d) the Product is subjected to any other misuse, abuse, neglect, accident, or external forces. This Limited Warranty does not cover normal wear and tear (including, without limitation wear and tear of the display screen). AliveCor does not warrant that the operation of the Product will be uninterrupted or error-free. To the greatest extent permitted by applicable law, the warranties set forth in this Limited Warranty are exclusive and in lieu of all other warranties, express or implied.

LIMITATION OF REMEDIES

Resellers, agents, or employees of AliveCor are not authorized to make any modification, extension, or addition to this Limited Warranty. This Limited Warranty replaces all other AliveCor warranties and liabilities whether oral, written, (non-mandatory) statutory, contractual in tort or

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otherwise, including without limitation, and where permitted by applicable law, any implied conditions, warranties or other terms as to satisfactory quality or fitness for purpose. To the extent permitted by applicable law, AliveCor does not assume any liability for loss of or damage to or corruption of data, for any loss of profit, loss of use of Products or functionality, loss of business, loss of contracts, loss of revenues or loss of anticipated savings, increased costs or expenses or for any indirect loss or damage, consequential loss or damage or special loss or damage. To the extent permitted by applicable law, AliveCor's liability shall be limited to the purchase value of the Product.

OTHER IMPORTANT NOTICES

The rights provided to you under this Limited Warranty are provided in addition to all rights and remedies conveyed to you by consumer protection laws and do not affect your legal (statutory) rights under your applicable national law. This Limited Warranty is offered subject to AliveCor's Heart Monitor Terms and Conditions, which may change from time to time. You can find the latest version on our website at: http://www.alivecor.com/tos or by contacting us directly at support@alivecor.com. In the case of any inconsistencies between the Terms and Conditions and this Limited Warranty, this Limited Warranty will prevail. This Limited Warranty does not apply to any Apple iPhone or the cellular and/or other network or system on which the Product operates. Therefore, AliveCor will not accept any responsibility under this Limited Warranty for the operation, availability, coverage, services or range of the cellular or other network or system. Always completely follow safety, use, operation, and maintenance instructions for the Product or any other AliveCor product. Please remember to make back-up copies or keep written records of all important content and data stored in your Product, because content and data may be lost during repair or replacement of the Product. AliveCor, shall not under any circumstance be liable either expressly or impliedly, for any damages or losses of any kind whatsoever resulting from loss of, damage to, or corruption of, content or data during repair or replacement of the Product.

European Authorised Representative:

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

Manufactured for:

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

08LB04 Revision A | March 2013

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AliveCor™

AliveCor™

Heart Monitor

ECG EVENT RECORDER

AliveCor.com
Compatible With iPhone® 5

iPhone not included.

AliveCor™

Heart Monitor

ECG EVENT RECORDER

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AliveCor™

AliveCor.com

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App Store is a service mark of Apple, Inc.

Contents: (1) Heart Monitor and (1) Quick Start Guide

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Heart Check™

New to the consumer market: The HeartCheck™

PEN Handheld ECG

with Smart Monitoring ~ Powered by CardioComm Solutions, Inc.

Recommended by the FOUNDATION FOR MEDICAL EDUCATION AND RESEARCH

*Unlocked view

Putting your heart health in your hands

Research has shown that regular ECG-based heart screening significantly reduces the risk of sudden cardiac death. Source: JAMA 2006 and Circulation 2012.

Using the HeartCheck™ PEN ECG device, you can now take heart readings the moment a symptom is felt. Whether at home, the gym, or at the office, the HeartCheck™ PEN is portable, easy to use, and takes accurate heart readings that can later be shared with a physician or HeartCheck™ ECG Coordinating Centre. Until now, monitoring this comprehensive would usually require a lengthy visit to a family physician or hospital.

With HeartCheck™ SMART Monitoring, you can enjoy the peace of mind of having your heart rhythm analyzed and interpreted by a physician, HeartCheck™ ECG Coordinating Centre, or both, at any time from anywhere in the world with an internet connection*

* The free GEMSTM Home software will need to be installed in order to upload your heart rhythm files containing your ECGs.

The first FDA-Cleared device that can be unlocked to allow consumers and patients to view and print their own ECGs.*

With the HeartCheck™ PEN device, it only takes 30 seconds to take a heart reading and the device can store up to 20 heart rhythms. Using a USB cable, simply connect the device to your PC and run the free GEMS™ Home software to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, can instantly view and analyze the results of your ECG and heart rhythm. This allows the physician or Coordinating Centre to identify any potential issues and provide the appropriate response.

for more information contact us today at

1 (877) 977.9425 or visit www.theheartcheck.com

how it works:

step 1 Using the HeartCheck™ PEN device, simply take heart readings the moment you feel any symptoms.

step 2 Using the USB cable provided, connect the device to your PC and run GEMS™ Home to upload your heart rhythm files containing your ECGs to a physician or HeartCheck™ ECG Coordinating Centre.

step 3 Once uploaded, a physician, HeartCheck™ ECG Coordinating Centre, or both, will view and analyze the results of your ECG and heart rhythms.

step 4 The HeartCheck™ ECG Coordinating Centre or physician will create an ECG report on your heart analysis identifying any potential issues.

The report will be made available on your PC through the GEMS™ Home application.

HeartCheck™ PEN Device

- ✓ *Cleared by the Food and Drug Administration (FDA)*
- ✓ *Easy to use*
- ✓ *Accurate heart readings in only 30 seconds*
- ✓ *Store up to 20 heart rhythms*
- ✓ ***Unlock the PEN to view and print your own ECGs****
- ✓ ***With SMART Monitoring, ECGs can be monitored remotely by a physician, clinic, or ECG coordinating centre****

* The HeartCheck PEN Handheld ECG can be unlocked to display your ECG waveform by CardioComm Solutions, Inc. under the direction of a physician.

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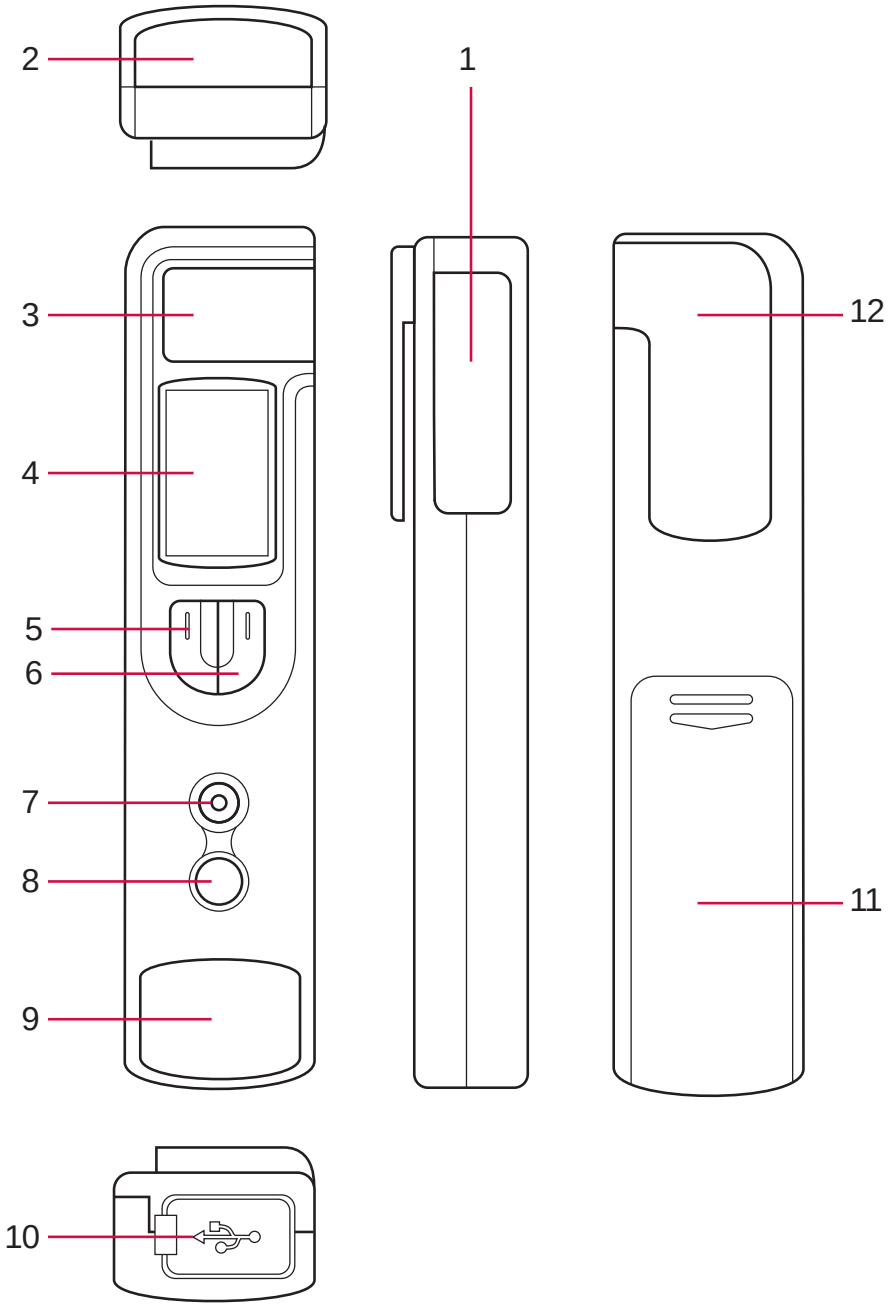
Heart Check™

The HeartCheck™ Pen Device

Specifications

Powered by CardioComm Solutions, Inc.



* The HeartCheck heart rhythm monitor can be unlocked by CardioComm Solutions, Inc under the direction of a physician. Visit www.theheartcheck.com for details.

1. Right index finger electrode
2. Left index finger electrode
3. Right thumb electrode
4. Display screen
5. Scroll right button
6. Scroll left button
7. Power / Select button: Use this button to power on the device and/or select a menu item from the display screen
8. Start button: Use this button to start taking a heart measurement
9. Left thumb electrode
10. USB Port: Plug USB cable into this port to connect device to PC
11. Battery cover
12. Clip

Mechanical Specfications

Lenght:	130mm
Width:	30mm
Height:	20mm
Weight:	110g (with batteries)

Technical Specfications

Lead Position:	Lead I - Hand lead only
Sampling Rate:	250Hz
Measuring Range:	30bpm - 240 bpm
Heart Rhythm Bandwidth:	1Hz - 40 Hz
Measuring Accuracy:	30 - 100bpm: ± 2bpm
	101 - 240bpm: ± 4bpm

Display

Display screen type:	OLED
Parameter:	Heart Rate
	* ECG option available when unlocked

Environmental Requirements

Operating temperature:	5°C - 40°C
Storage temperature:	-20°C - 55°C
Operating humidity:	≤80%, no condensation
Storage humidity:	≤90%, no condensation
Atmospheric pressure:	80kPa - 106kPa

Power Supply

Batteries:	2 AAA Alkaline batteries
Protection type:	Internally powered equipment
Degree of protection:	CF Type
Safety:	IEC 60601-1

Accessories

Standard Accessories:	2 x AAA Alkaline batteries
	1 x Instruction Manual
	1 x Quick Operation Guide
	1 x Warranty Card
	1 x USB cable
	Data Management Software

for more information contact us today at

1 (877) 977.9425

or visit www.theheartcheck.com

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the all new

Heart Check Pen 10

CardioComm Solution's new handheld Heart Check™ Pen gives you the benefit of quickly measuring your heart rhythm in just 30 seconds

- ✓ Very compact, portable and easy to operate
- ✓ Simply place your thumbs and index finger on the Heart Check™ Pen to see your heart rhythm
- ✓ 5 inches/130 mm in length and weighs only 3.8 oz/110 grams
- ✓ Saves 20 recordings of heart rate, data analysis and ECG
- ✓ Fast measurements in just 30 seconds
- ✓ Measure, record, and save or delete ECG waveform and Heart Rate
- ✓ Completely cable free
- ✓ Auto power-off
- ✓ Powered by two AAA batteries
- ✓ Transmit data to management software by USB cable

Heart Check

handheld ECG monitors

For more information contact:

CardioComm Solutions, Inc.

259 Yorkland Road, Suite 200
North York, Ontario M2J 0B5

Toll Free **1 (877) 977.9425**
Fax **1 (866) 576.4493**

email: **sales@cardiocommsolutions.com**

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

STERILIZATION AND SHELF LIFE

The *AliveCor Heart Monitor* is provided non-sterile but assembled and packaged in a clean environment to eliminate particulate contamination. AliveCor's Quality System and supplier management system ensure adherence to proper manufacturing conditions for the device. The *AliveCor Heart Monitor* has no sterilization requirements.

Officially, verification testing was performed at time-zero product with fresh batteries. Verification testing has been completed following standard environmental preconditioning and transit testing. This evaluation yielded passing results and showed the *AliveCor Heart Monitor* meets and exceeds all stated product requirements and that it conforms to applicable industry standards.

Additionally, battery testing and analysis was performed and proved that the device has a minimum operating time of 100 hours per the device specifications as defined in the Section 11 – Device Description. There are no critical device functions that deteriorate over time other than the battery life. The battery is a lithium coin cell that is commonly used in wrist watches and other miniature electronic equipment. The battery in the device is replaceable, and is readily available at retail/grocery stores that carry batteries. AliveCor has retention samples that are planned for use for real-time shelf life testing.

Note: At this time AliveCor does not believe there is a reasonable shelf life limitation for the device. If a shelf life limitation is identified, AliveCor has unit level traceability that will allow us to retrieve expiring product. Subsequently, all further shipped product would be assigned an expiration date.

All results related to shelf life testing for the *AliveCor Heart Monitor* can be found in the *ECG for iPhone Human Test Protocol, Systems Integration* (02VEP2) and associated report (02VER2), on file at AliveCor.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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510(k) PREMARKET NOTIFICATION

BIOCOMPATIBILITY ASSESSMENT

1. INTRODUCTION:

Both incidental and intended contact will occur by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the device or the stainless-steel electrodes.

The biocompatibility assessment for the *AliveCor Heart Monitor* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the device for its utility purpose (as a mobile device case or component thereof), and using the device for its medical purpose. All testing was performed by a certified laboratory, using ISO-10993 guidelines.

2. DEVICE MATERIALS TESTED:

Primarily two components of the device may contact skin: the plastic housing, and more significantly the stainless-steel electrodes. Currently all mechanical configurations of the *AliveCor Heart Monitor* are constructed differently than the predicate device; however, the primary patient-contact materials, are generally the same.

- The plastic housing components consists of Bayblend T85 (PC/ABS blend) and Huntsman Avalon 75AB thermoplastic polyurethane (specification pages attached). **(continuous contact)**

  Besides passing Biocompatibility testing as required, these materials are commonly used in consumer materials that are routinely handled by people without negative implications. They are generally considered safe by industry for consumer products including a primary use for Smartphone cases.

- The electrodes are made from 304SS which is a medical grade stainless-steel. **(continuous contact)**

Again, besides passing biocompatibility testing as required, this grade of stainless-steel is commonly used as a food grade processing material, mucous-membrane contact in medical device instrumentation, etc.

Samples were constructed to include all materials from all parts of the device that may contact the patient, including incidental contact. The *AliveCor Heart Monitor* Biocompatibility Test Sample drawings and specifications for material composition used in these test samples can be found in Appendix B – Biocompatibility Reports.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

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3. TEST METHODS:

To assess biocompatibility, the proposed patient-contact materials were subjected to the three standard tests for biocompatibility of medical devices for non-invasive long term wear (up to 30 days) on skin, as outlined in ISO 10993-1. These three tests were Cytotoxicity (MTT Method), Irritation (Animal intracutaneous reactivity test by means of polar extract), and Sensitization (GPMT), and were conducted by the Testing Center of Sanitation & Environment Technology Institute, Soochow University.

All three tests passed. See Appendix B – Biocompatibility Reports for the full test reports.

- The MTT Method Cytotoxicity test passed with a viability reduced to 81.7% minimum of all the samples where a passing viability is 70% or more. Under the conditions of this study, the test article did not show toxicity to L-929 cells.
- The Skin Irritation Test, conducted per ISO 10993-10:2010, passed with a Primary Irritation index of 0.0, where a score of 2 or greater is considered failing. The irritation response category for the test article was classified as slight.
- The Guinea pig maximization test (GPMT) Hypersensitivity, conducted per ISO 10993-10:2010, passed with the conclusion that no sensitization potential was observed.

AliveCor believes that the patient-contact materials proposed for use in the *AliveCor Heart Monitor* meet the requirements for biocompatibility and can therefore be safely used in the proposed application.

4. SCOPE:

All additional mechanical constructs of the *AliveCor Heart Monitor* intended to fit different form factors of various mobile computing platforms use the same materials tested in the reports listed above. According to FDA 510(k) memorandum #K97-1 (*Deciding when to Submit a 510(k) for a Change to an Existing Device*), any change to materials that requires retesting per ISO 10993-1 would require a new 510(k) and is not covered under the scope of this 510(k). AliveCor will not commercialize any mechanical construct without proper biocompatibility evaluation per 10993 and necessary clearance by FDA.

Questions? Contact FDA/CDRH/OCE/Director CDRH-PRAISTATUS@fda.hhs.gov or 301-796-8118

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510(k) PREMARKET NOTIFICATION

SOFTWARE

1. SOFTWARE – LEVEL OF CONCERN

Using methods described in the *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, issued by FDA on: May 11, 2005, AliveCor, Inc. (AliveCor) has made the determination from the decision tree and tables that the Level of Concern is Moderate because malfunction or latent design flaws could lead to erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury of the patient. See document 01DES1 - ECG for iPhone Design Description, Software, attached to this section.

The Moderate Level of Concern determination is consistent with our understanding of most if not all other ambulatory ECG Event Recorders on the market.

2. SOFTWARE REQUIREMENTS SPECIFICATION

Specific software requirements have been defined for the *AliveCor Heart Monitor*. Requirements are documented in 02REQ3 - ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS and 04REQ1 - ECG Website Human Design Input-Output Matrix on-file at AliveCor and attached to this section.

Note that "ECG for iPhone" is an internal project name while the "*AliveCor Heart Monitor*" is the proprietary product name. For all intents and purposes, these terms are equivalent.

3. SOFTWARE DESCRIPTION

An extensive description of the software written for the *AliveECG* App and applicable portions of the AliveCor Web Application (WebApp) can be found in the Software Design Description. See document 01DES1 - ECG for iPhone Design Description, Software, attached to this section.

Note that the majority of functionality of the WebApp is defined as a Medical Device Data System (MDDS) since it simply transfers and stores data on AliveCor servers. MDDS functionality is not described fully in the Software Design Description nor covered in this section since it is Class I medical device. The only elements of the WebApp covered here are those related to the *AliveCor Heart Monitor* as a system, e.g. the ability to modify metadata associated with an ECG recording just as the user can do on the AliveECG mobile application.

The description includes an architecture design chart, identifies key modules with description of functionality, security design, user interface, other design features and a discussion of the software development environment, and implementation/deployment methods. Although not required for Moderate Level concern software, AliveCor chose to provide this as it is meets many of the content requirements for this section.

4. SOFTWARE HAZARD ANALYSIS

Software Hazard Analysis is covered as part of the overall risk assessment. See Appendix A of this submission for the ECG for iPhone Risk Assessment and Hazard Analysis.

Questions? Contact FDA/CDRH/OCE/Director at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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5. DESIGN VERIFICATION AND VALIDATION

The ECG for iPhone Design and Development Plan outlines and provides traceability for the necessary design verification and validation activities. These activities include evaluation of the device for its intended uses and validation of the end-to-end, manufacturing-to-patient flow. These protocols include validating elements of the software that cannot be verified. This process is part of Design Control and reviewed at scheduled Design Review Meetings. See Section 21 for conformance to Design Controls.

6. SOFTWARE VERIFICATION AND VALIDATION

In addition to the general verification activities for User Needs and System Level Requirements, specific protocols are in place for verifying elements of the software that can be demonstrated by test or inspection, on file at AliveCor and listed in Section 21.

Custom software is validated during design validation (system level evaluation) – refer to 02VAP1 - ECG for iPhone Human Validation Protocol and 02VAR1 - ECG for iPhone Human Validation Report noted in Section 21. Off-the-shelf software is validated independently of the design validation. Each software package/module used in the device, used during design verification, or used as a development tool have been validated according to AliveCor's Quality Management System requirements for Software Validation. Reports are on file at AliveCor.

7. TRACEABILITY ANALYSIS

Each software requirement in 02REQ3 - ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS and 04REQ1 - ECG Website Human Design Input-Output Matrix correlates to a verification method and result listed within that document. See Section 21 for a complete list of related Design Control documents.

8. CHANGE CONTROL AND CONFIGURATION MANAGEMENT

AliveCor Inc. has established procedures for Design Control including software design and development. The Design Control Procedures follow a phased approach to development. The Software Design and Development procedure also defines the practices in place following commercialization under maintenance activities.

All design documents are considered controlled documents and thereby undergo review and approval prior to release. In the same way, software code is controlled and maintained in a code repository. Any changes made to the code during maintenance are evaluated and a test plan appropriate for the change is defined. Any software bugs or anomalies are logged and evaluate to determine the level of risk posed by the bug. Software releases are approved through technical review, and revision history is tracked and documented by AliveCor's Software Deployment procedures. As appropriate, risk assessment, hazard analysis, design requirements, verification plans and other necessary design control documentation will be revised with each software release.

Software releases are typically deployed with release notes describing necessary changes to the development environment that may necessitate revalidation of software. Regulatory and Quality sign-off on all official software releases. AliveCor has no control over iPhone Operation System (iOS) releases implemented by Apple for the iPhone, nor do we have much control over our users upgrading their iOS, but we believe we have a comprehensive test protocol to maintain seamless

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PGHSTATUS@fda.hhs.gov or 301-796-8118

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functionality of our software (02VEP1 - ECG for iPhone Human Verification Protocol, iOS Application in Section 21).

Since initial product release, we have responded to three iOS upgrades then justified and documented any changes to the software by means of a letter-to-file (LTF002, LTF003). AliveCor believes that we have adequate response time to mitigate the risk of a user operating the device on unverified operating system. The severity of the risk does not necessitate mitigation but we are developing internal procedures to ensure prompt response to operating system upgrades.

Additionally, this period of time after initial product release allowed us to strengthen our verification protocol with product expansion in-mind. We now believe that our general protocol can easily be adapted to additional mobile computing platforms. The iPhone 5 is the first additional mobile computing platform to be added to the protocol along with other design control documents.

9. SUMMARY OF VERIFICATION RESULTS

The *AliveECG* App has been verified according to the verification plans contained in 02REQ3 - ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS and 04REQ1 - ECG Website Human Design Input-Output Matrix. For a detailed description of verification results, refer to ECG for iPhone Human Verification Report, Systems Integration (02VER2), on file at AliveCor. All tests passed with zero deviations and the specifications have been fully verified. AliveCor believes the test methodology/protocol is strong enough to prove the safety and efficacy of the system.

10. UNRESOLVED ANOMALIES

There are zero open defects for the currently supported mobile computing platforms.

Upon addition of other compatible mobile computing platforms and their associated software operating systems into the *AliveCor Heart Monitor* device family, we expect to identify a multitude of bugs, defects or minor features that are necessary to accommodate the user experience or essential functionality. These cases are entered and tracked within AliveCor's bug tracking system and changes are reviewed and approved through AliveCor's change control system.

11. *ALIVEECG* APP FOR IOS REVISION LEVEL HISTORY

The production revision history for the *AliveECG* App software for iOS is attached. These software releases have been subject to the change control processes described above.

12. *ALIVEECG* APP FOR ANDROID REVISION LEVEL HISTORY

The production revision history for the *AliveECG* App software for Android OS is attached. These software releases have been subject to the change control processes described above.

13. ALIVECOR WEBAPP REVISION LEVEL HISTORY

The production revision history for the AliveCor WebApp software is attached. These software releases have been subject to change control processes described above. The attached list includes all website releases. Only releases affecting MDDS or WebApp (functionality related to the medical device system according to the appropriate input-output matrix) have verification plans and reports assigned in the Quality System.

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: v1.6.2.0
Date: 10/09/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/master' into rc10-09
- fix step definition to fix build
- gotta require spec helper here
- do not send guest recordings to a doctor's inbox
- turn on dashboard cuke
- fix date of birth display in dr. dashboard
- fix bug: last_ecg_taken is off by a few hours
- Added cucumber test for guest recordings in doctor dashboard.
- Marking test as work in progress.
- Added cucumber test for patient details.
- change url for scraped tos
- try to fix tddium build
- increase sleep - attempt to fix flaky test
- Update stats.scss to fix layout problem on the big screen
- Fixed typo for tddium.
- Updated cucucmber config for tddium.
- Merge branch 'master' into jj-ucsf-callback
- Add StudyInvite to StudyShippingAddress
- Explicitly check for enabled afib algorithm service
- Updated cucumber profiles and fixed tddium config typo.
- Updated hooks in tddium config.
- Forgot about actual tddium config.
- Updated config for tddium.
- Minor change to port checking
- Add study app callback url and notification

Release: v1.6.1.0
Date: 10/03/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc10-03' into prod
- update test
- fix bug: last_ecg_take date format is wrong
- fix WEB-291

Release: v1.6.0.2
Date: 10/02/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc10-02' into prod
- Fix structure on recordings.json

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PMASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: v1.6.0.1
Date: 10/02/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc10-02' into prod
- Skip tos check for json requests.
- Fix scripps web scraper when user session expires.
- fix bug: _admin is throwing 500 when not logged in

Release: v1.6.0.0
Date: 09/30/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc09-25' into prod
- Update create_account.html.haml
- update terms of service in join flow
- style admin and modals with bs3
- Fix patient_connections login error
- Moved gems out of assets.
- Merge branch 'master' into jj-ucsf
- Set admin class name to MedicalProfessional
- Merge pull request #32 from alivecor/jg-bootstrap3-upgrade
- delete unnecessary file
- fix borked tests
- update minitron styles
- Restrict medical professionals from study invites
- upgrade to bootstrap3 wip
- Set mobile user agent
- Restrict download and activate links to mobile only
- Rename study user to admin Update study migration
- Add error message on bad request
- Merge remote-tracking branch 'origin/rc09-25'
- Add ability to save shipping address on study invite
- use vcr for terms of service feature
- update controller spec
- fix WEB-287
- change tos iframe url
- fix WEB-289
- Fixed spec
- Check patient_connections before collecting study URLs
- Swap out hard coded link to app store.
- Removing unused spec.
- Add patient connection for study users
- update a spec
- Merge branch 'ao-dashboard-caching' into rc09-25

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PMSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Merge pull request #27 from alivecor/ao-dashboard-caching
- Merge remote-tracking branch 'origin/ao-dashboard-better-query' into rc09-25
- md5 the basic patients cache key
- Merge branch 'master' into ao-dashboard-caching
- Merge pull request #28 from alivecor/ao-dashboard-better-query
- fix n+1 problem in basic_patients endpoint
- Do not mark an invite as used until login
- Merge remote-tracking branch 'origin/master' into rc09-25
- Updated patient factory to create profile as well.
- turn caching on in production
- cache basic_patients json
- remove duplicated includes
- Fix syntax error
- Merge branch 'master' into jj-ucsf
- Merge pull request #25 from alivecor/ao-doctor-dashboard-2
- Added tos page object file.
- Rename afib algorithm service method from 'send' to 'process'
- do not eager load recordings here
- UCSF study invite infrastructure
- return 401's in require_medical_professional
- Added terms of service test.
- move seed data to a rake task
- fix bug in find_by_email method
- change how DEMOGRAPHIC_ATTRS is defined in Patient
- dry up DemographicProfile constants
- switch to a uuid in ConnectionInvitation
- add index to connection_invitations
- remove extra parens
- Added testrail ids to terms of service tests.
- Fixed broken cucumber test.
- refactor patient template by adding null value helper
- add index to inbox_recordings table
- use formatBoolean for smoker
- clean some dead code, created nested if to avoid double call to creatNewMsg
- refactor filter code
- change in responses to pull request comments
- Minor doctor dashboard test refactor.
- lock most gems down
- alphabetize the Gemfile
- fix PGM-25
- Added testrail ids to doctor dashboard tests.
- fix WEB-286
- fix responsive styles
- Return token when deleting a credit card
- fix bug with sending to a patient you're already connected to
- style tos update page
- fix WEB-283
- Merge branch 'master' into ao-doctor-dashboard-2

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

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- Merged recording_inbox and doctor_dashboard tests.
- put request ecg access view in its own file
- fix WEB-284
- add space between original and enhanced links
- fix last failing cuke
- make pending_connections endpoint faster
- fix bug: patient sorting was not handling nil last_ecg_taken correctly
- eager load recording_files in MedPro#inbox_for
- change patient invite to connect succes message
- handle redundant accept connection requests
- update doctor wants to connect email copy
- refactor PatientConnector#accept_connection!
- refactor PatientConnector#invite!
- add icons and new scss
- amend responsive styles
- style accept connection page
- add some comments
- sanitize patient filtering queries
- remove deleted recordings from the dr. dashboard
- fix specs: turn off afib service stuff unless it is under test
- fix a test typo
- terms of service verification does not make sense for api stuff
- Adding konacha gem for js tests.
- remove unneeded medical conditions from UI
- set items per page to 25
- Merge branch 'rp-credit-card'
- patch WEB-277, add units to height and weight
- WEB-270 Made credit card tokens unique in the db
- new feature: terms of service versions
- fix WEB-277
- add active class to sign in and sign up pages
- add handlebars helper
- fix nav style
- add active class to nav
- Enabled cucumber test per WEB-268 fix.
- Fixed incorrect function call.
- fix WEB-267 and WEB-268
- Enabled cucumber test.
- format smoker boolean
- map activity_level float to a descriptive string for UI
- WEB-270 Add credit cards to user profile
- fix WEB-272
- fix WEB-269
- fix WEB-275
- fix WEB-273
- fix must be logged in to accept
- More doctor dashboard tests.
- Minor refactoring to doctor dashboard tests.

Questions? Contact FDA/CDRH/OCE/Det at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- change last_ecg_taken to be more robust
- WEB-271 API endpoints for credit card management
- populate FilterPatientsView with string in params when directly visiting a filtered route
- switch footer icons to icon font
- remove unused footer scss file
- pagination plus sorting - woohoo
- fix bug: patient page should default to page 1 of inbox recordings
- paginate inbox recordings
- remove this cuke again
- add flag sprite
- WEB-270 Add braintree configuration
- Merge branch 'ao-doctor-dashboard-2' of github.com:alivecor/hum-webapp into ao-doctor-dashboard-2
- Merge branch 'master' into ao-doctor-dashboard-2
- make small changes to tables
- add flag icon
- remove unused files
- animate messages in patient connect panel
- change how responses are handled for connecting to patients
- Added first tests for doctor dashboard.
- change invite success text
- finish styling patient lookup area
- finish styling and alerts for patient connection sidebar
- turn pagination links into a component
- first cut at new flagged functionality
- show defaults for patient detail header
- forgot to add text key
- handle bad connection invitation links
- format gender and age display
- fix patient sorting for patients without recordings
- stop requesting BasicPatient model on every keyup
- Merge branch 'master' into jj-afib
- Rename send method to process, updated VCR cassette.
- fix recorded_at date format in json
- change pagination additions to a mixin
- Fix VCR cassettes for zeus
- calculate age based on dob
- correct date of birth time format in patient json
- display medical conditions with proper formatting
- medical conditions wip
- Fix VCR cassettes for Amazon SNS calls
- rename a controller
- load patients in application route
- smarter pagination
- redirect dashboard users to login when their session expires
- Add feature flag to enable/disable afig service
- Rename AfibAlgorithmConnector

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Add ability to push new recordings to afib service
- fix a date format
- implement ability to resend a connection invitation
- sort patients by last ecg taken
- small css fix
- sort inbox recordings by date desc
- messaging for no connected patients and no patient search results
- fix email alert msg, oops
- update email to connect functions
- back to all link style
- small tweaks
- search patients clear button style and behavior
- better patient search
- make patient search case insensitive
- dashboard display tweaks
- add pending connections count to patients view, fix filterPatients so filtered patient search puts you on page one of search
- patient table rows are now clickable
- make things look even prettier
- pagination is looking pretty good, pretty, pretty good
- make patient show page look better, only recordings are bold
- remove legacy stylesheets
- fix test for connecting to patients, other ember additions
- pending connections ember route wip
- back end code to support pending connections
- convert handlebars helper to coffee
- break up model files, convert to coffee
- first cut at adding emblem templates
- fix patients view post adding paging
- first cut at pagination
- make things more coffee-like
- this method needs to return the invitation
- fix bug: pdf is blank (requires underscore)
- show error messages when inviting a patient does not work
- refactor before filters
- rename PatientConnectionToken class to ConnectionInvitation
- mark recordings as read, first cut
- get the patient connection feature working again
- remove title tag from email layout
- fix app create for Em
- remove binding oooooops
- move ember and related scripts to their own file
- fixing up local dev issue
- continue patient search wip
- Revert "change pdf_urls to return an array of hashes"
- Revert "fix variable typo"
- fix variable typo
- fix seeds to associate profiles to patients

Questions? Contact FDA/CDRH/OCE/Director CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- change pdf_urls to return an array of hashes
- add search and clear, pdf display wip
- fix profile getter
- autosave FTW
- fix pdf generation
- fix spec - url changed
- set a default ember variant
- adding search wip
- allow medical_professionals to view patient's recordings
- create more realistic recordings in seeds
- Merge branch 'ao-doctor-dashboard-2' of github.com:alivecor/hum-webapp into ao-doctor-dashboard-2
- remove unnecessary files
- effing merge
- save flagged inbox_recordings, format dates
- show pdf urls in inbox_recording json
- fix for eager loading of profile
- separate dashboard page from json endpoint
- remove instance var and update json specs
- create basic_patients concept for jason
- make last_ecg_taken more performant
- add meta_request so we can use the rails panel extension
- eager load things for better endpoint performance
- show all patient json in patient base rabl
- resolve conflict in rebase
- finishing ember stuff for dashboard wip
- more realistic seed data
- seed 500 patients
- restructure patient show json
- add moment for time formatting
- Merge branch 'ao-doctor-dashboard-2' of github.com:alivecor/hum-webapp into ao-doctor-dashboard-2
- adding ember wip
- update seeds to work with inbox concept
- endpoint for updating inbox recordings
- implement doctor's inbox of recordings
- more json for the doctor dashboard
- fix merge
- ember integration WIP
- change patients json
- add rabl for json serialization
- make dr/patient connection more secure
- wip on connecting doctors to patients

Release: v1.5.5.0
Date: 09/09/2013
Site: app.alivecor.com, eu.alivecor.com

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Merge remote-tracking branch 'origin/rc09-04' into prod
- fix whitespace for names in ECG table
- fix WEB-266
- Merge branch 'master' into rc09-04
- Merge branch 'rc08-26'
- Extract public_id functionality into a module
- Added tests for type.
- Fixed typo in spec.
- Refactored unit tests.
- Allow only one user token per device.
- WEB-264: Show original if enhanced isn't available
- Skip verify_auth on destroy.
- WEB-263: Remove deleted recordings from stats
- Merge branch 'master' into jj-push-notifications
- Improved organization and readability.
- Merge pull request #21 from alivecor/ao-set-user-type-again
- modify set_type rake task to ensure that all users get a type set
- Add push notification job and call from overread
- Add Amazon SNS config settings
- Fixed vcr config for cucumber.
- Added tests for insights data.
- fix regression bug in insights data
- Add amazon sns spec
- Add push notification method. Fix missing method attribute.
- Add VCR matcher on uri
- New endpoint for saving device tokens.
- Fixed useless test.
- fix empty insights_data bug
- Merge branch 'rp-stats-page'
- WEB-255: Remove protocol from font to support https
- WEB-255: Remove irrelevant test
- WEB-255: Make it easy to change timeout on client
- WEB-255: Remove octopus, it causes zeus errors
- WEB-255: Fix scale on total recordings days graph
- WEB-255: Update settings to match actual protocols
- Add stats to the asset pipeline
- WEB-255: Change octopus to fix db:test:prepare
- allow text wrapping for names in ECG table
- Dump actual structure
- Merge pull request #13 from alivecor/ao-remove-spork
- add one style tweak
- fix styling for large words
- large stats page done for now
- Allow requests to testrail in cucumber not rspec
- Allow cucumber to make calls to testrail
- remove spork
- WEB-254: Change default_filter default to enhanced

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Merge branch 'rp-stats-page' of github.com:alivecor/hum-webapp into rp-stats-page
- large stat styling wip
- WEB-255: Fix week range on stats
- WEB-255: Change stats refresh rate
- WEB-255: Add EU to stats page
- WEB-255: Use follower for stats, add dow stats
- WEB-255: Add octopus for follower DB access
- WEB-251: Add support for atc version 4
- Merge branch 'rp-withings'
- fix build
- Merge pull request #9 from alivecor/ao-guest-flag
- change default - assume recordings are non-guest
- WEB-252: Add ability to connect with withings
- Setup better errors for the VM
- WEB-252: Add vcr to tests
- WEB-252: Add and upgrade gems
- start tracking if recording is from a guest
- Merge pull request #8 from alivecor/jj-insights
- Remove unused query.
- Revert date range to 3 days.
- remove log statement
- OK, finally got this right
- better check for the one data point case in the block that writes labels
- deal with null case and case with one data point
- Move HR trending stats to Patient class.
- move insights js to its own file
- first cut at insights graph
- insights chart WIP update
- Add trending heart rate method
- Merge branch 'jj-insights' of github.com:alivecor/hum-webapp into jj-insights
- insights chart WIP
- Add method to get minimum heart rate
- Add methods to calculate avg and max heart rate
- WEB-247: Fix server exception on missing user
- Merge pull request #7 from alivecor/ao-patients-doctors-sti
- remove circular reference from the User class
- Preload recording associations.
- delete erb file
- update remaining templates to current styling
- store profile_type to class mapping in a constant
- make init_user and init_profile private
- rename Doctor to MedicalProfessional
- break this into 2 lines
- rake task to update users to set new type column
- test profile_type getter on patient/doctor
- stop setting profile_type in signup
- use STI to define Patient and Doctor classes

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- use rails hash extension - slice
- Update json to include recording metadata.
- Add JSON response to RecordingsController#index
- Forgot to include some globals.
- Updated testrail formatter.
- WEB-246: Fix scale on inverted ECGs
- remove validation that requires country on user
- Add YAP (Yet Another Preamble)
- Add tos and privacy preamble.
- Added gems and config to speed up deploys on staging.
- Added ability to take screenshots.
- Refactored signup cucumber tests.
- Add down method to migration
- Merge remote-tracking branch 'origin/rc07-17'
- Add messages for oauth subscription errors

Release: v1.5.4.0
Date: 08/27/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc08-26' into prod
- Merge branch 'rp-stats-dow-fix' into rc08-26
- Changed backgroud of stats boxes
- update stats styles for better readability
- WEB-262: Remove defaults for gain and paper speed
- WEB-262: Fix paper speed in PDF generation
- Add fill and font size on day of week labels
- Change day of week to be in PST instead of UTC
- WEB-260: Made atc parser more robust

Release: v1.5.3.3
Date: 08/23/2013
Site: app.alivecor.com, eu.alivecor.com

- **Merge remote-tracking branch 'origin/rc08-23' into prod**
- **WEB-251: Add support for atc version 4**

Release: v1.5.3.2
Date: 08/21/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc08-21' into prod
- WEB-255: Remove protocol from font to support https
- WEB-255: Remove irrelevant test
- WEB-255: Make it easy to change timeout on client

Questions? Contact FDA/CDRH/OCE/DECI at CDRH-510KSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- WEB-255: Remove octopus, it causes zeus errors
- WEB-255: Fix scale on total recordings days graph
- WEB-255: Update settings to match actual protocols
- Add stats to the asset pipeline
- Fix broken test
- WEB-255: Change octopus to fix db:test:prepare
- Dump actual structure
- add one style tweak
- fix styling for large words
- large stats page done for now
- WEB-255: Fix week range on stats
- large stat styling wip
- WEB-255: Change stats refresh rate
- WEB-255: Add EU to stats page
- WEB-255: Use follower for stats, add dow stats
- WEB-255: Add octopus for follower DB access

Release: v1.5.3.1
Date: 08/07/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc08-07' into prod
- WEB-247: Fix server exception on missing user
- Preload recording associations.
- delete erb file
- update remaining templates to current styling

Release: v1.5.3.0
Date: 08/01/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc07-31' into prod
- Forgot to include some globals.
- Updated testrail formatter.
- Update json to include recording metadata.
- Add JSON response to RecordingsController#index

Release: v1.5.2.0
Date: unreleased
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc07-24' into prod
- WEB-246: Fix scale on inverted ECGs
- remove validation that requires country on user
- Add YAP (Yet Another Preamble)

Questions? Contact FDA/CDRH/OCE/Section at CDRH-EOIS-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Add tos and privacy preamble.

Release: v1.5.1.0
Date: unreleased
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc07-17' into prod
- WEB-240: Change ecardio to use recording files
- WEB-223: Dowload atc using recording file
- WEB-229: Update docstring
- WEB-229: Add oauth api support for multiple atcs
- Update tos and privacy statements
- WEB-225: Fix unit test to test PUT
- Updated sign in tests.

Release: v1.5.0.0
Date: unreleased
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc07-17' into prod
- Set recordings test to wip.
- remove unused columns from professional profiles
- Updated testcase id for recordings test.
- Added testcase ids to signup tests.
- WEB-231: View PDF retrieves the preferred filter
- Merge remote-tracking branch 'origin/rp-multi-atc'
- update join mailer spec
- update account created email text
- WEB-223: Use correct mains filter for pdf
- WEB-231 Move PDF generation to the recording files
- correct precompile config for moderinzr
- remove all empty helper files
- correct email form placeholder text
- add style patches for sign up flow
- add Modernizr, put js at bottom of layouts
- mock out the eu realm for development and test
- fix failing cuke test
- fix input control styling
- fix another cuke test
- fix cuke test
- update remainder of webapp faces
- WEB-230: Add filter settings to recording and user
- WEB-230: Change field from file type to filter
- make account setting dropdown responsive
- fix bug: cannot use a comma in the email from name
- remove dead mailer

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- fix whitespace
- fix country link subdomains
- fix failing cuke tests
- update cuke test for cookies message with correct text
- restyle cookies message
- setup redirect for people using the back button
- make the email footer skinny to match the banner at the top
- add link to settings on final account creation page
- correct signup layout for mobile
- WEB-230: Add selected_atc_file_type
- update the email address join emails are sent from
- fix asset compilation on heroku
- put log out below my account
- WEB-223: Refactor sync download
- WEB-223: Trigger sync when recording files change
- clean up oauth layout, move auth helper
- simplify oauth layout haml
- Merge branch 'ao-new-join-flow'
- fix remaining rspec tests
- update a controller spec
- update oauth view
- delete old oauth layout
- convert oauth layout to haml
- add styles for email verification error pages
- update and fix cukes based on Jason's UI changes :neutral_face:
- add launchy so that we can use save_and_open_page
- fix remaining cukes
- fix more cukes
- updated flash message design
- fix some cukes
- fix text in the account created email
- new column: email_verified for new users
- remove recordings erb view
- WEB-230: Update sync to support multiple atc files
- update recordings page style, convert to haml
- WEB-231: Cleanup waveform generation javascript
- WEB-225 Allow upload/dowload of multiple atc files
- fix weird space/tab issue
- style account page
- style login page
- email confirmation tokens are now one time use
- fix annoying whitespace crap
- update navigation
- handle join flow not found exceptions
- make the create account legal text human-readable
- update the account created email
- move config back into base settings.yml file and turn off RealmEmailValidator locally

Questions? Contact FDA/CDRH/OCE Section 10 at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- update route syntax
- make forgot password email pretty, added images
- verify email looks better
- spec out the create account class
- add some specs
- transitional navbar fix
- update sign in and footer
- add country to gen_data rake task
- disable enter key at create account page
- remove unused files
- downcase for consistency
- update spec
- update V1:UsersController to use new country_code param
- refactor to abstract error merging/validating
- update a spec
- update user factory
- link to app store and put countries in config
- fix typo
- save country to the users table
- spec out get email
- wip finished signup page
- spec for join flows controller
- delete old flags
- add new flags fix default for marketing opt in
- add account created email
- complete responsive styles for signup
- complete responsive styles for signup
- remove users controller, routes and views
- hard code this string because it never changes
- refactor to use exeption vs if statement
- remove unused @join_flow var from join controller
- remove needless migration
- remove columns from the migration I removed
- validates acceptance back to user for now
- fix specs: I took shoulda out
- integrate mail chimp stuff with new join flow
- put working url into text version of confirm email
- remove debugging token from confirm email
- position indicator with js
- remove eu realm from development
- add sleep to make admin_user_page less flaky
- merge master into ao-new-join-flow
- add responsive layout to first signup page
- add styles to form wip
- more legal stuff
- added legal mumbo jumbo to new signup
- dry up the layout files
- refactor error merging a bit

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- fix bug: password errors were not showing up
- remove unneeded view
- add first cut at progress bar
- wip progress indicator
- add font-awesome
- wip step progress
- don't create user until they have a password
- Merge branch 'ao-new-join-flow' of github.com:alivecor/hum-webapp into ao-new-join-flow
- remove flag sprite
- add nicer style to select country page
- add Ireland and flag sprite
- handle doctors vs patients
- handle doctors vs patients
- refactor to get rid of a before_filter
- remove separate name step from join flow
- update test and remove hidden input
- remove unused view
- submit role via hidden input
- remove commented out code
- collect password right after email is confirmed
- get country is now the first step
- put creates_users model back to proper state
- style create_account
- add styles for email validation page
- final pass at get_email page
- Merge branch 'ao-new-join-flow' of github.com:alivecor/hum-webapp into ao-new-join-flow
- autofocus for an admin page
- setting pass is working for doctors
- add new layout for joinflow, more styling
- fix merge conflict
- Merge branch 'ao-new-join-flow' of github.com:alivecor/hum-webapp into ao-new-join-flow
- add responsive stylesheets fix boilerplate
- small html changes
- add autofocus again and use new hash syntax
- add methods to user
- pry-rails to replace rails console woohoo!
- refactor User#profile getter
- fix up navbar styling
- remove old files
- Merge branch 'new_layouts' into ao-new-join-flow
- convert tabs to space, oops
- first cut part two
- first cut at form styles
- restructue SCSS temporarily hold on to old files for reference
- slight refactor of join controller

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- update signup feature
- sending email confirmation email
- sending a fake email confirmation email
- more wip
- more wip
- wip new join flow
- stubbed out view and debugging stuff in an email
- switch to using existing profile_type vs account_type
- organize the Gemfile
- only validate password fields when they change or are present
- one more step of the join flow
- more url friendly email confirmation tokens
- refactor to be less confusing
- complete merge after some updates
- merge from master
- slight refactor of join controller
- update signup feature
- sending email confirmation email
- sending a fake email confirmation email
- more wip
- more wip
- wip new join flow

Release: v1.4.4.0
Date: 07/11/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc07-10' into prod
- Add constant for default expiration date
- WEB-224: Add new storage location for atc files
- WEB-222 Add oauth subscriptions
- Merge remote-tracking branch 'origin/rc06-26'
- fix styles for forms

Release: v1.4.3.2
Date: 06/26/2013
Site: app.alivecor.com, eu.alivecor.com

- fix styles for forms

Release: v1.4.3.1
Date: 06/26/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc06-26' into prod

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Moved SimpleCov.start to beginning of env.rb.
- Added test for cookie notification.
- WEB-220: Prevent invalid timezone offsets
- make sites singular to be consistent with the rest of the text
- Added test for enabling accelerometer data collection.
- WEB-218: Change from email address to support@
- Merge remote-tracking branch 'origin/rc06-17'
- finish conversion to sass
- fix asset compilation in development
- remove unused gem
- convert to sass wip
- rebase from master and resolve conflicts
- move less files to sass
- Update comment for raised exceptions
- Raise exception when sending deleted recordings.

Release: v1.4.3.0
Date: 06/18/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc06-17' into prod
- WEB-217: Change website subscribe to use new lib
- Merge pull request #4 from alivecor/rp-mailchimp-opt-in
- WEB-217: Add support for phone API
- WEB-217: Made marketing opt-in hit mailchimp
- WEB-216: Fix error calling prepare_pdf
- fix coffeescript syntax error
- set cookie domain such that all subdomains can read it
- use google analytics in staging
- Fixed typo in new signup.
- WEB-215: Change pdf_status to auto generate
- WEB-215: Cleaned up specs a bit more
- WEB-215: Cleaned up subject in spec
- Used css for checkbox locators in signup.
- slight tweak and move things around on signup form
- new fields for signup
- simple_form FTW!!!
- add real privacy link
- disable analytics if user has opted out of cookies
- added cookie messaging
- convert layout to haml and break it up a bit
- organize javascripts
- add jquery.cookie plugin
- remove empty javascript files
- WEB-215: Add exception to generate method
- WEB-215: Fix PDF status, add auto gen, refactor
- DRY'd up recording cucumber step.

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Fixed typo in spec.
- dry up the recording validations
- Minor text update for stats.
- Updated testrail formatter to provide date/time to test run.
- Added config to rspec to allow color in Jenkins.
- only use RealmEmailValidator when email changes
- fix WEB-213 kaminari 500 due to haml conversion
- convert password reset views to haml
- convert stats page to haml
- convert user views to haml
- convert user settings views to haml
- convert groups views to haml
- add too_big_for_pdf method to recording
- add comment about microseconds back in
- convert kaminari views to haml
- convert doorkeeper views to haml
- remove Gemfile comments and add quiet_assets in development
- rename migration to fix build
- convert sign in page to haml and autofocus email field
- comment this out to get zeus working
- fix default sql value for group_participants column
- regenerate recording pdf when recording changes
- Add log message for overread transmission failure
- Revert "check to regenerate recording pdf whenever recording changes"
- check to regenerate recording pdf whenever recording changes
- WEB-212: Update rails version to 3.2.13
- change synchable attrs to a constant
- output the slowest specs examples
- respond with more json - v1/users-controller#authenticate
- remove comments from routes file
- Added tests for manage user accounts.
- WEB-208: Fix search for non existent user
- WEB-209: Fix user page for no recordings
- Updated cucumber.
- add .ruby-version for rbenv
- change default url for OverreadReport attachment to avoid confusion
- move SimpleCov.start into test helper files
- add to setup instructions

Release: v1.4.2.1
Date: 05/29/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc05-29' into prod
- Added tests for manage user accounts.
- WEB-208: Fix search for non existent user
- WEB-209: Fix user page for no recordings

Questions? Contact FDA/CDRH/OCE/DEC at CDRH-FOIASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Merge remote-tracking branch 'origin/master' into rc05-29
- Set weekly stats to only run on Monday
- Add david to weekly stats, add realm to stats
- Add user management to admin panel
- Updated cucumber.
- Merge remote-tracking branch 'origin/rc05-22'
- Haml conversion

Release: v1.4.2.0
Date: 05/23/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge remote-tracking branch 'origin/rc05-22' into prod
- Updated api recordings spec.
- Merge remote-tracking branch 'origin/master' into rc05-22
- Add HAML support, change main admin page to haml
- WEB-207: Add unit test
- WEB-207: Fix bug with password reset
- Updated database cleaner.
- Updated database.yml for test so reduce warning messages during cucumber run.
- Merge branch 'rc05-16'
- Remove unused parameter
- Fix paperclip downloads for an s3 backend
- Merge branch 'rc05-16'
- Refactor to eliminate repeated code for paperclip
- WEB-206 Improve unit tests
- WEB-206 Add accelerometer data collection

Release: v1.4.1.1
Date: 05/16/2013
Site: app.alivecor.com, eu.alivecor.com

- Add report_completed_at time to json response
- Add page showing recording metadata in json

Release: v1.4.1.0
Date: 05/15/2013
Site: app.alivecor.com, eu.alivecor.com

- Updated verification step for model recording spec.
- Updated verification step for rspec test.
- Merge branch 'master', remote-tracking branch 'origin' into rc05-15
- WEB-205: Add ability to get the users public id
- Added spec for initial overread report data.
- Refactored api recordings spec.

Questions? Contact FDA/CDRH/OCE/Section at CDRH-AFIBSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- WEB-204: Add atc endpont to oauth
- Remove unused environment configs
- WEB-139: Reorder recordings list in sync and oauth

Release: v1.4.0.0
Date: 05/09/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge branch 'master', remote-tracking branch 'origin' into prod
- Add pdf link for qualcomn's screen scraper
- WEB-203: Over read report oauth endpoint
- Change to support rspec test uploads
- Change auth tokens so they don't expire
- Add pry to Gemfile
- Fix mass assignment bug when creating reports
- Return error when report_file is empty
- WEB-200: Add more fields to the over-read report
- Add patient id to values set to ecardio
- Fix bug when generating no_symptoms parameter
- WEB-202 Add country to newsletter subscription.
- Merge branch 'rc04-24', remote-tracking branch 'origin'
- Updated paramenters for sending to ecardio
- Fix s3 development config to match latest format
- WEB-201: Autosend to eCardio
- Merge remote-tracking branch 'origin/rc04-17'
- WEB-200 Add endpoint for over-read reports

Release: v1.3.0.1
Date: 04/24/2013
Site: app.alivecor.com, eu.alivecor.com

- Refactored ecg file and version number spec.
- Added /lib to code coverage report.
- Moved junit rspec formatter.
- Added cucumber test for 0 bpm HR in pdf.
- WEB-103: Should not display 0bpm in recordings list or PDF

Release: v1.3.0.0
Date: 04/18/2013
Site: app.alivecor.com, eu.alivecor.com

- Merge branch 'rc04-17', remote-tracking branch 'origin' into prod
- Updated oauth specs.
- Added cucumber tests for oauth admin functionality.
- Adding link to oauth/applications from support dashboard.

Questions? Contact FDA/CDRH/OCE/DEC at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Added test to api ext recording spec.
- Small change to railroady rake task.
- Added test to api ext recordings spec.
- Refactored api ext recordings spec.
- Added cucumber tests for oauth application.
- Add overread link for qualcomm scrapper
- Minor change to create recording step definition.
- Fix stats mailer for nil durations
- add alivecor styles to oauth authorized apps page
- WEB-191: Add PDF endpoints to external API
- WEB-190: Add list API endpoint for all recordings
- WEB-187: Add enpoint for recording details
- WEB-187: Add oauth authentication and endpoints
- Refactored recordings controller spec.
- Change web server from thin to unicorn
- Merge branch 'b1.2.1.1'
- Remove unused code

Release: v1.2.1.0
Date: 04/10/2013
Site: app.alivecor.com, eu.alivecor.com

- Added exception handling to testrail formatter.
- Added cucumber tests for pdf header.
- Fixed typo in pdf. Bumped pdf version.

Release: v1.2.0.0
Date: unreleased
Site: app.alivecor.com, eu.alivecor.com

- Updated code coverage filters to exclude interal weekly stats mailer.
- Merge branch b1.1.2.1
- WEB-73 Fix year format. Bumped pdf version.
- Updated testrail formatter to show name.
- remove commented style
- style header with dynamic ellipses
- WEB-73 Fix cucumber tests for ambiguous dates
- WEB-73 Make dates less ambiguous
- WEB-195: Change quotes to match guidelines
- WEB-195: Fix gender on recording create
- Updated faraday gem.
- Minor updates to rspec models tests.
- Reenabled recording pdf cucumber test.
- Updated pdf-reader gem.
- Updating rspec to 2.13.0.
- Refactored models recording spec.

Questions? Contact FDA/CDRH/OCE/Section 510(k) at CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Fixed broken tests from merge in models/recording_spec.rb.
- Refactored models app_version spec.
- Refactored models consumer and professional profile specs.
- Merge branch 'v1.1.1.2'
- add maintenance page
- update styles for 404 and 500 pages
- update style for 422
- update style of 403 page
- add new 401 page
- PGM-16: Add symptoms and activites to PDF header
- WEB-183, PGM-16 Add activities and symptoms to db

Release: v1.1.2.0
Date: 03/27/2013
Site: app.alivecor.com, eu.alivecor.com

- Refactored recording spec.
- Refactored demographic_profiles spec.
- Updated test gems.
- Refactored api users controller spec.
- WEB-186: Fix incorrect gender sync
- Refactored group controller spec.
- Refactored professional profile spec.
- Added unit tests for male. Some refactoring.

Release: v1.1.1.1
Date: 03/18/2013
Site: app.alivecor.com, eu.alivecor.com

- Updated simplecov gem.
- Fixed broken test.
- Change stats to reflect users with uploads

Release: v1.1.1.0
Date: unreleased
Site: app.alivecor.com

- WEB-176: Restructure realm settings
- merge
- add styles for realm redirect page
- WEB-177: Change medications to a text field
- WEB-175: Add multi-region password reset
- WEB-175: Add multi-region forgot password
- WEB-175: Add login unit tests
- WEB-175: Add multi-region redirect on login

Questions? Contact FDA/CDRH/OCE/DEC at CDRH-EOLSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: v1.1.0.0
Date: unreleased
Site: app.alivecor.com

- Add s3 host to paperclip config
- Add realm configuration for staging
- Change error message for email used on other realm
- Remove trailing whitespace
- WEB-112: Add profile_type to user login
- WEB-175: Fix realm connector
- WEB-175: Multi realm configuration
- WEB-171 Fix consumer demographic updating
- WEB-174: Add units metric to professional profile
- Updating phantomjs gem.
- Added ALL_DATA scenario to test deletion.
- WEB-171, WEB-172: Add demographic fields
- Add paperclip secret for dev to fix cucumber tests
- WEB-173: 500 is returned when querying for app version without passing any arguments
- Added tests for ALL_DATA and REPORT user permissions.
- WEB-140: Add version check API
- Updating site_prism gem declaration in Gemfile.
- Reverting capybara, poltergeist and site_prism. Causing error in Jenkins.
- Change config for better multi environment support
- Updating capybara, phantomjs, poltergeist and site_prism.

Release: v1.0.1.6
Date: 02/06/2013
Site: app.alivecor.com

- Add new group for development and staging
- Remove jQuery arg in self executing function
- Move setTimeout to the "complete" callback.
- Ignore public/spree directory
- Update gen data to run in staging
- Fix dob in test data generation script

Release: v1.0.1.5
Date: 01/30/2013
Site: app.alivecor.com

- precompile stats.css
- add styles for large stats
- WEB-144: Add web stats page

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- WEB-141: Fix view PDF button in IE8

Release: v1.0.1.4
Date: 01/24/2013
Site: app.alivecor.com

- Updating selenium-webdriver gem.
- WEB-138: Fix off by 1 and commit libs
- WEB-138: Add tools to for dev db population
- WEB-137: Add more data to weekly stats email
- WEB-136: Limit stats to web views only
- WEB-130: Status dialog appears before redirect

Release: v1.0.1.3
Date: 01/15/2013
Site: app.alivecor.com

- Setup dev environment to use mailcatcher
- Add rake task for weekly stats email
- Add weekly stats email
- WEB-134: Don't display delete ECGs in all
- Updated testrail id for recordings test.

Release: v1.0.1.2
Date: 01/11/2013
Site: app.alivecor.com

- WEB-132: Update rails to latest version
- WEB-131: Skip pdf creation on upload for long ecgs
- WEB-129: Change pagination theme to bootstrap
- WEB-128: Sort all recordings view by date
- WEB-127: Admin view and delete of all data users
- WEB-127: Allow all data user access to all ecgs
- WEB-127 Rename superuser to support_user
- WEB-127: Make support user permission more generic
- Updated phantomjs gem with specific ref.
- Downgrade aws and paperclip gems.
- Added pdf test for medical professional.
- Added testrail id to recordings test.
- Added pdf test for non medical professional.
- Added test for pdf footer.
- Added rake task to return emails of active users.
- Added recordings test for sort order.
- Updating poltergeist and phantomjs.
- Add reset password job

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: v1.0.1.1
Date: 12/12/2012
Site: app.alivecor.com

- Upgrade new relic
- Register .atc mime type
- Add ability to download .atc file
- Added tests for WEB-98.
- WEB-98: Fix Invalid email error message does not appear during signup
- WEB-17: Adjust sizing on pdf header to match phone
- WEB-17: Don't wrap just truncate values
- Added unit tests for users api spec.
- Removed redundant test in users_controller_spec.
- Upgrade rails version to 3.2.9
- IOS-56: Replace server value when sync times match
- Removed redundant test in users_controller_spec.
- WEB-17: Fix truncation in PDF Header
- Add shop development environment config files
- Add verify environment config file
- Update start services instructions
- Add config for verify site
- Add config for verify environment
- WEB-105: Fix back button from PDF under IE
- Alter encrypted columns to text fields
- Change FDA and copyright notice
- Change redirect url to work with shop
- WEB-111 Correctly display duration and patient age
- WEB-109: Validate the length of attribute values
- WEB-104: Add name and institution to create API
- WEB-102: Add public id to account create
- WEB-101 Add API for forgot password
- Added recordings test for upload.
- WEB-100: Add user public id to API

Release: r20121126
Date: 11/26/2012
Site: app.alivecor.com

- Fixed broken recordings tests.
- Add error handling on pdf load
- Add foreman
- Remove newrelic config
- Set newrelic monitor true
- Move newrelic off heroku
- Fixed recordings test.

Questions? Contact FDA/CDRH/OCE/Section 510(k) at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Added recording_pdf factory instance. Fixed test for view action in audit logs.
- WEB-91 - Remove hover to view pdf button
- WEB-4: Change PDF to generate in offline process
- Adding audit log test for update action.
- Removed whitespace.
- Adding testrail ids to automated tests.
- Adding railroady rake tasks.
- New cucumber formatter that integrates with testrail api.
- Revert "Updating poltergeist gem." Premature.
- Updating poltergeist gem.
- Adding railroady to Gemfile.
- Refactored login tests. Added testcase id from testrail to scenario name.
- Adding faraday to Gemfile. Used for communicating with the testrail api.
- Updated scenario name for signup test.
- Change repo name from alivecorweb
- Text update in rake task.

Release: r20121107
Date: 11/07/2012
Site: app.alivecor.com

- Added new rake task to calculate stats.
- Check for presence of values on PDF header.
- Added tests for view and create action in audit logs.
- Added patient name to recordings factory. Added function to find table row based on patient name in recordings page.
- Allow enter key to submit a log search
- Fix return value for an invalid public id
- Display user in audit log even on api
- Removed trailing whitespace
- Add internal tool page for viewing audit log
- Add auditing and logging

Release: r20121031
Date: 10/31/2012
Site: app.alivecor.com

- Add newrelic to staging
- Some minor changes to groups automation code.
- Removing youtube link from footer.
- Added automated test for group membership.

Release: r20121024
Date: 10/24/2012
Site: app.alivecor.com

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Fix typo in rake task
- Fixed delete groups element locator.
- Add tools for administrators to manage groups
- Fix server error when using and invalid group id
- Add public id to users
- Added another group deletion verification.
- Added automated tests for admin groups page.
- Make support tool for creating groups
- Added tags for smoke.

Release: r20121017
Date: 10/17/2012
Site: app.alivecor.com

- Rename group permissions table to participants
- Use an authorization library for recording access
- Remove unused spec files
- Correct description of unit test
- Fix bug with syncing new user profiles.
- Fix raw ecg dowload when files are on S3
- Remove username and fix full name for users
- Add user information to sync.
- Add consumer and professional profile tables

Release: r20121010
Date: 10/10/2012
Site: app.alivecor.com

- Duration on PDF should display mins and seconds
- Minor update to user steps.

Release: r20121003
Date: 10/03/2012
Site: app.alivecor.com

- Clean up and rearrange unit tests
- Updated simplecov config.
- Updated code coverage configuration. Removed simplecov-rcov gem.
- Fix PDF generation with a nil patient dob
- Fix error when viewing PDF with nil DOB
- Remove unit test that called out to MailChimp
- Fix error that occurs when a patient DOB is empty
- Move raw_ecg files in dev to persist on VM reboot
- Add tests for rendering deleted PDFs

Questions? Contact FDA/CDRH/OCE/Section 10 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Prevent user from viewing deleted recording as PDF
- Remove unused environment variable
- Fix invalid byte sequence and UTF8 string in tests
- Updated simplecov to support rcov output format.
- Removed user_sessions factory.
- Added cucumber test for deleted ecg.

Release: r20120926
Date: 09/26/2012
Site: app.alivecor.com

- Hide deleted recordings on View Recordings page
- Add ability to mark recordings as deleted
- Remove require junit.rb from spec_helper.
- Added junit output formatter for rspec.
- Updated cucumber ci profile to exclude vet specific tests.
- Change format of date fields for sync
- Fix sync request not returning any recordings
- Added recordings test.
- Add ability get fetch raw ecgs via api
- Fix wrong number of recordings returned on sync
- Add coverage directory to .gitignore
- Add ability to get updated recordings
- Added simplecov to Gemfile.
- Added more tests for password reset.

Release: r20120919
Date: 09/19/2012
Site: app.alivecor.com

- Allow updating of metadata by phone
- Add sync fields to database

Release: r20120912
Date: 09/12/2012
Site: app.alivecor.com

- Change 200 to 201 to support the older app
- Add email address to fix_dups task
- Add script to cleanup duplicate recordings
- Broke test in last commit. Fixed.
- Cleaned up some code.
- Added tests for superuser
- Allow updates to existing ECG recordings
- Added tests for admin page.

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Release: r20120905
Date: 09/05/2012
Site: app.alivecor.com

- Fix default action mailer host
- Added cucumber profile for CI.
- Remove swap file
- Add link to manage superusers
- Add superuser tools framework

Release: r20120829
Date: 08/29/2012
Site: app.alivecor.com

- Add group tables.
- Add touch icon link.
- Add apple touch icon for mobile bookmarks
- Fix pdf generation error when dob is nil
- Improve documentation
- Fix remote auth when the first login fails
- Remove unused test file
- Caculate patient age based on recording date
- Calculate patient age based on recording date.
- Specify ruby version for heroku

Release: r20120822
Date: 08/22/2012
Site: app.alivecor.com

- Launch

Questions? Contact FDA/CDRH/OCE/Section 513(g) STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveECG for Android Change Log

V1.0.2 (Oct 4, 2013)

- Released to Google Play Store.
- Added user manual, which can be accessed from Settings->User Manual.
- Added compatibility warning.
- PDF now includes symptoms.

v0.0.25 (Sept 27, 2013) (FINAL BETA)

- Released to Google Play Store Beta.
- Added background pattern to signup page.
- Limited max length of text fields to 120 characters, except for notes and medication which are unlimited.
- Fixed user profile cancelling (Issue DROID-64).
- ECG acquisition is now stopped and started when Record screen loses or gains focus (Fixes issue DROID-57).
- Fixed bug where non-professional user profile was not saved after sign up (Issue DROID-60)
- Added check for unsynced changes to the user profile before logging out.
- Now prompts for Terms of Service agreement every time you create an account, even if you have just accepted the Terms of Service after new install.
-

Questions? Contact FDA/CDRH/OCE/Section 18 at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveECG Revision Level History

Software revision history of the AliveCor Heart Monitor iPhone App

Version:	1.4.0 (Build 1)
Date:	14-Sept-2013
Distribution:	App Store
Provisioning:	Alive Cor, Inc
Identifier:	com.alivecor.aliveecgprofessional
Location:	US and UK App Stores
PDF Report:	Version 2.0.0
Web upload:	app.alivecor.com
Analytics:	apsalar.com. Account name alivecor_analytics_production
Requirements:	Requires iOS5.0 or later

Changes:

- AliveInsights
- ECG reminders
- UCSF study support (custom scheme and perishable token exchange)

Version:	1.3.1 (Build 1)
Date:	23-Aug-2013
Distribution:	App Store
Provisioning:	Alive Cor, Inc
Identifier:	com.alivecor.aliveecgprofessional
Location:	US and UK App Stores
PDF Report:	Version 2.0.0
Web upload:	app.alivecor.com
Analytics:	apsalar.com. Account name alivecor_analytics_production
Requirements:	Requires iOS5.0 or later

Changes:

- Bug fixes

Version:	1.3.0 (Build 1)
Date:	20-Aug-2013
Distribution:	Internal Testing
Provisioning:	Alive Cor, Inc
Identifier:	com.alivecor.aliveecgprofessional
Location:	TestFlight
PDF Report:	Version 2.0.0
Web upload:	app.alivecor.com
Analytics:	apsalar.com. Account name alivecor_analytics_production
Requirements:	Requires iOS5.0 or later

Changes:

- Enhanced filter
- Sliding menu
- Other bug fixes

Version:	1.2.1 (Build 2)
Date:	12-Jun-2013

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US and UK App Stores
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- New Terms and Conditions, Privacy Notice
- Enabled background accelerometer collection (for research purposes), won't be on most of the time
- Other bug fixes

Version: 1.2.0 (Build 2)

Date: 12-Apr-2013
Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US, UK, Ireland App Stores
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- FIGS translations
- User confirmation after record
- Symptoms and activities associated with recordings
- Recording tips on ECG monitor screen
- Improved crash log reporting
- Other miscellaneous bug fixes

Version: 1.1.0 (Build 8)

Date: 18-Mar-2013
Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US and UK App Stores
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- Support for EU server
- Allow user to identify as a non-professional
- Patient lookup and select for professional users
- New consumer profile and ECG fields (gender, smoker, weight, height, units, medical conditions, medications)
- Many UI tweaks and changes

Version: 1.0.2 (Build 1)

Date: 15-Jan-2013

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US App Store
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- Added Offline mode, not requiring user to log in to use app

Version: 1.0.1 (Build 1)

Date: 3-Jan-2013
Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US App Store
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- Changed Terms and Conditions

Version: 1.0.0 (Build 6)

Date: 10-Dec-2012
Distribution: App Store
Provisioning: Alive Cor, Inc
Identifier: com.alivecor.aliveecgprofessional
Location: US App Store
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics_production
Requirements: Requires iOS5.0 or later
Changes:

- Added full 2-way syncing
- Changed startup screens for new flow
- Added forgot password functionality
- Require user to be logged in to an account
- Added “How It Works” screens
- Added privacy notice to settings

Version: 2.1.0 (Build 14)

Date: 30-Oct-2012
Distribution: Enterprise
Provisioning: Alive Technologies Enterprise Account
Identifier: com.alivetec.v1.AliveECG
Location: alivecor.com/apps
PDF Report: Version 2.0.0

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PAQISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

Web upload: app.alivecor.com
Analytics: apsalar.com. Account name alivecor_analytics
Requirements: Requires iOS5.0 or later
Changes:

- Added 'Auto send' option to automatically send ECGs to your AliveCor web account after recording and making changes.
- Improved selection of sweep speed and gain that also prevents them from being changed unintentionally.
- Added analytics to gather usage statistics.
- Updates for iPhone5 and iOS6.
- Fixed bug where DOB displayed in list, email, review title, and PDF could be wrong by one day depending on timezone (Human version of the app only - vet version not affected).
- Fixed bug where the background on first time startup screens was not resized for iPad or if orientation changed to landscape.
- Fixed bug that in rare cases when low memory warning, it could cause the app to crash.
- Fixed timezone bug that would crash the app if user in Venezuela, Newfoundland and Labrador, or Marquesas Islands, where timezone diff is negative and includes 1/2 hour offset.
- Enabled web links in Terms view to open in Safari.
- Fixed bug where sometimes no mic input after a phone call on iOS6. Audio from background apps is now stopped while running the AliveECG app.
- Formatting changes to PDF to truncate long fields.

Version: 2.0.0 (build 50)

Date: 28-Sept-2012
Distribution: Ad Hoc
Provisioning: Alive Technologies Developer Account
Identifier: com.alivetec.v1.AliveECG
Location: alivecor.com/alivetec/AliveECGv200
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Requirements: Requires iOS4.2 or later

Version: 2.0.0 (build 41)

Date: 30-Aug-2012
Distribution: Enterprise
Provisioning: Alive Technologies Enterprise Account
Location: alivecor.com/apps
PDF Report: Version 2.0.0
Web upload: app.alivecor.com
Requirements: Requires iOS4.2 or later

Changes:

- Fixes to handle split or undocked keyboard on iPad.
- Default server is now app.alivecor.com
- Added measurement position to PDF report.

Questions? Contact FDA/CDRH/OCE/Section at CDRH-PMOSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Fix for grouped table view background deprecation in iOS6

Version:	2.0.0 (build 12)
Date:	22-Aug-2012
Distribution:	Enterprise
Provisioning:	Alive Technologies Enterprise Account
Location:	alivecor.com/appv1
PDF Report:	Version 2.0.0
Web upload:	alivecor-staging.com
Requirements:	Requires iOS4.2 or later

Changes:

- Added support for changing the gain and sweep speed in the recording screen, review, and printout. Gain options are 5, 10, and 20mm/mV. Sweep speed options are 12.5, 25, and 50mm/s.
- Supports heart rates up to 300bpm. Previous max was about 270bpm.
- Invalid HR is now displayed as --- bpm in review and PDF, rather than 0 bpm.
- Added new icons are splash screens.
- Measurement position added to PDF report.
- User is prompted to login or create account if they select 'Send to Alivecor' without an account setup. Also prompts user to enter password if current authentication token has been revoked by the server.
- Updated ECG details in the email content.
- Added clear button to all text fields.
- Enabled hardware encryption of the database file for when user has set a passcode lock.
- Fixed bug where some audio apps running in the background could prevent the app from receiving audio and acquiring an ECG.
- Various minor UI improvements and bug fixes.

Version:	1.9.0 (build 58)
Date:	27-July-2012
Distribution:	Enterprise
Provisioning:	Alive Technologies Enterprise Account
Location:	alivecor.com/appv1
PDF Report:	Version 1.9.0
Web upload:	alivecor-staging.com
Requirements:	Requires iOS4.2 or later

Notes:

- App Icon has not been updated
- Missing logo from Terms and Conditions and other startup views

Changes:

- First time startup screens include terms and conditions page, and other minor changes.
- Average HR displayed when reviewing an ECG.
- Changed the default 'Normal' mode so that it does not require the iPhone to be in Airplane mode to record an ECG. Added 'Airplane / ICU' mode setting which enables the Airplane mode restriction.
- Added 'Delete ECG' confirmation.
- PDF formatting changes.

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Added additional info in subject and content when emailing an ECG.
- Age in PDF report is now age at date of the recording, not the current age.
- Fixed bug where if you edit ECG details a second time, the comments and other fields might get deleted if viewing in landscape orientation and if comments are not scrolled into view.
- Fixed DOB handling for different time zones and calendars.
- Fix bug where scrolling an ECG would cause a crash in iOS6.
- Added heads up display when verifying or creating a new account.
- Changes where web account now requires email address rather than username.
- Each ECG is stored with a flag to indicate if recorded in Professional mode or not. This is also sent to the web site and the PDF includes the health professionals name and institution if entered in the settings when the ECG was recorded.
- Minor UI improvements.

Version:	1.8.0.588
Date:	9-July-2012
Distribution:	Enterprise
Provisioning:	Alive Technologies Enterprise Account
Location:	alivecor.com/appv1
Web upload:	alivecor-staging.com

Changes:

- UI changes and new splashscreen for iPad.
- UI disabled during account verification and when creating new account to prevent multiple requests.
- Select/Cut/Copy/Paste action removed from DOB fields as not appropriate.

Version:	1.8.0.538
Date:	5-July-2012
Provisioning:	Enterprise Account
Location:	alivecor.com/appv1
Web upload:	alivecor-staging.com

Changes:

- Uploads ECGs to the new web site. Currently using temporary URL https://alivecor-staging.com
- Verifies account details with web server anytime you change them.
- Option to create a new web account from in the app.
- Added ability to enter patient ID, first name, last name, DOB and measurement position, in addition to comments for each ECG.
- If configured for patient use, the patient details will be filled out automatically if configured with default patient details in the settings.
- First time setup. The first time you run the app after install, the app will run through a series of prompts to configure the app and setup or create a web account.
- In App Settings. All settings are now accessible from within the app by tapping the 'gear' icon at the bottom right of the main screen.
- Added a setting to select if the device is for use by a health professional or not.
  - If the health professional option is enabled, they have the option to enter their name and institution which will be stored with each ECG and printed on the reports.
  - If the health professional option is not enabled (ie a patient), they have the option to enter default patient details (ID, First name, Last name, DOB), that will be stored with each new ECG.

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

- Updated PDF and printed reports to include all patient details, HR, health professional name and institution if applicable, and new AliveCor logo.
- ECG list items now include patient name, DOB, and HR, in addition to the date/time of recording, duration, and 'Sent' indication.
- Title in review screen now includes the patient name and DOB.
- Send option not available if an Account has not been setup.
- New splashscreen with fade in.
- Page size is set to A4 or Letter based on the time zone info when you first run the app. It can be manually changed anytime after.
- Changed PDF drawing to use rounded line joining style for smoother ECG trace.
- Fixed error so date/time of recording is displayed in the time zone where it was recorded, not the current time zone. This also matches the date/time of ECG displayed on the web site.
- Improved handling and display of status and errors from server when sending ECGs or authenticating.
- Password and authentication token is now stored securely in the keychain.
- User is now forced to wait while sending ECGs to server to prevent ability to record ECGs while sending in progress.

Version:	**1.7.2.314**
Date:	31-May-2012
Distribution:	Enterprise
Provisioning:	Alive Technologies Enterprise Account
Location:	alivecor.com/enterprise3
Web upload:	alivecor.com

Questions? Contact FDA/CDRH/OCE/Section 13 at CDRH-PAGESTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE:	ECG for iPhone Design Description, Software

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Change History

Revision	Date	Description of Change	Author
(b)(4)			

(b) (4) Engineering Specifics for Software Design

(b) (4) Engineering Specifics for Software Design

(b) (4) Engineering Specifics for Software Design

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
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Change History

Revision	Date	Description of Change	Author
(b)(4)			

(b) (4) Engineering Specifics for Software Design

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG Website Human Design Input-Output Matrix
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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG Universal Module Design Input-Output Matrix, Mobile Software for Android OS

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AliveCor

510(k) PREMARKET NOTIFICATION

ELECTROMAGNETIC COMPATIBILITY AND ELECTRICAL SAFETY

The original *AliveCor Heart Monitor* (for the iPhone 4/4S) and the *AliveCor Heart Monitor Universal Module* were evaluated for electromagnetic compatibility (EMC), including both emissions and immunity. We tested the device according to ANSI/AAMI/IEC 60601-1-2 Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility - Requirements and Tests to demonstrate the EMC characteristics of the device. The device was tested according to IEC 60601-1, ANSI/AAMI EC38 and ANSI/AAMI/IEC 60601-1-2 for patient safety.

Standard	**Description**
IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
ANSI/AAMI/IEC 60601-1-2	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral standard: Electromagnetic compatibility – Requirements and Tests
ANSI/AAMI EC38	Medical Electrical Equipment – Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems

All subsequent mechanical configurations will comply with the above safety standards and test methodologies. Some renditions of the *AliveCor Heart Monitor* may not require retesting under these protocols due to the scope of the change. For example, following the progression of iPhone hardware, the iPhone 5 compatible device has nearly the same form factor, allowing us to use the same printed circuit board assembly (PCBA) in a new mechanical construct. Essentially the design remains the same while the iPhone case portion of the design is lengthened to accommodate the larger iPhone 5.

In the event of a PCBA redesign, it is likely that the change will justify retesting according to the above standards, hence the retesting of the *Universal Module* design. AliveCor will have these protocols and reports published and available upon commercialization of any additional mobile computing platform compatibility.

The *AliveCor Heart Monitor* has been designed to meet the set requirements of the above standards, and has been tested against those standards to assure compliance. Each applicable requirement from the individual standard has been translated to a specific requirement in design control documentation. Each of the requirements has been verified. A list of the verification activities are described in Section 21 and are on file at AliveCor. The majority of requirements related to EMC and Electrical Safety are tested within the ECG for iPhone Human Test Protocol, Systems Integration (02VEP2 and 09VEP2).

The Electrical Safety and Compatibility Information is in compliance with ANSI/AAMI/IEC 60601-1-2 is contained in the device labeling (see Section 13).

The Extent of Standard Compliance to each of these standards can be found in Section 9 of this submission.

Questions? Contact FDA/CDRH/OCE/Director at CDRH-PRAStatus@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

AliveCor

510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING - BENCH

The following bench testing was performed on the *AliveCor Heart Monitor*.

Full test protocols, results and conclusions are provided in the report location specified below, or on-file at AliveCor.

Description of Test	Standard/Protocol	Test Report Located
System Integration Verification Testing	02VEP2.B 09VEP2.B On-file at AliveCor	02VER2.A 09VER2.A On-file at AliveCor
General Safety	IEC 60601-1	Appendix C On-file at AliveCor
EMC Testing	ANSI/AAMI EC38, and 60601-1-2	Appendix D On-file at AliveCor
Environmental Testing	ANSI/AAMI EC38	Appendix D On-file at AliveCor
Biocompatibility Testing	ISO 10993-1	Appendix B On-file at AliveCor
Ambulatory ECG Safety Testing	ANSI/AAMI EC38 60601-2-47	Appendix E On-file at AliveCor

All additional bench testing resulted in confidence that the *AliveCor Heart Monitor* performs to the development team's expectations. No additional concerns related to safety and effectiveness resulted from the above testing.

System Integration (Apple iOS and AliveCor Heart Monitor for iPhone 5)

Documents necessary for system integration testing of the *AliveCor Heart Monitor for iPhone 5* coupled with the *AliveECG for iOS* mobile application are on file at AliveCor, Inc. The *iPhone 5* is a particular hardware configuration mentioned in K130409 under Section 11: Design Description. The mechanical configuration looks substantially similar to Figure 7 in that section. The System Integration Protocol (02VEP2), Test Plan (PLN012) and Report (RPT124) for iPhone 5 system integration together verify that the device paired with the *AliveECG* app work appropriately as a system. Additional datasheets related to the report are on file at AliveCor.

Note that the protocol (02VEP2) will cover other iOS devices of similar form factor, screen size, etc. (iPod Touch, iPhone 5s, etc.) as we determine necessary to support additional hardware from Apple. A specific plan and report are on file for each MCP we market as compatible with the AliveCor Heart Monitor (to date, that list includes the iPhone 4/S and iPhone 5).

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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In summary, AliveCor has performed system integration verification similar to the *AliveCor Heart Monitor for iPhone 4/4S* with the *AliveECG for iOS* mobile app. System integration passed with zero defects and no deferrals. This protocol, plan and report show that as a system, the *AliveCor Heart Monitor for iPhone 5* hardware configuration and *AliveECG for iOS* software performs equivalent to the *AliveCor Heart Monitor for iPhone 4/4S* and *AliveECG for iOS*.

Performance Comparison to Support Substantial Equivalence

Although we believe that compliance with standards and testing according to our strong in-house developed design verification protocols are sufficient to prove equivalency of software and hardware designs, we recently added a side-by-side performance comparison between our cleared device and proposed device configurations. Upon development and execution of this test we determined that it is a useful final gut-check that we will continue to perform when testing additional MCPs in the Android or iOS families. The Performance Comparison Test Plan (PLN020) is intended to compare the essential performance between verified/cleared configurations and future iOS for Android OS revisions.

The attached Test Plan (PLN020) and associated Report (RPT133) and ECG comparison datasheet (RPT133-datasheet) compare the *AliveCor Heart Monitor for iPhone 4/4S* on an iPhone 4S running iOS v5.1.1 and *AliveECG for iPhone* v1.2.1 to the proposed *AliveCor Heart Monitor Universal Module* on a Samsung Galaxy S3 running Android v4.1.2 and *AliveCor ECG for Android* v1.1.3.0(beta). The Report concludes upon examination by a medical professional that simulated ECG recordings are clinically equivalent and within a tolerance that would not affect a diagnostic decision that could be made by examination of the two ECG data sets.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PMA-STATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: AliveECG for iPhone and AliveECG for Android Performance Comparison Test Plan

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Change History

Revision	Date	Description of Change	Author
A	July 3, 2013	Initial version	Michael Righter

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PGHSTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/Director at CDRH-PMASTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

1. BACKGROUND

AliveCor, Inc. (AliveCor) has conducted both formal and informal performance comparison studies against the AliveCor Heart Monitor with devices such as the Omron HGC-801 Portable ECG Monitor, and technical specifications comparison with the predicate device Cardiocomm's HeartCheck Pen Handheld Heart Rhythm with GEMS Home proposed in K122356. The AliveCor Heart Monitor was concluded as substantially equivalent to the predicated device.

This protocol has been developed to provide an essential performance comparison to previously a cleared device, AliveCor Heart Monitor for the iPhone 4/4s.

Further product development activities and evolution of the Mobile Computing Platform (MCP: e.g. mobile phones, tablets) industry required new AliveCor Heart Monitor hardware/software configurations to meet the needs of our user base. AliveCor configured the electronics to be placed into several different mechanical constructs to adapt to different form factors of many MCPs with very few changes to the basic design, and no changes to the fundamental design. Each mechanical configuration has identical hardware performance characteristics and they utilize the same materials.

One of the primary user needs AliveCor plans to meet is the addition of an Android OS compatible mobile application. Note: The AliveCor Heart Monitor hardware has been design to be compatible with any MCP that meets the basic MCP requirements. The major goal of those development activities was the conversion from developing Objective C software code in the iOS SDK to using Java in the Android SDK coding environment. As part of this conversion, many sections of software code were touched requiring specific performance testing equivalence to ensure there are no negative implications of the software design differences.

This protocol and report may be used as a basis for future additions of hardware software configurations, in addition to system integration tests.

2. INTRODUCTION

The purpose of this study is to provide an essential performance comparison between an FDA cleared [Mobile Computing Platform – AliveECG App – AliveCor Hardware] configuration and a proposed configuration. This particular protocol is written to compare the following:

- iPhone 4S/iOS 6.1.3 – AliveECG for iPhone v.1.2.1 – AliveCor Heart Monitor for iPhone
- Galaxy S3/Android 4.0 – AliveECG for Android (beta) – AliveCor Heart Monitor Universal Module

Ultimately the diagnostic performance equivalence can be determined by the analysis of the ECG on a standard PDF report independently created by the two software apps. Creation of the PDF is the final step of ECG data management – any performance differences between the software apps would result in visible distortion or other adulteration of the ECG data strip. ECG analysis is typically done by a trained eye, therefore visual comparison is the most clinically relevant and diagnostic comparison.

3. LOCATION

This study will be conducted at AliveCor, Inc. headquarters in San Francisco, CA. The engineering lab has appropriate tools, materials, equipment and safety controls to ensure this protocol is executed appropriately.

Questions? Contact FDA/CDRH/OCE/Director CDRH-PRESTATUS@fda.hhs.gov or 301-796-8118

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4. CONDITIONS

There are no special environmental conditions necessary for this protocol given that the AliveCor Heart Monitor is intended for ambulatory use. The conditions in an office setting such as the AliveCor engineering lab are considered a typical and acceptable environment for the test. The personnel executing the test should understand the purpose of the test and impact they may have on the results given their activities. Test personnel are chosen with necessary education, background, training, and experience to assure that all activities required by this protocol are correctly performed.

5. MATERIALS

- Apple iPhone 4S running iOS 6.1.3
- AliveCor Heart Monitor for iPhone (AC-001, S/N: <serial number>)
- AliveECG for iPhone software from Apple iTunes App Store (Version: <ver>)
- Patient Simulator (<name>, EIN#<num>, Calibration Due: <date>)
- Office PC with PDF viewer such as Adobe Acrobat
- Transparency film for laser printing
- Office laser printer
- Samsung Galaxy S3 running Android OS 4.0
- AliveCor Heart Monitor Universal Module (AC-004, S/N: <serial number>)
- AliveECG for Android software (beta) (Version: <ver>)

6. ACCEPTANCE CRITERIA

(b) (4)

[redacted]

7. METHOD(S)

7.1. Data Collection: AliveECG for iPhone

1. Connect an iPhone 4S to the *AliveCor Heart Monitor for iPhone*
2. Download and install the *AliveECG for iPhone* Mobile App to the iPhone 4S
3. Connect the *AliveCor Heart Monitor for iPhone* to the Patient Simulator
4. Set the Patient Simulator to 60BPM, 2 mVp-p
5. Launch the *AliveECG for iPhone* app
6. Initiate a 30 second recording using *AliveECG for iPhone* app
7. Save than email the PDF of the recording to an appropriate storage location for access by a PC
8. From the PC, print the PDF of the recording at 100% scale on transparent film

7.2. Data Collection: AliveECG for Android

1. Connect a Galaxy S3 to the *AliveCor Heart Monitor Universal Module*
2. Download and install the *AliveECG for Android* Mobile App to the Galaxy S3
3. Connect the *AliveCor Heart Monitor Universal Module* to the Patient Simulator
4. Set the Patient Simulator to 60BPM, 2 mVp-p
5. Launch the *AliveECG for Android* app

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6. Initiate a 30 second recording using *AliveECG for Android* app
7. Save than email the PDF of the recording to an appropriate storage location for access by a PC
8. From the PC, print the PDF of the recording at 100% scale on transparent film

7.3. Data Comparison

1. Physically align the two transparent film prints so the ECG waveforms generally align and test according to the acceptance criteria
2. The transparencies shall be reviewed by a qualified medical professional according to the acceptance criteria.

8. REFERENCES

None

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: Report AliveECG for iPhone and AliveECG for Android Performance Comparison
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Change History

Revision	Date	Description of Change	Author
A	July 17, 2013	Initial version	Stephen Mordue

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1. BACKGROUND

This report will cover the results of the test protocol executed, including the hardware and software used to execute the protocol. This report will also identify the defect traceability for failed test cases, any deviations or modifications to the test protocol, and any defects deferred.

2. INTRODUCTION

AliveCor has developed an AliveECG application for iOS and another AliveECG application for Android. This report shows the results of equivalency testing between the iOS and Android versions of the application. Further verification of software, universal module hardware, and systems integration verification testing is documented in different test reports. The AliveECG app for Android is essentially equivalent to the AliveECG app for iOS.

3. REFERENCES

- PLN020 – AliveECG for iPhone and AliveECG for Android Performance Comparison Test Plan

4. MATERIALS

4.1. Versions Verified

- iPhone 4S/iOS 5.1.1 AliveECG for iPhone v.1.2.1 – AliveCor Heart Monitor for iPhone
- Galaxy S3 Android 4.1.2 AliveECG for Android (Beta 1.1.5) – AliveCor Heart Monitor Universal Module

4.2. Equipment

- Apple iPhone 4S running iOS 5.1.1 SN DNPHCWABDT9Y
- AliveCor Heart Monitor for iPhone (AC-001, S/N: 01125201730)
- AliveECG for iPhone software from Apple iTunes App Store (Version: 1.2.1)
- Patient Simulator (PS410 EIN#002 Calibration Due: 7/13)
- Office PC with PDF viewer such as Adobe Acrobat MacBook Pro C02HR08GDV7P
- Transparency film for laser printing
- Office laser printer
- Samsung Galaxy S3 running Android OS 4.1.2 SN RF1C982K0CT
- AliveCor Heart Monitor Universal Module (AC-004, S/N: 131)
- AliveECG for Android software (beta) (Version: 1.1.5)

5. RESULTS

Summary of results:

Test Run	Application Version	Tests Passed	Tests Failed

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1	iOS 1.2.1 Android 1.1.5	1	0

6. DEVIATIONS FROM TEST PROTOCOL

Test Case ID	Original	Deviated	Justification	Resolution
Equipment	Use iPhone 4S running iOS 6.1.3 Use Samsung S3 running Android OS 4.0	Used iPhone 4S running 5.1.1 Used Samsung S3 running Android OS 4.1.2	The oldest version of the iOS compared to the newest version of Android is the most applicable test case.	Modify plan.

7. SUMMARY

(b) (4)

[redacted]

8. APPENDIX A

The datasheet for this test run can be found in this directory, filename: RPT133-datasheet.pdf

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 1-29-2024 by CDRH under #2024-2424.

Recorded: Friday, 12 July 2013 09:31:53 AM **Activities:** (0)
Heart Rate: 60 bpm **Duration:** 30s **Symptoms:** (0)

Identical

AliveCor

iOS David Albert, MD 7/12/2013

Mains filter: 50Hz Scale: 25mm/s, 10mm/mV

(c) Copyright 2012-2013, AliveCor Inc, Alive Beta v1.2.1.386, Report v2.1.0, UUID: 7987CB8A-01E9-4E79-8C1C-0635FEE7E93D

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Identical

Patient:
Recorded: 12 Jul 2013 10:37:37
Heart Rate: 60 bpm **Duration:** 40s

AliveCor

Android

David Albert, MD
7/12/2013

Mains Filter: 60Hz Scale: 25mm/s, 10mm/mV

(c) Copyright 2013 AliveCor Inc. AliveECG 1.1.5 UUID: aed37baa-a251-498b-a3aa-c1069a7095df

Questions? Contact FDA/CDRH/OCE Section/CDRH Page I STATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING – ANIMAL

This section **does not apply**.

Questions? Contact FDA/CDRH/OCE/Desk at CDRH-PRGSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

PERFORMANCE TESTING – CLINICAL

This section **does not apply**.

The previous submission for the *AliveCor Heart Monitor for iPhone* (K122356) included clinical testing that was performed using prototype devices under IRB approval that provides some indication of design efficacy. Those studies are still valid but not applicable directly to this submission, therefore omitted.

After clearance of the original 510(k) submission (K122356) AliveCor conducted formal design validation testing to support the clinical data submitted in the previous submission. Similar design validation testing will be performed on additional mechanical configurations of the AliveCor Heart Monitor that AliveCor deems necessary by our Design Control process and Design Development Plan(s).

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRASTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

Declaration of Conformity with Design Control Activities

All design control activities have been performed per the AliveCor, Inc. Quality System Procedures and in compliance with Title 21 CFR part 820.30.

The following is a summary of the design control activities completed for the *AliveCor Heart Monitor* and *AliveCor Heart Monitor Universal Module* design history files:

(b)(4)

ECG for iPhone Hazard Analysis
ECG for iPhone Risk Assessment
ECG for iPhone Design Description, Software
ECG for iPhone Human Design and Development Plan
ECG for iPhone Human Design Input-Output Matrix, Hardware
ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
ECG for iPhone Human Validation Protocol
ECG for iPhone Human Validation Report
ECG for iPhone Human Verification Protocol, iOS Application
ECG for iPhone Human Verification Report, iOS Application
ECG for iPhone Human Verification Protocol, System Integration
ECG for iPhone Human Verification Report, System Integration
ECG Website Human Design Input-Output Matrix
ECG Website Human Verification Protocol, Web Application
ECG Website Human Verification Report, Web Application
ECG Universal Module Design and Development Plan
ECG Universal Module Design Input-Output Matrix, Hardware
ECG Universal Module Design Input-Output Matrix, Mobile Software for Android OS
ECG Universal Module Verification Protocol, Android Application
ECG Universal Module Systems Integration Verification Protocol
ECG Universal Module Verification Report Systems Integration
ECG Universal Module Mechanical Verification Protocol
ECG Universal Module Mechanical Verification Report
AliveECG App and Mobile Device Compatibility Validation Protocol

Note that the titles of the above referenced documents are specific for the first, second and third mechanical configuration of the *AliveCor Heart Monitor* released for the iPhone 4/4S, iPhone 5 and Universal Module. The project name "*ECG for iPhone*" which was originally chosen for the general project may apply to several mechanical configurations despite the fact they may not be specific to an "iPhone" design. For example, it was natural for us to add the iPhone 5 mechanical configuration hardware into the scope of these documents rather than create a duplicate set of design control documentation. Very few changes were necessary due to the similarity of products for the iPhone 4/4S and iPhone 5 devices. Another example is the risk management documents apply to all three configurations.

Questions? Contact FDA/CDRH/OCE/Decat CDRH-PQMSTATUS@fda.hhs.gov or 301-796-8118

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AliveCor

Declaration of Conformity with Design Controls

All design control activities including verification activities, as required by the design and development plan, and risk assessment for the additional mechanical configurations of the *AliveCor Heart Monitor* and necessary software (*AliveECG* App) changes shall be performed by the designated individual(s) and the results shall demonstrate that the predetermined acceptance criteria were met.

The manufacturing facility, IDT Technology Ltd. is in conformance with the design control requirements as specified in 21 CFR part 820.30. Records will be available for review for each mechanical configuration of the *AliveCor Heart Monitor* family of products.

_____

Michael S. Righter
Director, Regulatory Affairs

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San Francisco, CA 94103

email: mike@alivecor.com
main: 415.795.9812
fax: 415.397.0440

Questions? Contact FDA/CDRH/OCE/DHC at CDRH-PRAStatus@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

RISK ASSESSMENT

This section contains the following reports:

(b)(4) – ECG for iPhone Risk Assessment

– ECG for iPhone Hazard Analysis

AliveCor, Inc. considers Risk Management to be a continual process and each of the documents contained in this section to be 'living' documents. These documents will be updated upon future device/system verification and validation, product surveillance, and other activities as described in AliveCor's Quality Management System procedures.

Upon the initiation of a design development plan for a new mechanical configuration of the *AliveCor Heart Monitor* to fit additional mobile computing platform units (such as Android phones or next generation of iPhone), AliveCor will either update the Hazard Analysis and Risk Assessment above to include the new mobile computing platforms in the scope of the document. Both the Risk Assessment and Hazard analysis show an example of this methodology with the addition of the iPhone 5 compatible mechanical configuration.

Risk management methods have been applied to accommodate the new use model for the Health Conscious Individual (HCI) using the device Over-the-counter according to:

- ISO14971 - Medical devices. Application of risk management to medical devices
- FDA Draft Guidance: Design Considerations for Devices Intended for Home Use
- FDA Draft Guidance: Applying Human Factors and Usability Engineering to Optimize Medical Device Design (June 22, 2011)
- IEC 60601-1-6 – Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366 – Medical devices – Application of usability engineering to medical devices

As a result of the additional process considerations and use case, the most notable newly identified hazard is for the health conscious individual that does not have the required specialty knowledge (or access to consult a medical professional) to properly view the ECG, leading to misguided concerns/reactions. AliveCor chose to mitigate that risk by hiding the ECG waveform (de-featured app) from the health conscious individual. To accommodate our current "for prescription" user, and if a health conscious individual becomes a under the care and guidance of a physician, AliveCor has the ability to unhide the ECG waveform (fully featured app) if there is a clinical need.

Other additional areas of risk identified include some more in-depth analysis of how the device may be used in ways that are not anticipated and other user-centric design considerations especially those related to the devices graphical user interface.

The guidance documents and standards listed above led to a significant improvement to our validation plans is the initiation of Human Factors Validation testing to support many of the mitigations identified in the hazard analysis. The scope of that protocol and report are growing as we better understand our user groups since we did not have the opportunity to perform formative research early on in the design process. We feel that the robustness of our verification and validation activities are building a great foundation for future development of mechanical configurations that fit into the *AliveCor Heart Monitor* family of products.

Questions? Contact FDA/CDRH/OCE/Document Control Room at CDRH-REGSTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE:	ECG for iPhone Risk Assessment

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Change History

Revision	Date	Description of Change	Author
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(b) (4) Internal Risk Analysis Procedures

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG for iPhone Hazard Analysis
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Change History

Revision	Date	Description of Change	Author
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AliveCor

510(k) PREMARKET NOTIFICATION

Biocompatibility Testing

This section contains the following reports:

1. **ALIVECOR HEART MONITOR BIOCOMPATIBILITY TESTING PER ISO 10993-1**

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2. **SCOPE**

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

To: ECG Universal Module DHF

From: Michael Righter

Date: October 1st, 2013

Subject: AliveCor Heart Monitor Universal Module addition of Housing Material

1. PURPOSE:

This memo is intended to be used for evaluation of additional materials included with the AliveCor Heart Monitor Universal Module as compared to the design proposed in the FDA regulatory submission (K130409) for the AliveCor Heart Monitor. This memo addresses continued compliance with ISO 10993-1 biocompatibility requirements.

2. BACKGROUND:

The biocompatibility assessment for the *AliveCor Heart Monitor for iPhone* was conducted according to the recommendations in Blue Book Memorandum #G95-1, entitled Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". The required biocompatibility tests according to ISO10993-1 were performed to ensure User safety while handling the Case for its utility purpose (as an iPhone case), and using the device for its medical purpose. All testing was performed by a certified laboratory, using IS 10993 requirements, methods and guidelines.

Subsequently the AliveCor Heart Monitor for iPhone 5 was added to the product line that used identical materials as the original device. No additional testing was necessary as a result of a risk assessment. Similarly, the AliveCor Heart Monitor Universal Module was designed with the exact same materials as the previous mechanical configurations. No additional testing was necessary to establish equivalence to previous designs based on a risk assessment. This conclusion was in accordance to the Design and Development Plan for the Universal Module.

3. INTRODUCTION:

Recently, a change in design of the Universal Module was considered to change the housing material of the Universal Module to reduce stress cracking due to exposure to chemicals that users may have on their hands while holding the device such as particular oil based hand lotions.

Through an investigation, it was determined that the original PC/ABS blend is more susceptible to cracking than other polymer blends in the same family. Makroblend UT5205, a PC/PBT blend offers very similar material characteristics while improving chemical resistance and improving the manufacturing process with better mold release and flow characteristics, ultimately reducing manufacturing fall out.

Questions? Contact FDA/CDRH/OCE/DHC and CDRH-REGISTATUS@fda.hhs.gov or 301-796-8118

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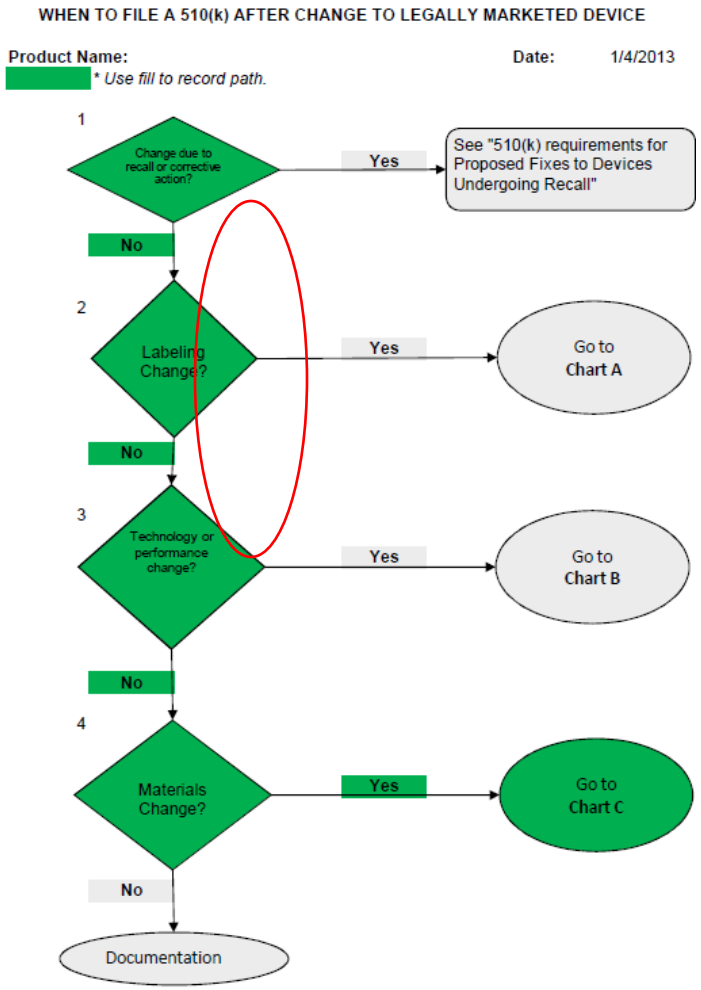
As with the previous "mechanical configuration" of the AliveCor Heart Monitor, the Universal Module is subject to incidental and intended contact by the clinician handling the device and by the patient during ECG acquisition. This interaction is typical and necessary for most, if not all portable ECG monitors. Incidental contact may come from handling the device or the stainless-steel electrodes.

The modification of materials to use Makroblend UT5205 must be considered in the biocompatibility assessment.

4. JUSTIFICATION:

All tests originally performed on the AliveCor Heart Monitor for the iPhone 4/4S are still applicable to the Universal Module. The risk evaluation associated with the exposure of a user to the additional polymer housing does not justify additional testing to mitigate the risk of harm.

Following the FDA guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device", the following flowcharts were followed:



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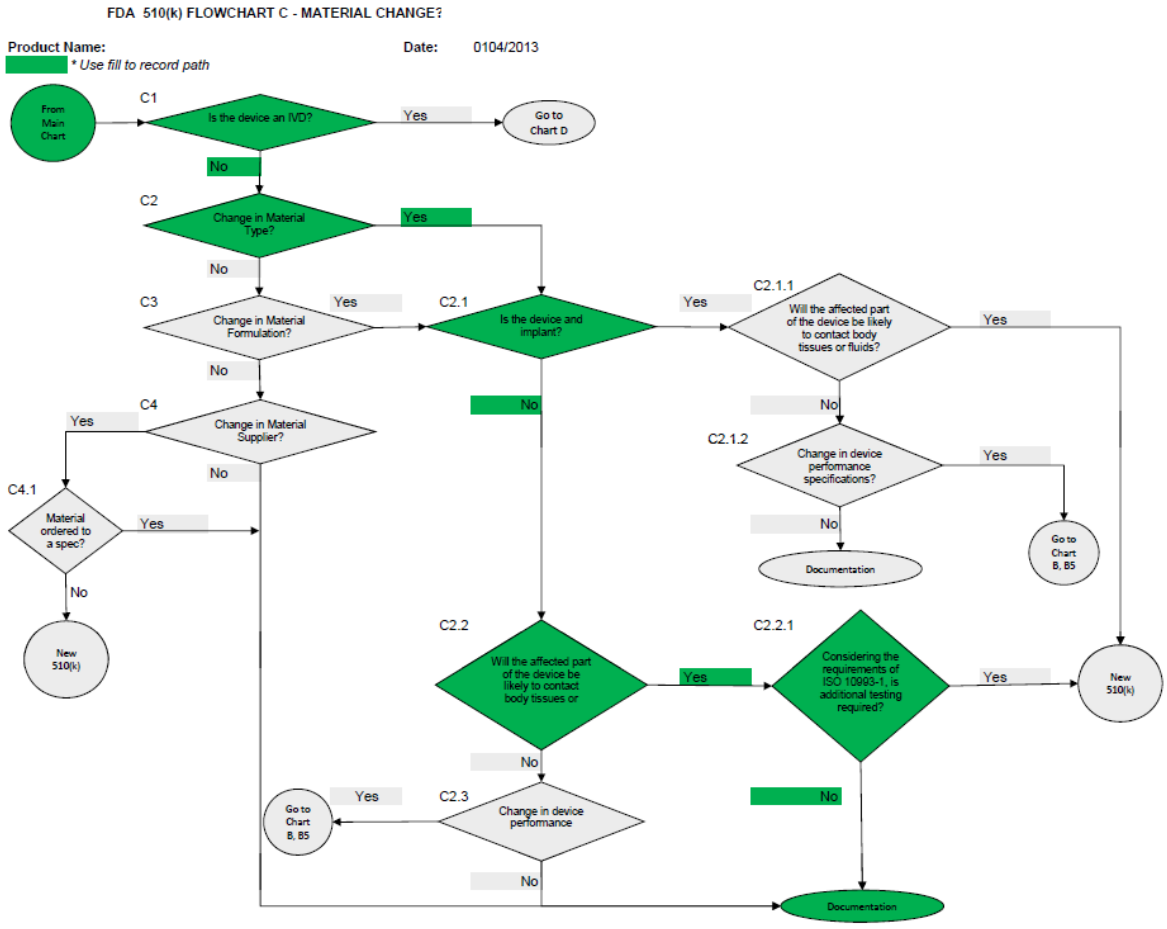

All answers and decisions above are self explanatory until Question C2.2.1:

Considering the requirements of ISO 10993-1, is additional testing required?

Following methods described in ISO 10993-1:2009 (BIOLOGICAL EVALUATION OF MEDICAL DEVICES EVALUATION AND TESTING: Annex B - Guidance on the risk management process) and ISO 14971 (MEDICAL DEVICES — APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES), if the evaluation of the biological risk concludes from existing data that the identified risks are acceptable, no further testing is needed. Otherwise, additional information should be obtained. Testing should only be undertaken if the additional tests are judged likely to assist in reaching a conclusion, i.e. the rationale for testing should be based on an analysis of the relevant risks from the existing data.

As a result of our risk assessment of the additional materials (Makroblend UT5205), the residual hazards are acceptable and are deemed acceptable without additional biocompatibility testing.

RESULT: DOCUMENTATION

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5. CONCLUSION:

AliveCor believes that the patient-contact materials proposed for use in the *AliveCor Heart Monitor Universal Module* meet the requirements for biocompatibility and can therefore be safely used in the proposed application.

_____

MICHAEL RIGHTER
DIRECTOR, REGULATORY AFFAIRS

Questions? Contact FDA/CDRH/OCE/DHT4 at CDRH-STATUS@fda.hhs.gov or 301-796-8118

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AliveCor

510(k) PREMARKET NOTIFICATION

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Names: AliveCor Heart Monitor

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.

Prescription Use X		Over-The-Counter Use X
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TITLE: ECG for iPhone 5 Quick Start Guide, OTC
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Change History

Revision	Date	Description of Change	Author
A	March 26, 2013	Initial Release, modifications to 08LB02 for OTC	Michael Righter
B	December 19, 2013	Modification of indications for use according to FDA submission K130921	Michael Righter

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AliveCor

Heart Monitor

Quick Start Guide

for iPhone® 4/4S or 5

NOTE: For the most up-to-date information on your product please visit www.alivecor.com/manuals

For more info visit AliveCor.com or follow us on Facebook at Facebook.com/AliveCor or Twitter @AliveCor

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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.

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- Request analysis by a medical professional.

1.1. Indications for Use

~~The Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.~~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.
- 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,

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- 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.

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- 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.

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.

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

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 the AliveECG app will allow you to 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. LIMITED WARRANTY AND RETURNS POLICY

This Limited Warranty and Returns Policy ("Limited Warranty") applies to AliveCor Heart Monitor (the "Product") and is given by AliveCor, Inc., to the individual or entity (the "Owner") who purchased the Product from AliveCor or an AliveCor authorized dealer. This Limited Warranty applies only within the United States, European Union and within countries of the European Free Trade Association where the products are available for sale to customers located in such countries, and is not transferable.

14-DAY RETURN POLICY

If you purchased the Product directly from AliveCor or an AliveCor authorized dealer, you may return the Product within 14 days of receiving it. In order for a refund under this Returns Policy to be granted, you must request a Return Merchandise Authorization (RMA) number from AliveCor during the 14-day period following the date you received the Product from AliveCor or an

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authorized dealer. You may request an RMA number by submitting a request at https://support.alivecor.com. If the Product is returned in accordance with this Returns Policy, AliveCor will credit the account you used to make the original purchase with the full purchase price you paid for the Product and any applicable taxes minus any shipping and handling charges you paid when you purchased the Product. The time to credit your account may vary, depending on processing time. Please allow a minimum of 4 weeks for AliveCor to credit the account used to make the original purchase. If you received a damaged Product directly from AliveCor, please contact AliveCor's Customer Service at https://support.alivecor.com. If you purchased the Product from a retailer or distributor other than AliveCor, please contact that retailer or distributor regarding non-warranty returns.

MANUFACTURER'S LIMITED WARRANTY

AliveCor warrants to the Owner that the Product will materially conform to its published specifications and be free from defects in materials and workmanship under normal use for a period of ONE YEAR commencing on the date of delivery (the "Warranty Period"). If the Product proves defective during the Warranty Period, we would ask you to follow the instructions set out below for returning the Product, and AliveCor will take one of the following actions: (i) replace the Product with a product that is the same or equivalent to the Product you purchased: (ii) repair the Product; or (iii) refund to you the whole or part of the purchase price of the Product. A repaired or replacement Product or part assumes the remaining warranty of the original Product, or 30 days from the date of replacement or repair, whichever is longer. If AliveCor determines that a returned Product is irreparable, AliveCor will not return that Product to Owner and that Product becomes the property of AliveCor. AliveCor reserves the right to either replace any discontinued Product with a new product of comparable value and function, or to refund the purchase price paid for the Product by Owner.

HOW TO OBTAIN WARRANTY SERVICE

To obtain warranty service, please follow the instructions found at http://www.alivecor.com/warranty. If AliveCor determines that a Product is eligible for warranty service, AliveCor shall bear the costs associated with returning a Product for warranty service. AliveCor is not responsible for items damaged or lost in transit. A replacement Product provided under this Limited Warranty will only be dispatched to addresses within the United States, European Union and addresses within countries of the European Free Trade Association where the Product is available for sale to customers in such countries.

WHAT IS NOT COVERED?

This Limited Warranty will be void if the Product: (a) is used in any manner that is inconsistent with the intended purpose or design of the Product as described in AliveCor's published documentation for the Product, (b) is altered in any way, (c) the Product is used or maintained in any manner that is inconsistent with AliveCor's instructions or warnings included with the Product or (d) the Product is subjected to any other misuse, abuse, neglect, accident, or external forces. This Limited Warranty does not cover normal wear and tear (including, without limitation wear and tear of the display screen). AliveCor does not warrant that the operation of the Product will be uninterrupted or error-free. To the greatest extent permitted by applicable law, the warranties set forth in this Limited Warranty are exclusive and in lieu of all other warranties, express or implied.

LIMITATION OF REMEDIES

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Resellers, agents, or employees of AliveCor are not authorized to make any modification, extension, or addition to this Limited Warranty. This Limited Warranty replaces all other AliveCor warranties and liabilities whether oral, written, (non-mandatory) statutory, contractual in tort or otherwise, including without limitation, and where permitted by applicable law, any implied conditions, warranties or other terms as to satisfactory quality or fitness for purpose. To the extent permitted by applicable law, AliveCor does not assume any liability for loss of or damage to or corruption of data, for any loss of profit, loss of use of Products or functionality, loss of business, loss of contracts, loss of revenues or loss of anticipated savings, increased costs or expenses or for any indirect loss or damage, consequential loss or damage or special loss or damage. To the extent permitted by applicable law, AliveCor's liability shall be limited to the purchase value of the Product.

OTHER IMPORTANT NOTICES

The rights provided to you under this Limited Warranty are provided in addition to all rights and remedies conveyed to you by consumer protection laws and do not affect your legal (statutory) rights under your applicable national law. This Limited Warranty is offered subject to AliveCor's Heart Monitor Terms and Conditions, which may change from time to time. You can find the latest version on our website at: http://www.alivecor.com/tos or by contacting us directly at support@alivecor.com. In the case of any inconsistencies between the Terms and Conditions and this Limited Warranty, this Limited Warranty will prevail. This Limited Warranty does not apply to any Apple iPhone or the cellular and/or other network or system on which the Product operates. Therefore, AliveCor will not accept any responsibility under this Limited Warranty for the operation, availability, coverage, services or range of the cellular or other network or system. Always completely follow safety, use, operation, and maintenance instructions for the Product or any other AliveCor product. Please remember to make back-up copies or keep written records of all important content and data stored in your Product, because content and data may be lost during repair or replacement of the Product. AliveCor, shall not under any circumstance be liable either expressly or impliedly, for any damages or losses of any kind whatsoever resulting from loss of, damage to, or corruption of, content or data during repair or replacement of the Product.

European Authorised Representative:

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

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20041 Agrate Brianza (MI), Italy

Manufactured for:

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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08LB04 Revision ~~A~~ B | ~~March~~ December 2013

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AliveCor

AliveCor Heart Monitor

User Manual

iPhone® 4/4S/5

OTC

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

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08LB05 Revision BA | March December 2013

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AliveCor

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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 Heart Monitor is intended to record, display, store and transfer single-channel electrocardiogram (ECG) rhythms.~~ 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.
- 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.

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- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- 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).

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- **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 the AliveECG app will allow you to view the recording to share with your personal physician.

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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.

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.

- 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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- 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.

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12. 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: • 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 *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 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 *AliveECG* App on your phone. Launch the *AliveECG* 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).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Problem	Solution
I forgot my password and I'm unable to reset it.	Ensure that you've downloaded the *AliveECG* App on your phone. Similarly, ensure that you are logging into www.alivecor.com (not www.alivecorvet.com). 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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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 ..... 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 ..... iPhone® 4/4S CR2016, iPhone® 5 CR2025 3V Coin Cell
Battery life ..... 100 Hours 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	

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.

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14. ALIVECOR CONTACT INFORMATION

AliveCor, Inc.

30 Maiden Lane, 6th Floor

San Francisco, CA 94108

United States

www.alivecor.com

15. EUROPEAN AUTHORIZED REPRESENTATIVE

Oregon Scientific Italia S.p.A

Centro Direzionale Colleoni -

Viale Colleoni 3, Palazzo Taurus 2,

20041 Agrate Brianza (MI), Italy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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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	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	

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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.			

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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** $d = [\frac{3.5}{V_1}]\sqrt{P}$ $d = [\frac{3.5}{E_1}]\sqrt{P}$ 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:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
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.			

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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.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17. 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

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TITLE: ECG for iPhone Human Design Input-Output Matrix, Mobile Software for iOS
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Change History

Revision	Date	Description of Change	Author
(b)(4)			

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(b) (4) Software Matrix Specifications

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TITLE:	ECG for iPhone Human Verification Protocol, iOS Application

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(b)(4)			

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(b) (4) Software Test Plan and Apps Set up for Device

(b) (4) Software Test Plan and Apps Set up for Device

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Records processed under FOIA# 2014-9908; Released by CDRH on 6-22-2015. Rereleased 7-29-2024 by CDRH under #2024-2424.

TITLE: ECG for iPhone Human Verification Report, iOS Application

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Change History

Revision	Date	Description of Change	Author
(b)(4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b) (4) Test Cases that Passed Specific Requirements and Set up for Device

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