

Pg 1 of 2

k121197

AUG 10 2012

8 510(k) Summary

Submitter:	Preventice, Inc. 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Contact Person:	Drew Palin, M.D. Medical Innovation Officer dpalin@preventice.com Mobile: 414-688-6858 Office : 507-322-3712 FAX: 507-281-3630 Preventice 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Date Prepared:	April 18, 2012
Trade Names:	BodyGuardian System [Preventice BodyGuardian Device (BodyGuardian Control Unit and BodyGuardian SnapStrip), Preventice BodyGuardian Connect, BodyGuardian Application, Preventice PatientCare, PatientCare Portal for the Web, and PatientCare for iPad
Classification:	21 CFR 870.1025 <ul style="list-style-type: none"> • Patient Physiological Monitor (with arrhythmia detection) • Arrhythmia Detector and Alarm
Product Codes:	MHX, DSI
Predicate Device:	AVIVO Mobile Patient Management System (k083287)
Device Description:	The BodyGuardian System is an ambulatory cardiac monitoring system prescribed by healthcare providers. It monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.

k121197

510(k) Summary (Continued)

Intended Use:	<p>The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:</p> <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity
Comparison of Technological Characteristics:	<p>Both the predicate system and the BodyGuardian System are small, ambulatory cardiac monitors that measure ECG, heart rate, respiration rate and activity levels. Both transmit their data to an external device which, in turn, broadcasts the data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics.</p>
Non-Clinical Testing:	<p>The following bench testing was conducted on the BodyGuardian System:</p> <ul style="list-style-type: none"> • EMC and electrical safety testing • ECG performance testing • Activity level measurement validation • Respiration rate measurement validation • Software verification and validation • Biocompatibility testing
Clinical Testing	<p>Not applicable.</p>
Conclusion:	<p>We conclude that the results of testing show the BodyGuardian System to be substantially equivalent to the predicate device.</p>



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 10 2012

Preventice, Inc
c/o Drew Palin, M.D.
Medical Innovation Officer
2765 Commerce Drive NW, Suite 220
Rochester, MN 55901

Re: K121197
Trade Name: Preventice BodyGuardian System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
(including ST-segment measurement and alarm)
Regulatory Class: II (two)
Product Code: DSI
Dated: August 2, 2012
Received: August 3, 2012

Dear Mr. Palin:

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.

Page 2 – Mr. Drew Palin

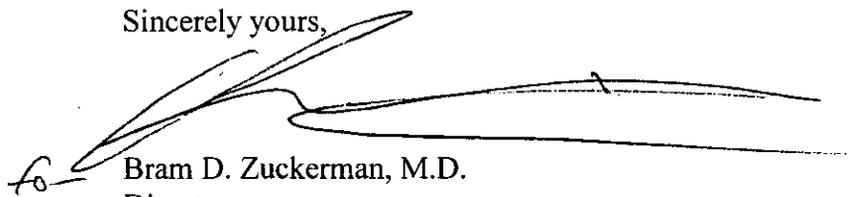
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

Enclosure

K121197

7 Indications for Use Statement

510(k) Number (if known):

Device Name: BodyGuardian System

Indications for Use:

The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

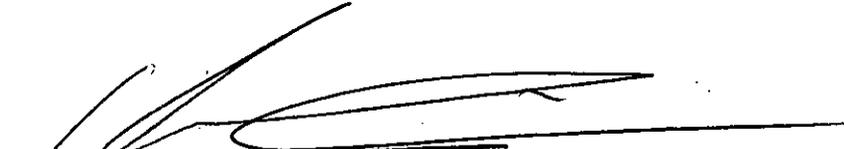
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121197

K121197 / OR v.1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 09, 2012

PREVENTICE, INC.
 2765 COMMERCE DRIVE NW
 SUITE 220
 ROCHESTER, MINNESOTA 55901
 ATTN: DREW PALIN

510k Number: K121197

Product: BODYGUARDIAN SYSTEM
 BODYGUARDIAN
 On Hold As of 7/9/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModer nizationAct/ucm136685.htm>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Director, 510(k) Program
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

* * * COMMUNICATION RESULT REPORT (JUL. 9. 2012 1:32PM) * * *

FAX HEADER 1:
FAX HEADER 2:TRANSMITTED/STORED : JUL. 9. 2012 1:31PM
MODE OPTION

MODE	OPTION	ADDRESS	RESULT	PAGE
7387	MEMORY TX	915072813630	OK	2/2

REASON FOR ERROR
R-1) HANG UP OR LINE FAIL
R-3) NO ANSWER

E-2) BUSY
E-4) NO FACSIMILE CONNECTION



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center W068-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

July 09, 2012

PREVENTICE, INC.
2765 COMMERCE DRIVE NW
SUITE 220
ROCHESTER, MINNESOTA 55901
ATTN: DREW PALIN

510k Number: K121197
Product: BODYGUARDIAN SYSTEM
On Hold As of 7/9/2012

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

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

COVER SHEET MEMORANDUM

From: Reviewer Name Orlando Lopez
Subject: 510(k) Number k121197
To: The Record

Please list CTS decision code TH

- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	<i>Attach IFU</i>	√	
510(k) Summary /510(k) Statement	<i>Attach Summary</i>	√	
Truthful and Accurate Statement.	<i>Must be present for a Final Decision</i>	√	
Is the device Class III?			√
If yes, does firm include Class III Summary?	<i>Must be present for a Final Decision</i>		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		√	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			√
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			√
Is this device intended for pediatric use only?			√
Is this a prescription device? (If both prescription & OTC, check both boxes.)		√	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, <i>Certification with Requirements of ClinicalTrials.gov Data Bank</i> ? (If not, then applicant must be contacted to obtain completed form.)			√
Does this device include an Animal Tissue Source?			√
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)			
Nanotechnology			

Is this device subject to Section 522 Postmarket Surveillance? (Postmarket Surveillance Guidance, http://www.fda.gov/cdrh/osb/guidance/316.html)	Contact OSB.
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.

Regulation Number	Class*	Product Code
21 CFR 870.1025	II (*If unclassified, see 510(k) Staff)	DSI

Additional Product Codes: _____

Review: _____
 (Branch Chief) (Division Code) (Date)

Final Review: _____
 (Division Director) (Date)

Lopez, Orlando

From: Lopez, Orlando
Sent: Friday, July 06, 2012 2:36 PM
To: 'Drew Palin'
Cc: Aguel, Felipe
Subject: BodyGuardian system (K121197) - placed on telephone hold - Additional Information request

Importance: High

Dear Mr. Palin:

We have reviewed your 510(k) submission for a premarket notification of intent to market the BodyGuardian ambulatory ECG monitor system. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided.

To complete the review of your submission, we require the following additional information:

Wireless Technology

- 1) Because this device incorporates RF wireless technology the sponsor should address safety and effectiveness concerns involving the wireless technology, which are largely outside the scope of the IEC 60601-1-2 standard for EMC. The sponsor should address the following areas with testing and information that describes the device wireless specifications and characteristics, the device functions and associated risks, testing results, and acceptable tolerances for: data integrity (ensuring proper wireless function), data latency (ensuring functions occur in a timely fashion), coexistence with other RF wireless (see point 3 for details), EMC of the wireless signals, and data security.

Please provide a brief summary of the testing and results for wireless testing including the following points:

- a. Provide detailed information on the RF wireless technology implemented on the proposed device, including: transfer power, RF frequency (and scheme), modulation, data rate, data flow, protocol, security. The information should indicate whether other devices (medical or non-medical) can operate on the same network.
- b. Summary of claims for the device wireless function and performance, including safeguards and redundancy. The claims should be related to the risks for the device functions and their failure.
- c. A summary of all wireless data integrity, coexistence, EMC, and security testing of this device, with justifications for what was done, test results and data to support all claims, and the pass/fail criteria.

Wireless Coexistence

- 2) Your 510(k) submission includes a reference to wireless communication. Wireless communication can change the risk profile of the device and thus FDA recommends that you address safety and effectiveness concerns for the use of RFID in your device. Wireless coexistence is the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules. Wireless coexistence issues are not adequately addressed via the IEC 60601-1-2 EMC standard or any other current standards. To address these concerns properly the sponsor should define all functions which will be implemented wirelessly, speak to the likelihood of other wireless devices operating in the same vicinity as your device and perform reasonable testing with such devices if appropriate. In addition, if the sponsor foresees multiple copies of your device to be operated in the same area then this situation should also be included in the testing.

Please provide a brief summary of the wireless coexistence testing including the following points:

- a. Define all functions to be implemented wirelessly. Describe safeguards and redundancy for the wireless function and possible risks associated with latency and function failure.
- b. Explain all devices to be included in the coexistence test plan and justify their choice and how they represent a reasonable worst case scenario. Include all pertinent information such as transfer power, frequency (and scheme), modulation, data rate, data flow, protocol, security, etc for your device and all possible interfering devices.

- c. Explain the pass/fail criteria for your device and the interfering devices with justifications on how these criteria were chosen and how they will be quantified and measured. Important parameters to keep in mind while testing are data integrity (ensuring proper function performance) and latency (ensuring functions occur within a timely fashion).
- d. Explain how the wireless coexistence testing was performed and how the testing addresses the possible risks from other wireless devices. Important parameters are separation distances, number of interferers, location, orientation, etc.
- e. Proper labeling should be included not only in a user manual, but also on the device itself cautioning users about the risks associated with the use of RF wireless technology and what can be done to mitigate possible interference issues.

Your submission will be placed on telephone hold until you reply to these deficiencies. Please send your response to the FDA Document Mail Center and provide an electronic copy to facilitate and expedite the review:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please acknowledge that you have received this e-mail.

Kind regards,
Orlando Lopez

Orlando Lopez, PhD, GWCPM

*Biomedical Engineer & Scientific Reviewer
Cardiac Electrophysiology & Monitoring Devices Branch •
Division of Cardiovascular Devices FDA / CDRH / ODE •
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002 •
Phone: 301-796-6161 • Email: Orlando.lopez@fda.hhs.gov*



DEPARTMENT OF HEALTH AND HUMAN SERVICES M E M O R A N D U M

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

**Premarket Notification [510(k)] Review
Traditional
K121197**

Date: July 6, 2012
To: The Record
From: Orlando Lopez, Ph.D., GWCPM

Office: ODE
Division: DCD

510(k) Holder: Preventice, Inc
Device Name: Preventice BodyGuardian System
Contact: Drew Palin, M.D. (Medical Innovation Officer)
Address: 2765 Commerce Drive NW, Suite 220
Rochester, MN 55901
Phone: 507-322-3712 (Office) / 414-688-6858 (Mobile)
Fax: 507-281-3630
Email: dpalin@preventice.com

Purpose and Submission Summary

The 510(k) holder, Preventice, Inc ("Preventice" or "the firm") would like to introduce into interstate commerce the BodyGuardian system for cardiac monitoring. The BodyGuardian system detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time, including: ECG, heart rate (HR variability and HR reliability), respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.

The firm has identified the AVIVO Mobile Patient Management System (K083287) as an appropriate predicate device for consideration towards establishing substantial equivalence in this submission.

The firm has appropriately indicated that the device should be regulated under 21 CFR 870.1025 (Arrhythmia detector and alarm - including ST-segment measurement and alarm) with a product code of DSI (detector and alarm, arrhythmia), hereunder considered as Class II device. The proposed device is not considered a combination product (code N).

Reviewer's Recommendation

I recommend this submission be placed on telephone hold requesting the sponsor to provide wireless coexistence test results for the proposed device. Please see attached email with AI request sent to sponsor.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Rx		
Truthful and Accuracy Statement	√		
510(k) Summary or 510(k) Statement	√		
Standards Form	√		

Standards Referenced

The sponsor indicated the proposed device has been tested in accordance to standards below:

	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	IEC	Medical electrical equipment- Part 1: General requirements for safety,	1998; Amendment 1, 1991-11, Amendment 2, 1995	1998
2	60601-1-2	IEC	<i>Medical Electrical Equipment- Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic compatibility Requirements and Tests</i>	<i>(editor 2: 2001; Amendment 1:2004)</i>	2004
3	60601-1-4	IEC	<i>Medical Electrical Equipment- Part 1-4: General Requirements for Safety. Collateral Standard: Programmable Electrical Medical Systems</i>	<i>Edition 1.1</i>	2000
4	60601-1-6	IEC	<i>Medical Electrical Equipment. Part 1-6: General Requirement for Safety. Collateral Standard: Usability</i>	<i>Edition 1</i>	2004
5	60601-2-47	IEC	<i>Medical Electrical Equipment- Part 2-47: Particular requirements for the safety including essential performance, of ambulatory electrocardiographic systems</i>	<i>Edition 1</i>	2001

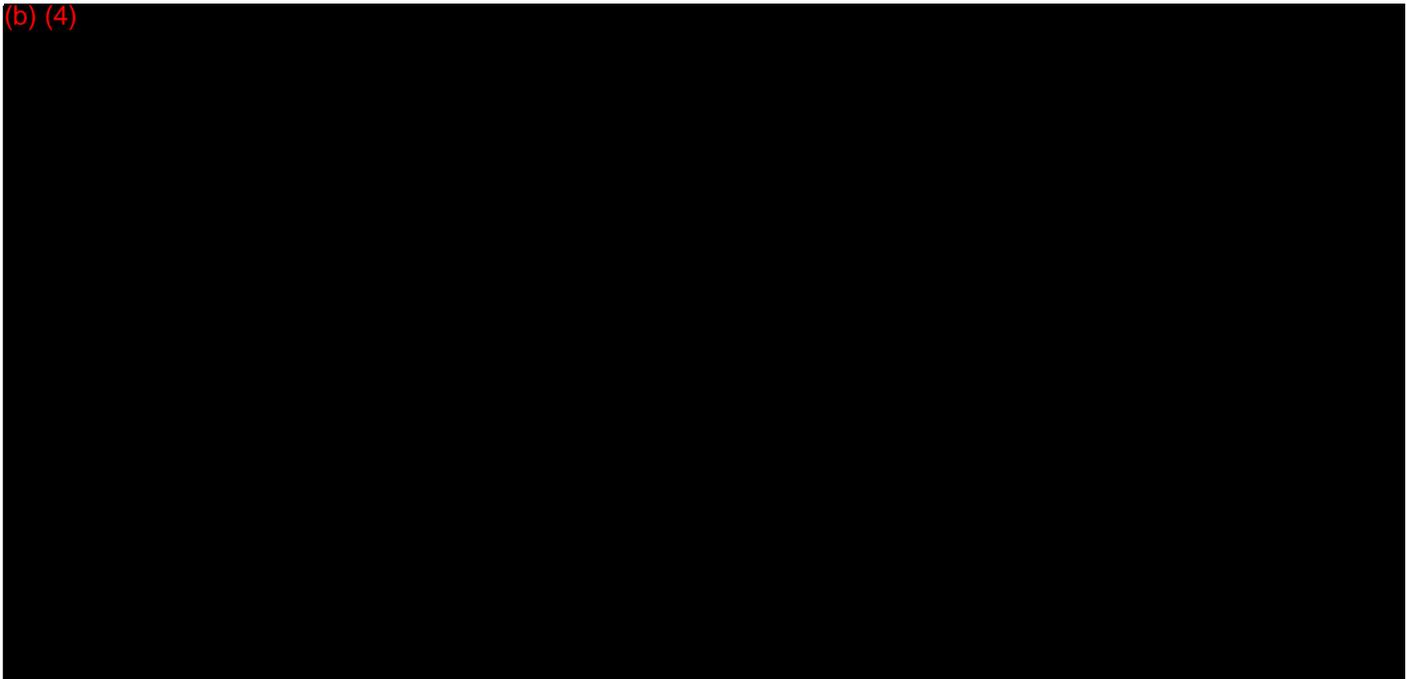
	Standards No.	Standards Organization	Standards Title	Version	Date
6	60601-2-49	IEC	<i>Medical Electrical Equipment- Part 2- 49: Particular requirement for the safety of the multifunction patient monitoring equipment</i>	Edition 1	2001

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		√	
Is the device an implant (implanted longer than 30 days)?		√	
Does the device design use software?	√		
Is the device sterile?		√	
Is the device reusable (not reprocessed single use)?	√		
Are "cleaning" instructions included for the end user?			

The proposed device, Preventice BodyGuardian, is a cardiac monitoring system prescribed by healthcare providers. It monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, sends the data to a remote Preventice computer server, stores the data in secure databases and presents the data for review by healthcare professionals

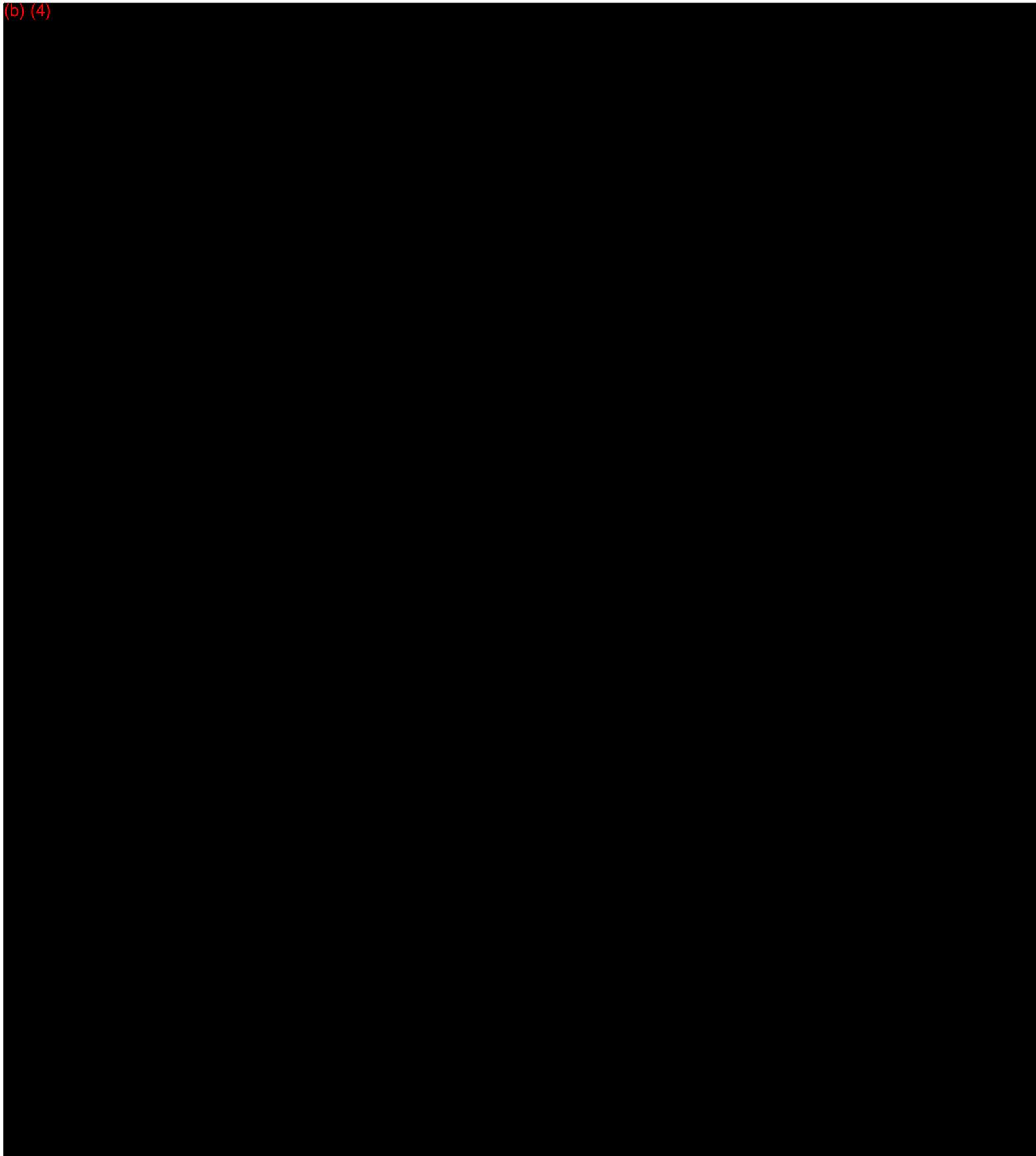
(b) (4)



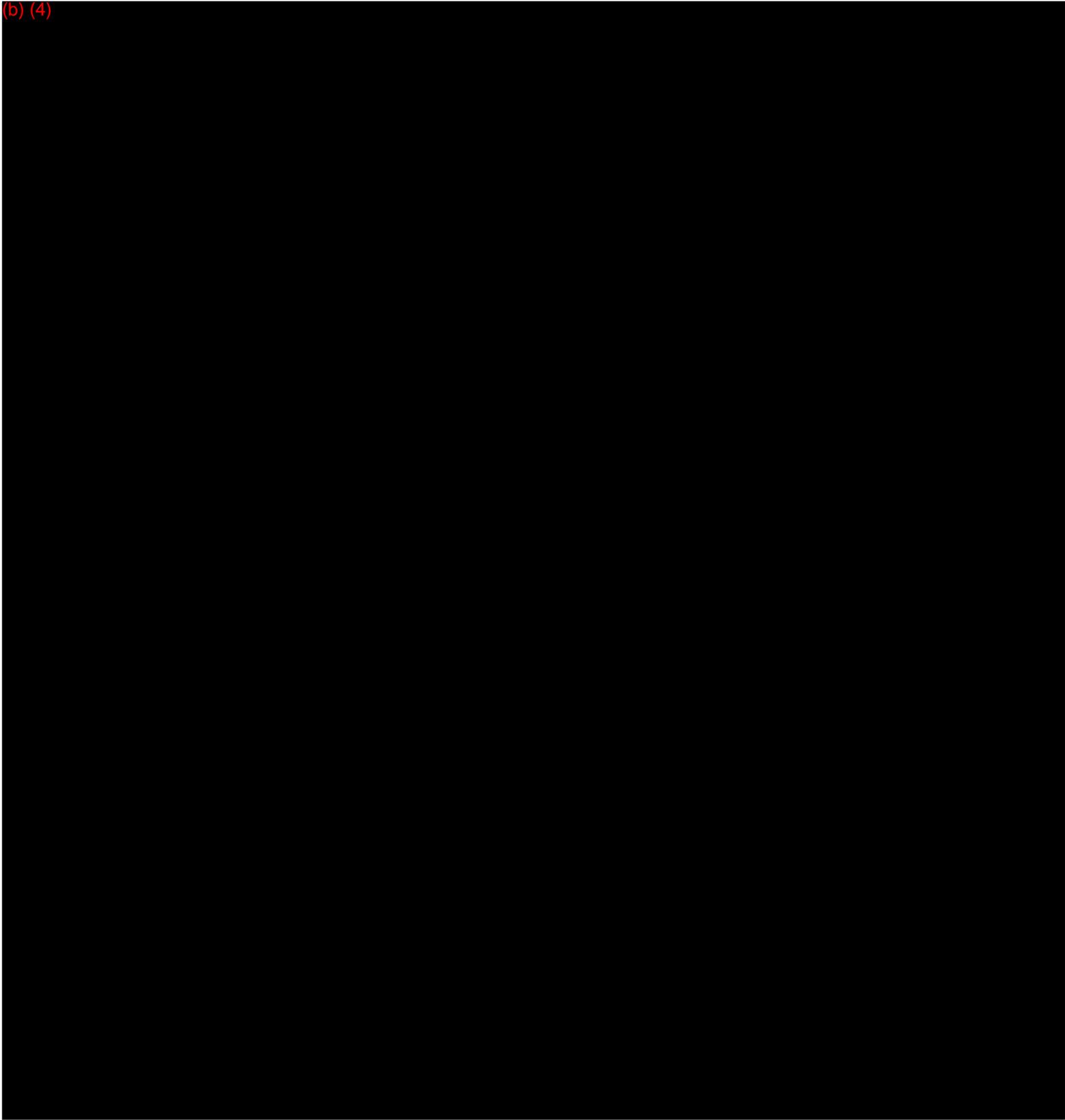
(b) (4)



(b) (4)

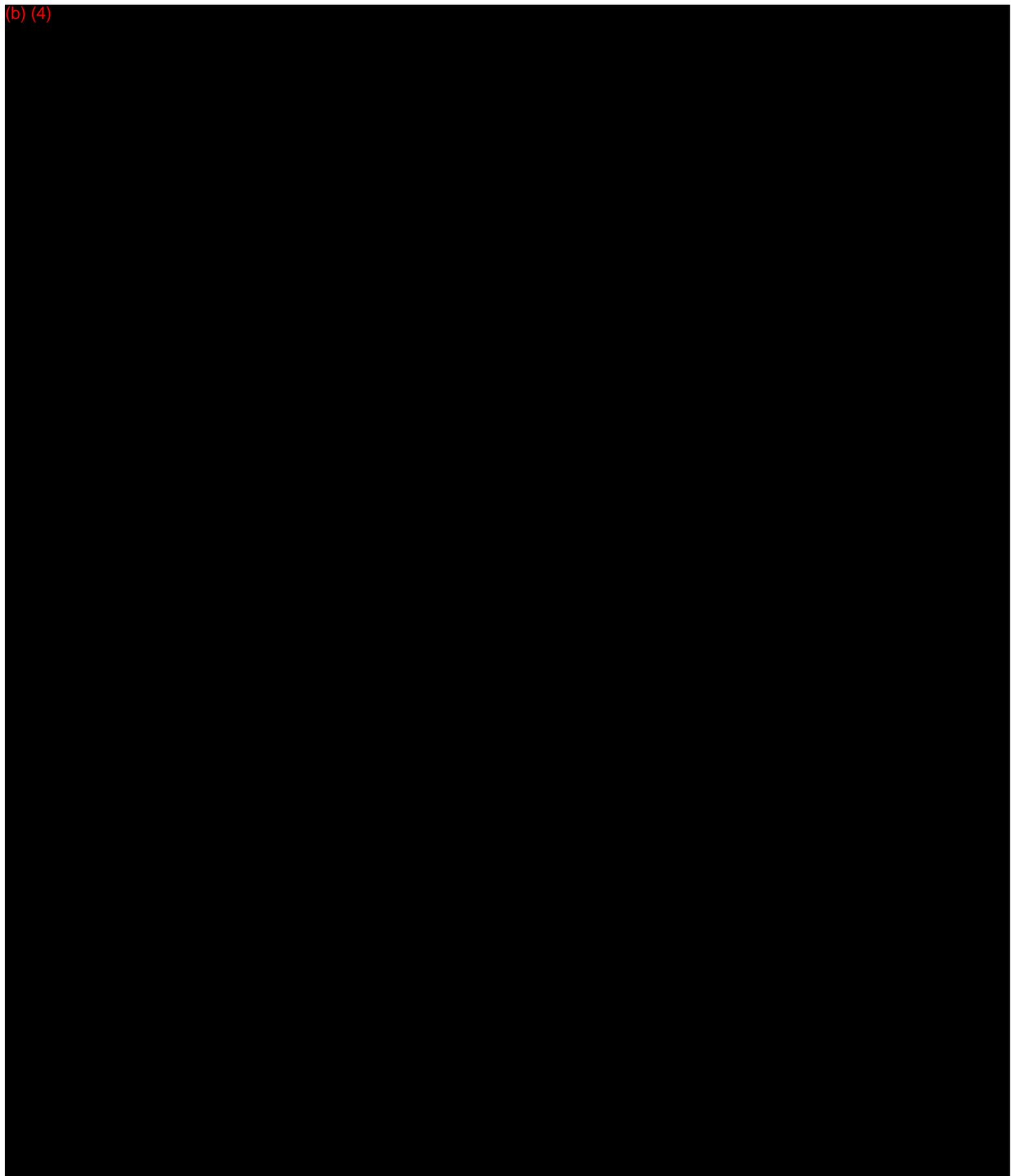


(b) (4)



BodyGuardian Control Unit

(b) (4)



(b) (4)

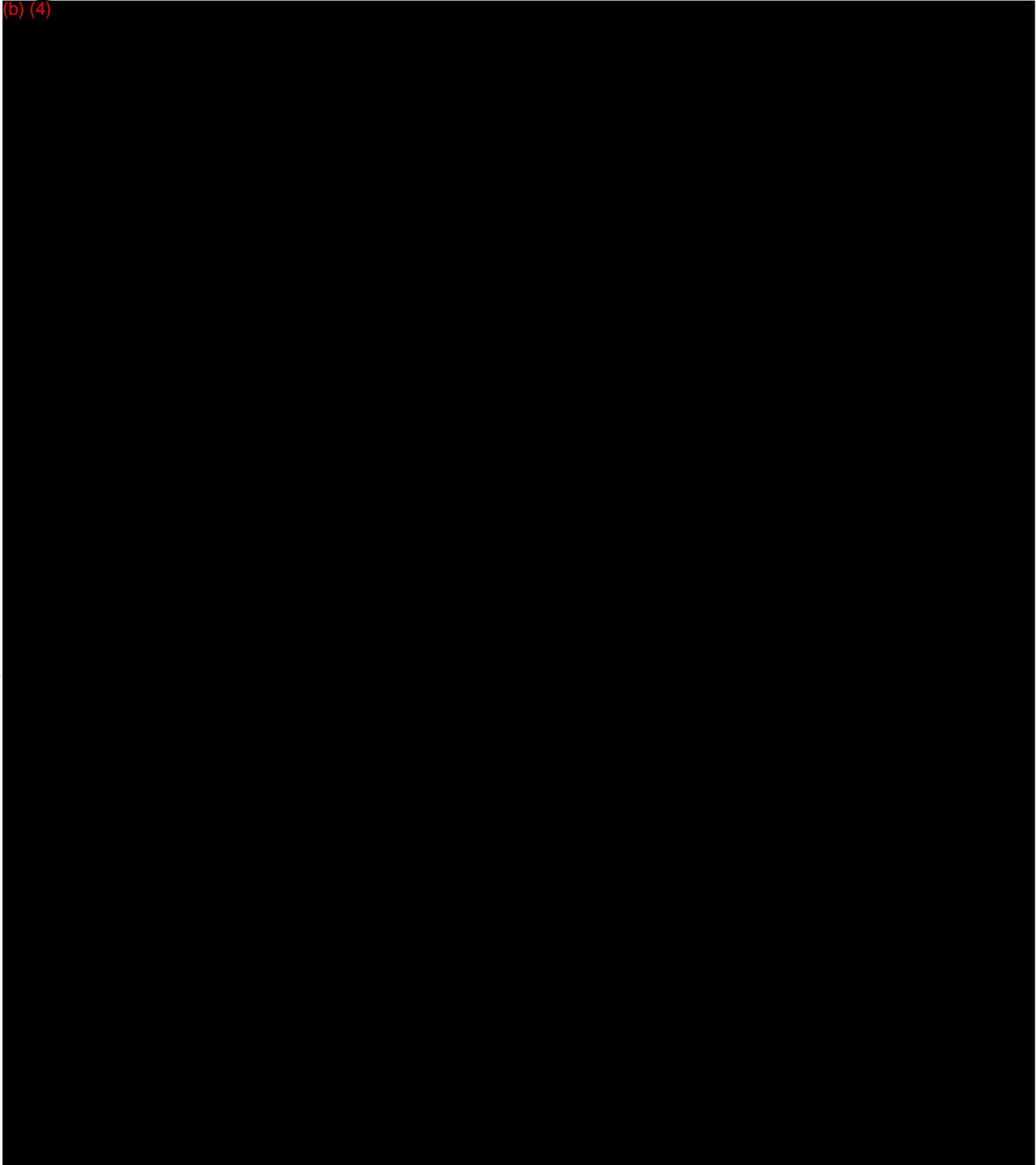
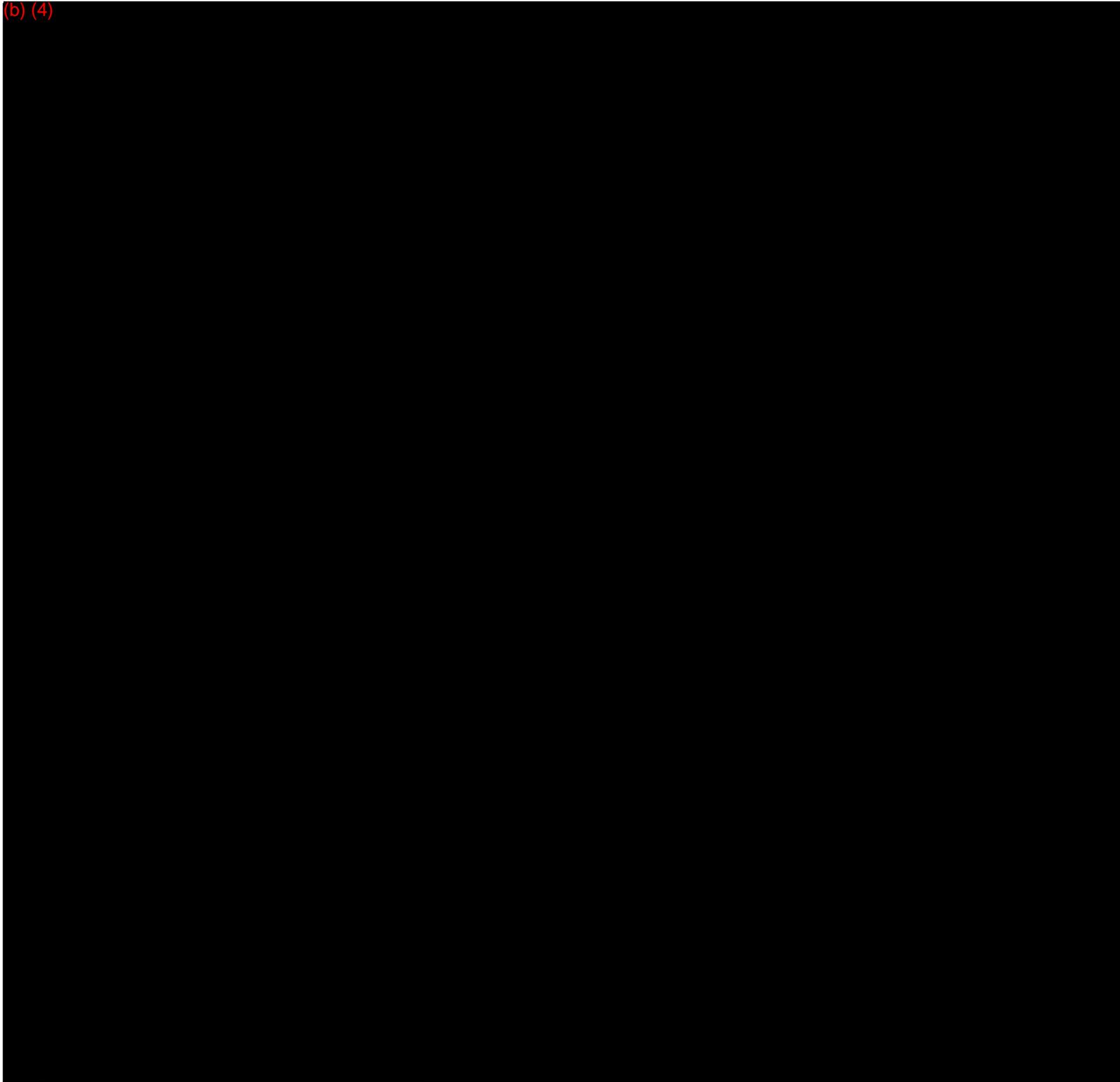
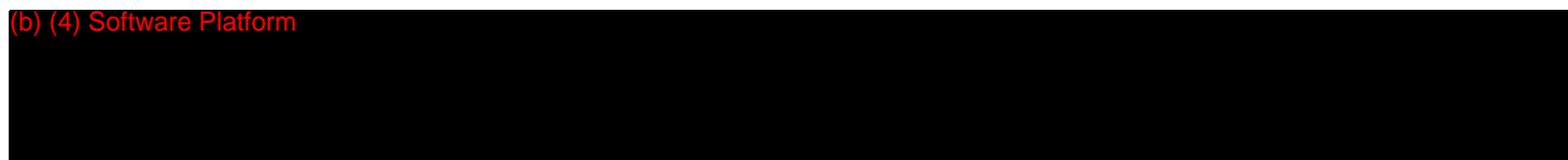


Figure 7: Photograph of BG Connect

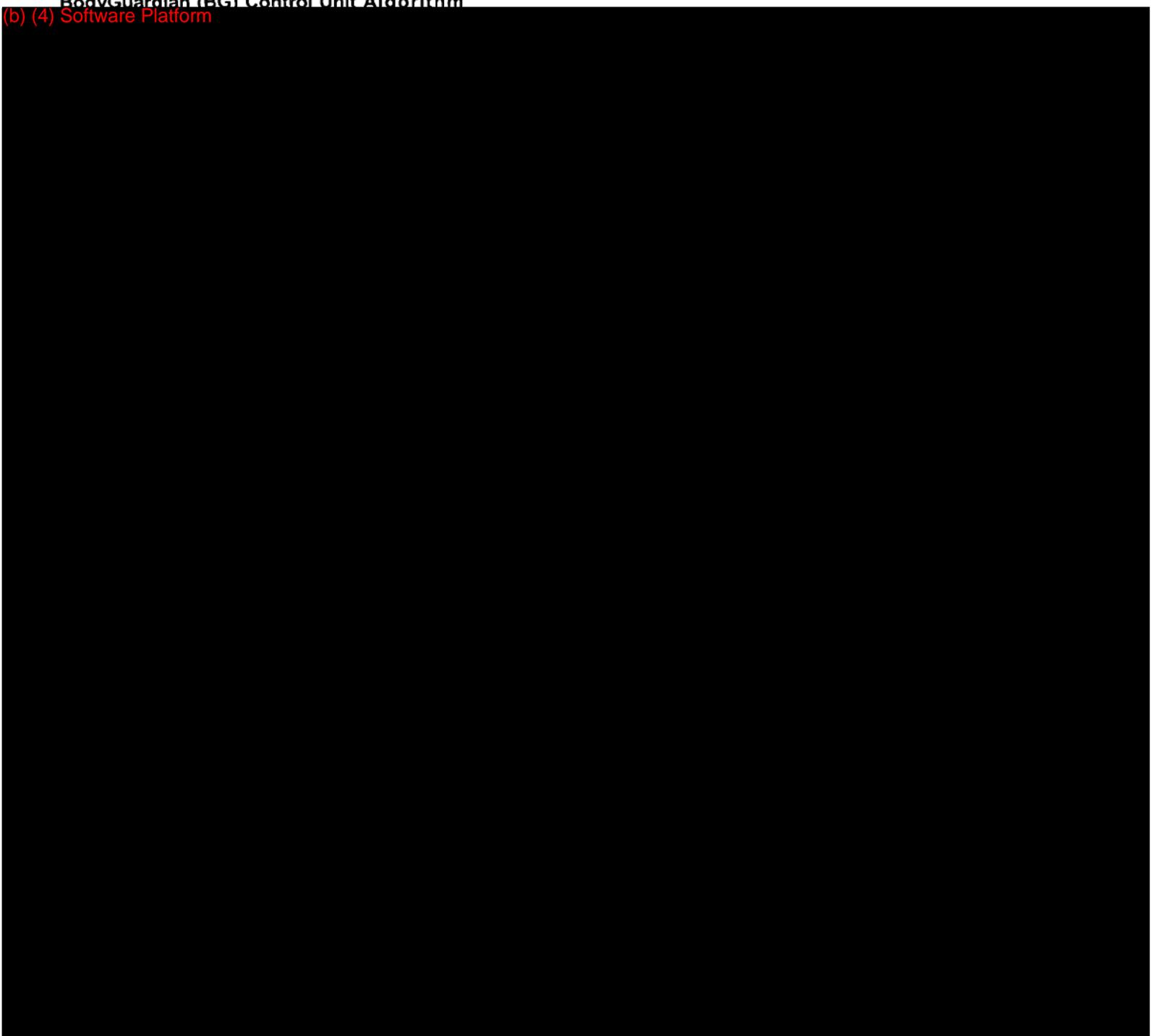


(b) (4) Software Platform

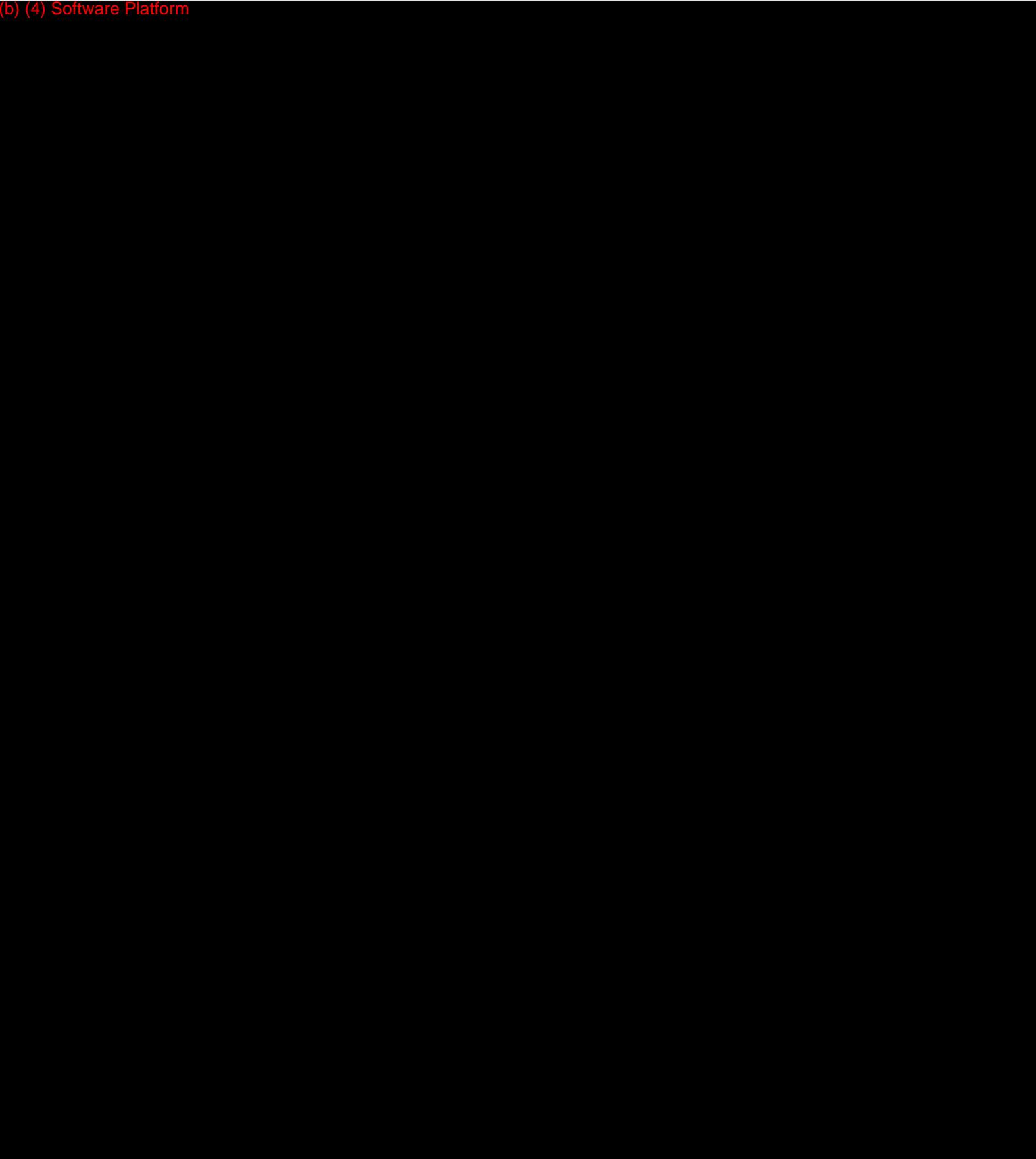
A large black rectangular redaction box covering the top portion of the page.

BodyGuardian (BG) Control Unit Algorithm

(b) (4) Software Platform

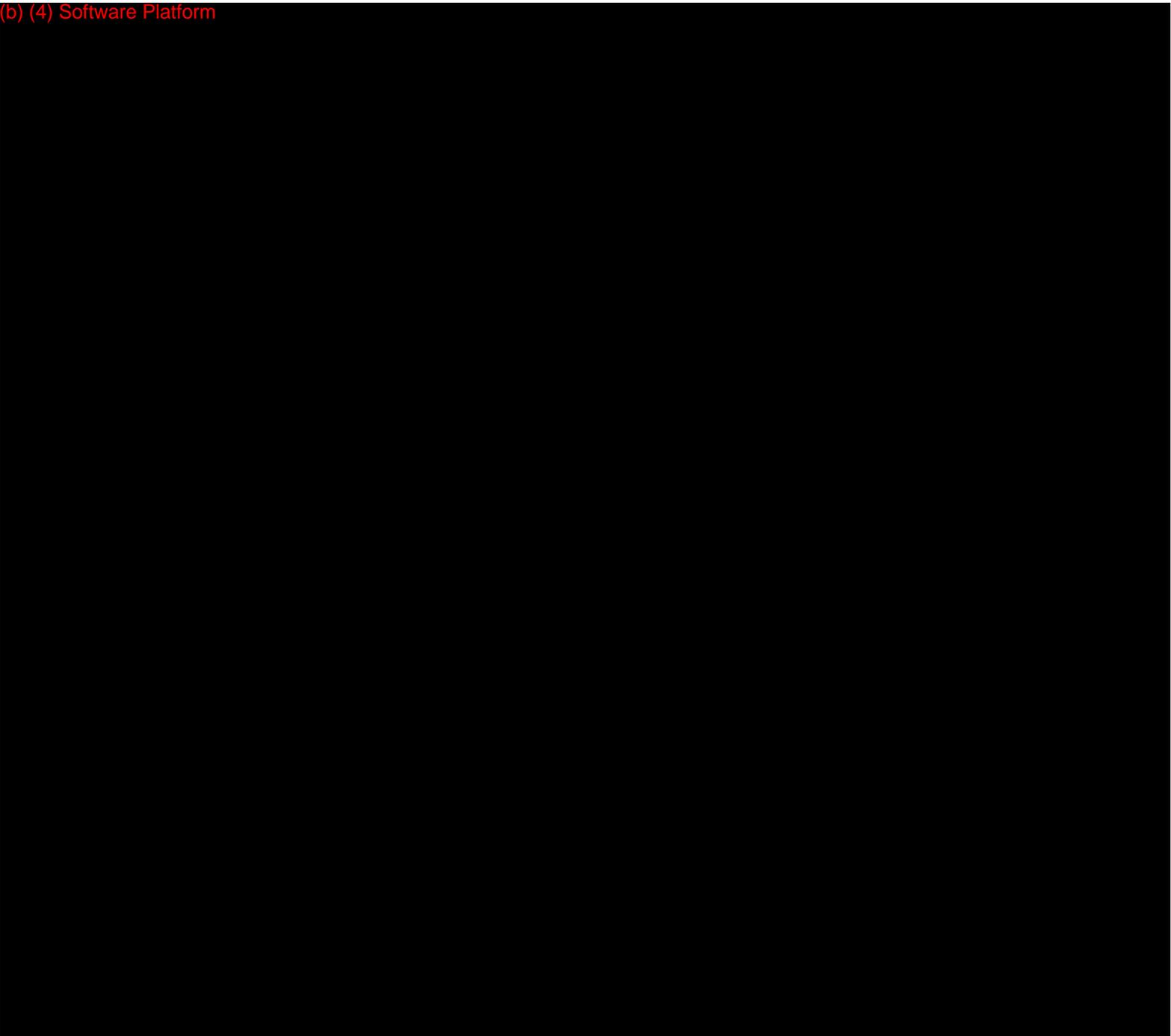
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(b) (4) Software Platform



Page 14 of 43 - Lead Review for K121197 - Preventice / BodyGuardian System

(b) (4) Software Platform



Reviewer's Comments:

- *The sponsor provided detailed description of the device in the context of the algorithms involved in the collection, analysis, storage and transmission of ECG, Heart rate (including HR variability and HR reliability), Respiration rate and Activity level.*
- *The information provided by the sponsor is considered acceptable.*

IV. Indications for Use (IFU)

The IFU provided for the proposed device states the following:

- **K121197** – Preventice BodyGuardian System – The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:
 - ECG
 - Heart rate (including HR variability and HR reliability)
 - Respiration rate
 - Activity

Indications for Use – as described in labeling section of submission (pg221)

Physicians prescribe the BodyGuardian System for patients who require monitoring for cardiac events. The BodyGuardian monitors:

- Patients with non-lethal cardiac arrhythmias
- Sinus bradycardia and sinus tachycardia
- Patients at risk for stroke from cardiac arrhythmias

Using collected data, the BodyGuardian allows the healthcare provider to:

- Assess supraventricular arrhythmias to include atrial fibrillation
- Assess cardiac contributions to syncope and dizziness

Contraindications for Use

Patients with any of the following conditions should not use the BodyGuardian:

- Known skin allergies or sensitivities to acrylic, hydrogel or silicone adhesives
- Fragile skin
- Pregnancy
- An implantable device or a bed partner with an implantable device.

The submission lists one predicate device with the following IFU:

- **K083287 - AVIVO Mobile Patient Management System** - The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The A VIVO Mobile Patient Management System also monitors, derives and displays:
 - ECG
 - Heart Rate (including Heart Rate Variability)
 - Activity
 - Posture
 - Body Temperature
 - Respiration Rate (including Respiratory Rate Variability)
 - Body Fluid Status

Reviewer's Comments:

The IFU of the proposed device is similar to that of predicate device and is considered acceptable

V. Predicate Device Comparison

The BodyGuardian System is compared against the predicate AVIVO Mobile Patient Management System by Corventis, Inc. (k083287). Both devices are battery-operated cardiac monitors with Rx indication that attach to the chest using adhesive electrodes. Similar to the predicate, the BodyGuardian System collects the following physiological data:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

The BodyGuardian System differs from the predicate primarily by lacking measurements of posture, temperature, respiration rate variability and body fluid status.

Both systems have a monitor and electrode that attach to the chest and transmit their data wirelessly to a separate data transmission module which in turn transmits data wirelessly to a central computer server. Both systems monitor both patient-initiated events and medical protocol events. The BodyGuardian System also can be set to transmit ECG tracings periodically independent of the other two event types. Both devices allow the healthcare physician to review patient data remotely, via the internet.

ECG properties are nearly identical. Both systems are single channel with similar or identical attributes such as sampling rate, digital resolution, input dynamic range, input offset dynamic range, and measurement range.

Both systems have very similar technical attributes for measurement of respiration rate. The BodyGuardian System tops out at 40 breathes per minute versus 60 breathes per minute in the predicate device. For the purposes of ambulatory monitoring an upper limit of 40 breathes per minute is more than adequate.

The BodyGuardian System matches the activity measurement range of the predicate and provides a faster sampling rate which supports an accurate measurement of respiration rate. As shown in Section 21 (page 156), bench testing has been done to show that cardiac measurements and measurements of respiration rate and activity level achieve an appropriate level of effectiveness.

The table below provides a comparison of the technical characteristics of the proposed and predicate devices:

#	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
Regulatory			
1	Manufacturer	Corventis Inc.	Preventice, Inc.
2	510(k) number	K083287	Not yet assigned
3	Device Class	Class II	Class II
4	Product Code(s)	MHX. DSI	MHX. DSI
5	Device Type	Arrhythmia Detector and Alarm; Patient Physiological Monitor (with arrhythmia detection)	Arrhythmia Detector and Alarm; Patient Physiological Monitor (with arrhythmia detection)
6	Regulation number	21 CFR 870.1025	21 CFR 870.1025
7	Model Name	AVIVO Mobile Patient Management System	BodyGuardian System
8	Intended Use Statement	<p>The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:</p> <ul style="list-style-type: none"> • ECG • Heart Rate (including HR variability) • Activity • Posture • Body Temperature • Respiration rate (including RR variability) • Body fluid status 	<p>The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:</p> <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity

#	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
System Components			
9	Ambulatory Monitor (Sensor)	PiiX Adherent Device	BodyGuardian (BG) Control Unit
10	ECG/Bioimpedance Electrode	Integral to PiiX Adherent Device (disposable with PiiX ambulatory monitor)	SnapStrip (replaceable and disposable)
11	Wireless data transmission module	Zlink (custom wireless receiver/transmitter)	BodyGuardian Connect (customized, commercial smartphone)
12	Data management software	Operates on Corventis computer server	Operates on Preventice computer server
13	System Measurements	<p>ECG Heart Rate Heart Rate Variability Respiration rate Activity</p> <p>Posture Body fluid status Respiration variability</p>	<p>ECG Heart Rate Heart Rate Variability Respiration rate Activity</p> <p>Heart Rate Reliability</p>

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
	Ambulatory Monitor (Sensor)		
14	Basic Design	Disposable (built-in electrode)	Reusable (with replaceable electrode)
15	Events Monitored	<ul style="list-style-type: none"> • Patient-initiated event trigger - Patient applies a magnet to PiiX • Medical Protocol event - Thresholds for medical events are set by healthcare professionals in server software 	<ul style="list-style-type: none"> • Patient-initiated event trigger - Patient presses button on BodyGuardian Control Unit • Medical Protocol event - Physician sets parameters defining events, such as "HR >120" using server software • On regular time intervals set by physician (e.g. every 60 minutes) the BodyGuardian will record and store a random 120-second ECG
16	Communication Protocol	Two-way link with Zlink wireless data transmission module using Bluetooth V2.0 (2.402 to 2.480 GHz)	Two-way link with BG Connect wireless data transmission module using Bluetooth V2.0 (2.402 to 2.480 GHz)
17	Protocol when wireless data transmission cannot be done	Multiple readings are stored on the Ambulatory Monitor (Sensor) device and the wireless transmission module as a backup if data needs to be re-sent to the server	IDENTICAL

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
18	ECG <ul style="list-style-type: none"> • Channels • Sampling Rate • Digital Resolution • Input Dynamic Range • Input Offset Dynamic Range • Measurement Range 	Single Channel 200 Hz 10 bits ± 5 mV ± 300 mV 25 - 250 Beats per Minute	Single Channel 256 Hz 12 bits IDENTICAL IDENTICAL IDENTICAL
19	Respiration Rate (Bioimpedance subsystem) <ul style="list-style-type: none"> • Sampling rate • Measurement Range (electrical) • Measurement Range (physiological) 	4 Hz 10 - 150 Ohms 4 - 60 Breaths per Minute	32 Hz 10 - 120 Ohms 1 - 40 Breaths per Minute
	Activity <ul style="list-style-type: none"> • Sampling Rate • Measurement Range 	0.25 Hz ± 2 g range in x, y, z direction	50 Hz IDENTICAL
ECG/Bioimpedance Electrode			

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
21	Basic Design Features	Integral to Ambulatory Monitor (Sensor) Discarded with the single-use Sensor Non-replaceable	Attached to Ambulatory Monitor (Sensor) by four snap connectors Discarded after use, separate from reusable Sensor Replaceable
22	Number of contacts	2 contacts for ECG, 2 for bioimpedance	IDENTICAL
Wireless data transmission module			
23	Module name	ZLink (Gateway)	BodyGuardian Connect
24	Data Storage	Yes. in Zlink memory	Yes. in BodyGuardian Connect memory
25	Data Transmission: Communication Protocol with Server	Cellular link between Zlink and Server Cellular frequency: GSM:850/900/1800/1950 MHz	Cellular link between BG Connect and Server Cellular frequency: GSM:850/900/1800/1950 MHz
26	Protocol when wireless data transmission cannot be done	Multiple readings are stored on the Ambulatory Monitor (Sensor) device and the wireless transmission module as a backup if data needs to be re-sent to the server	IDENTICAL
Data Management Software			
27	Location	Corventis Server	Preventice Server
	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
28	Functionality	<ul style="list-style-type: none"> • Display the physiological parameters in trend graphs • Display ECG waveform that corresponds to a detected arrhythmia • Provide visual notifications for the detected arrhythmia • Provide the users the ability to acknowledge or dismiss events • Provide afibrillation burden, if applicable to patient 	<ul style="list-style-type: none"> • IDENTICAL • IDENTICAL • IDENTICAL • Not provided • Not provided
29	Access	Web browser on Personal Computer (PC)	Web browser (PC) or via iPad
30	Internet Communication	Secure Sockets Layer (SSL) via HTTPS	IDENTICAL
31	Security Administration	Yes	IDENTICAL
32	Viewing Software	Web browser	Web browser, iPad

Reviewer's Comments:

The substantial equivalence comparison information provided by the sponsor is considered acceptable

Device description for the predicate device:

• **K083287 - AVIVO Mobile Patient Management System –**

The A VIVIO Mobile Patient Management System includes the following components:

- Adherent Device
- Gateway
- Server

The Adherent Device

is a patient-worn device. It collects, stores and transmits user physiological parameters. The Adherent Device, when applied to the user's torso, will automatically activate and measure the above mentioned physiological parameters. Data collected by the sensors are transmitted to the Server for derivation and display via the Gateway periodically. ECG signals recorded by the Adherent Device will be transmitted on a heart rate trigger basis with predetermined thresholds that are not user adjustable. The ECG signals are also transmitted periodically and will be displayed via the Server.

Arrhythmia Processor and Analysis Software

The Adherent device performs beat detection based on the monitored ECG waveform and uses the beat information to detected tachycardia and bradycardia. The tachycardia is declared using an X/Y criteria with a heart rate threshold defined as any Y-beat window, X or more beats above the threshold. The tachycardia episode persists until a W/Z criteria is met as defined as in any Z-beat window, W or more beats below the tachycardia threshold are required to end the episode. The nominal values for X/Y and W/Z are 12/15 and 12/15. One tachycardia episode must terminate before a new one is declared.

Bradycardia is declared based upon 2 criteria: 2 consecutive heart rate intervals of 1500 ms or more followed by an interval of 1500 ms without a detected bear, or an interval of 3000 ms without a detected beat. ECG will be displayed by the Server when the heart rates fall below the specified criteria above. This serves as a visual notification to the healthcare professionals.

Gateway

The Gateway receives information from the Adherent Device and transmits it to the Corventis Server. It also interacts with the Server to receive configuration updates and other hardware information.

Server

The Server receives information from the Adherent Device via the Gateway. The server performs the following functions:

- Derives physiological parameters using the raw data collected by the Adherent device
- Displays the physiological parameters in trend graphs
- Displays ECG waveform when the heart rates are beyond the prescribed threshold
- Provides visual notification when healthcare professionals need to be aware of heart rates that are beyond the specified threshold
- Provides patient summary reports.

The communication between the Adherent Device and the Gateway is enabled via the BlueTooth™ Technology. The Gateway transmits the data to the Server via cellular technology, where healthcare professionals can access with standard browsers.

Labeling

The submission includes the relevant labeling for the BodyGuardian System. The draft contains appropriate indications, contraindications, warnings/precautions, set up, installation requirements, directions for use, maintenance, error messages, troubleshooting tips, and specifications. The labeling is well crafted and comprehensive.

Reviewer's Comments:

The labeling information provided by the sponsor is considered acceptable

VII. Sterilization/Shelf Life/Reuse

The BodyGuardian system is nonsterile with both disposable and reusable components. The BodyGuardian SnapStrip (the patch) is supplied non-sterile and is disposable between patients. Contact is non-critical in nature, e.g., the device is handled manually by attending health care providers and applied to the skin. Adequate cleaning instructions are provided in the labeling materials.

Reviewer's Comments:

The labeling information provided by the sponsor is considered acceptable

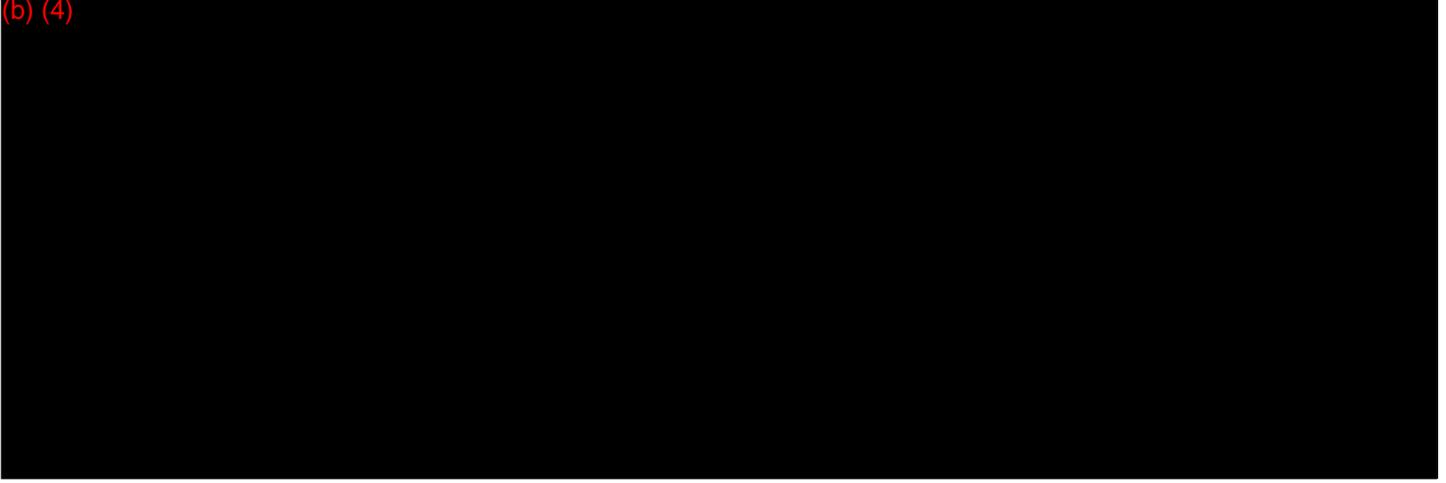
VIII. Biocompatibility

The BodyGuardian SnapStrip (BG SnapStrip) is in direct contact with the patient. It is a disposable adhesive patch that connects the BG Control Unit to the body for reading and sending electrical signals. The patch consists of multiple layers of medical grade materials and contains four imbedded electrodes:

(b) (4)



(b) (4)

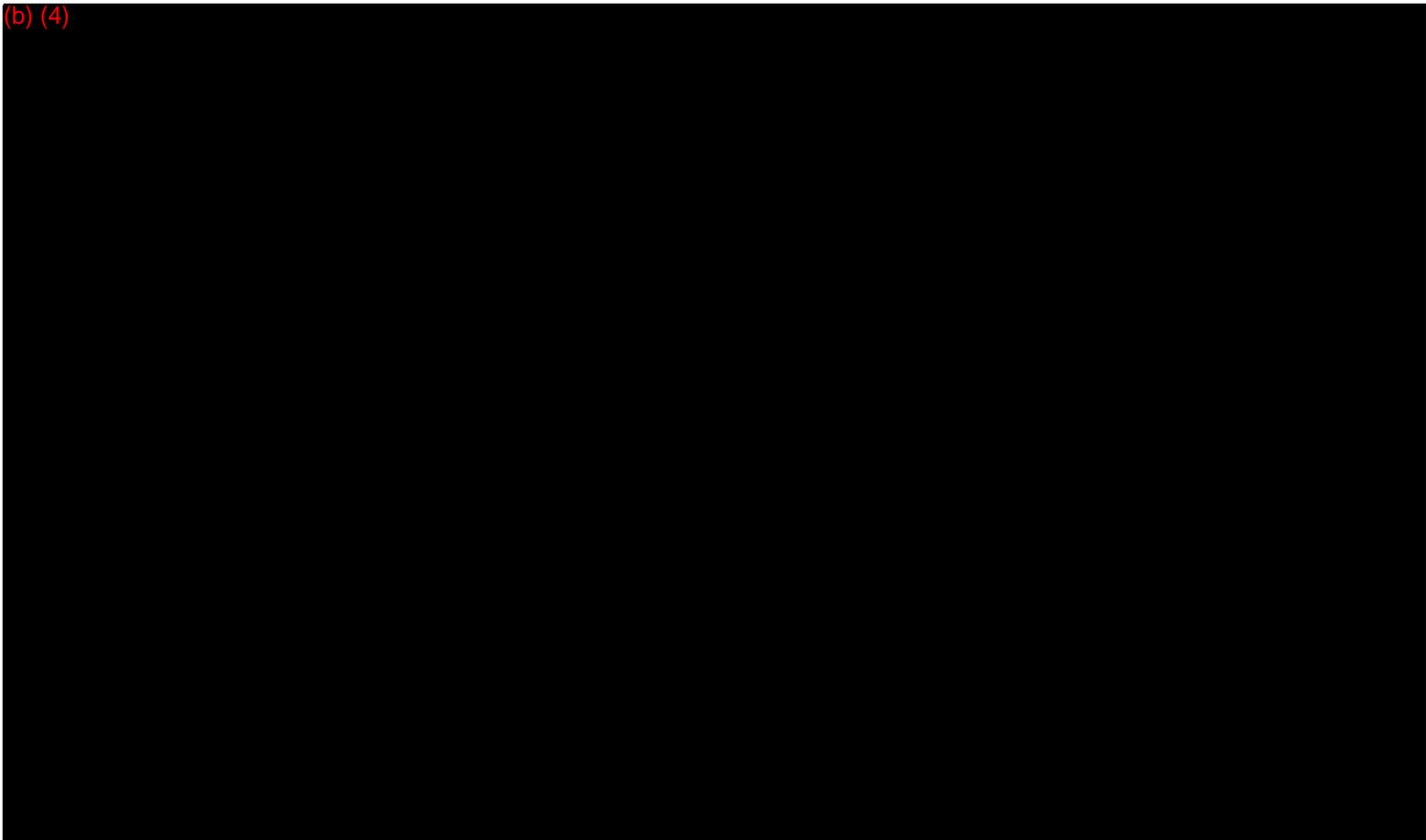


Reviewer's Comments:

The biocompatibility information provided by the sponsor is considered acceptable

IX. **Software**

(b) (4)



Version: 1.0

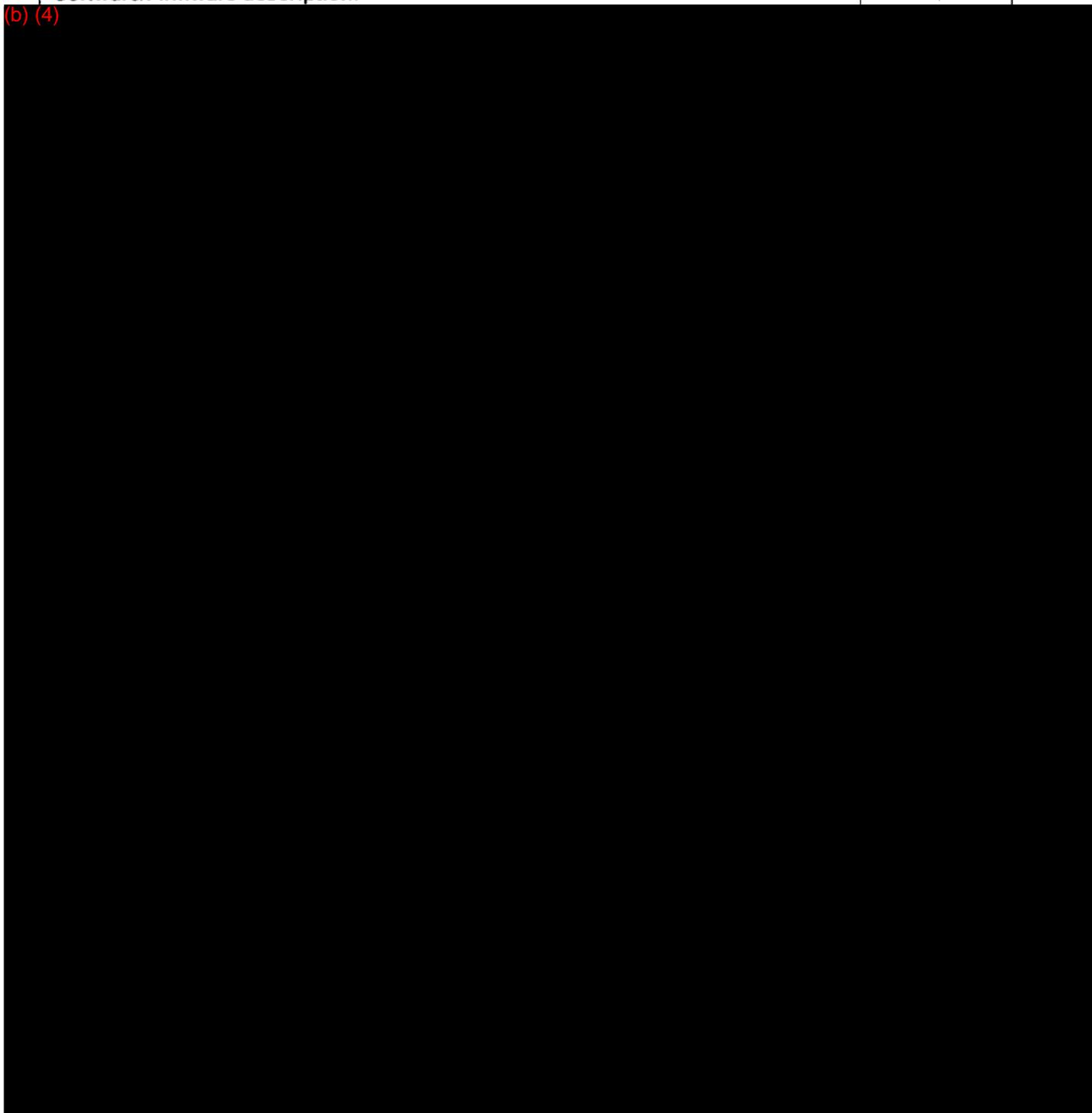
Level of Concern: The sponsor has appropriately evaluated the LOC for the software component of this device and determined it to be of **MODERATE** LOC.

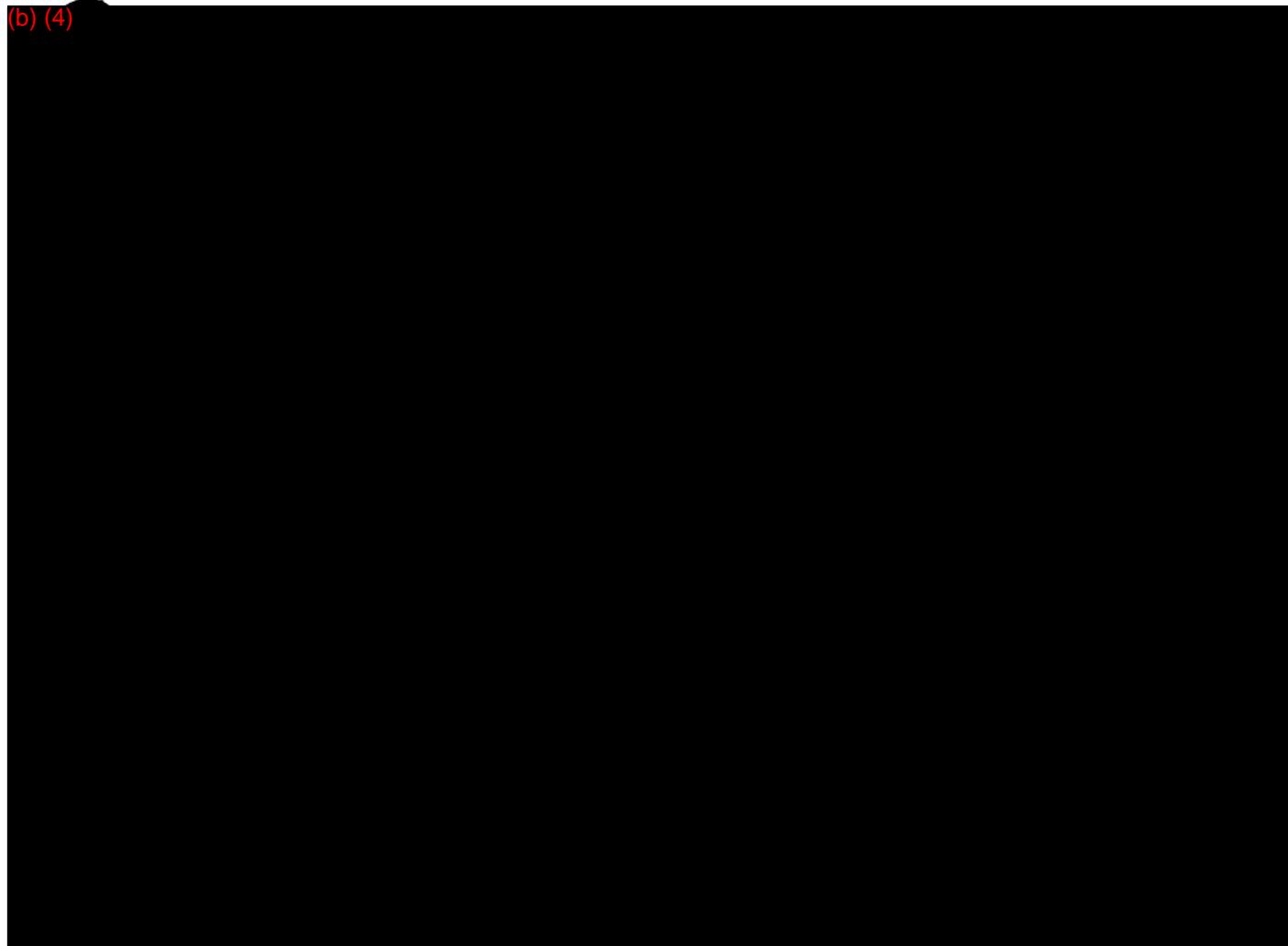
Yes

No

Software/Firmware description:

(b) (4)

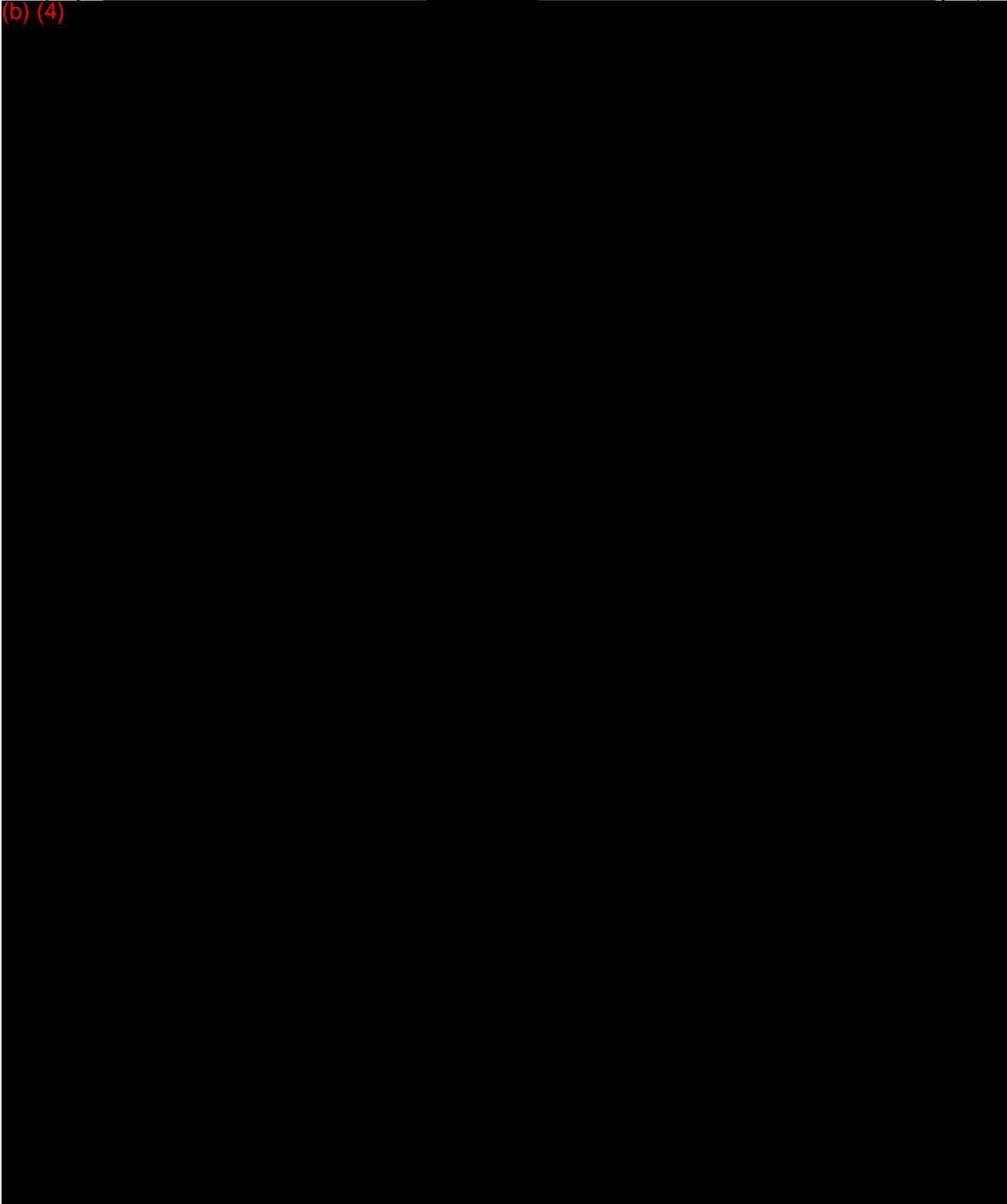




(b) (4)

pkg State Machine

(b) (4)



Device Hazard Analysis:

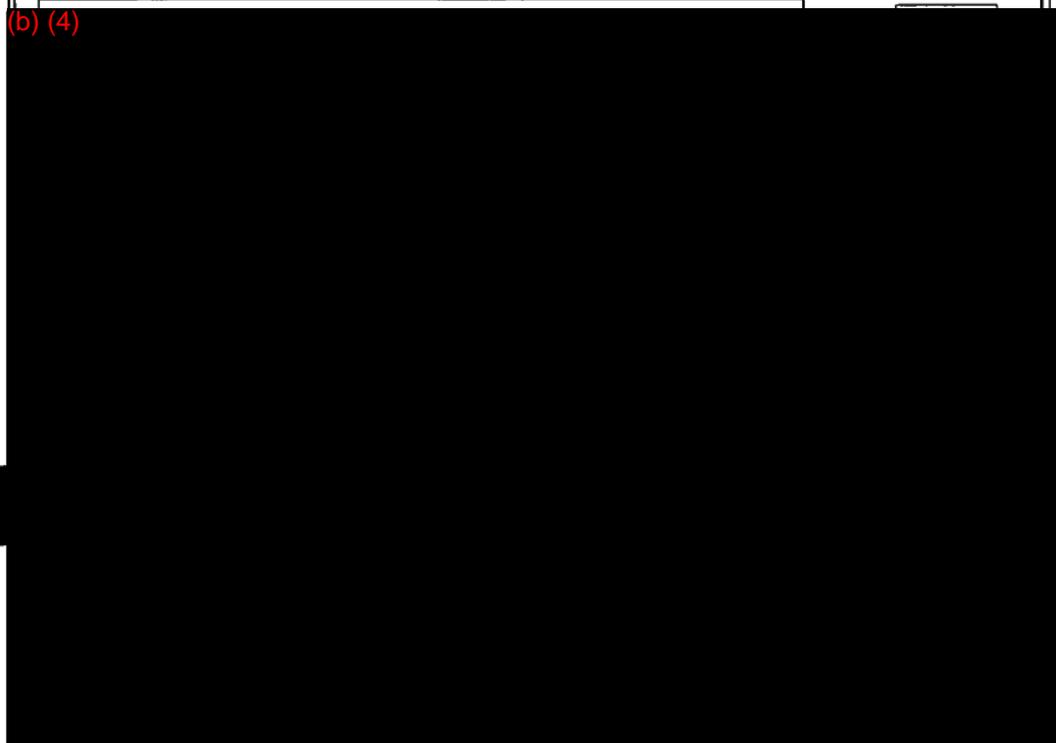
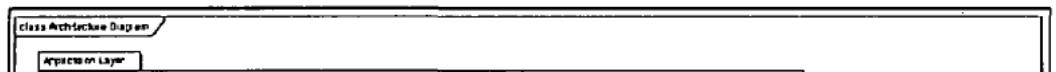
The sponsor has provided a HA which is targeted to this component. The hazards identified are consistent with what would be expected for this type of device, including wireless connectivity and functionality. The sponsor has adequately described the hazard and mitigations for these items. The information provided is adequate.

x

Software Requirements Specifications:

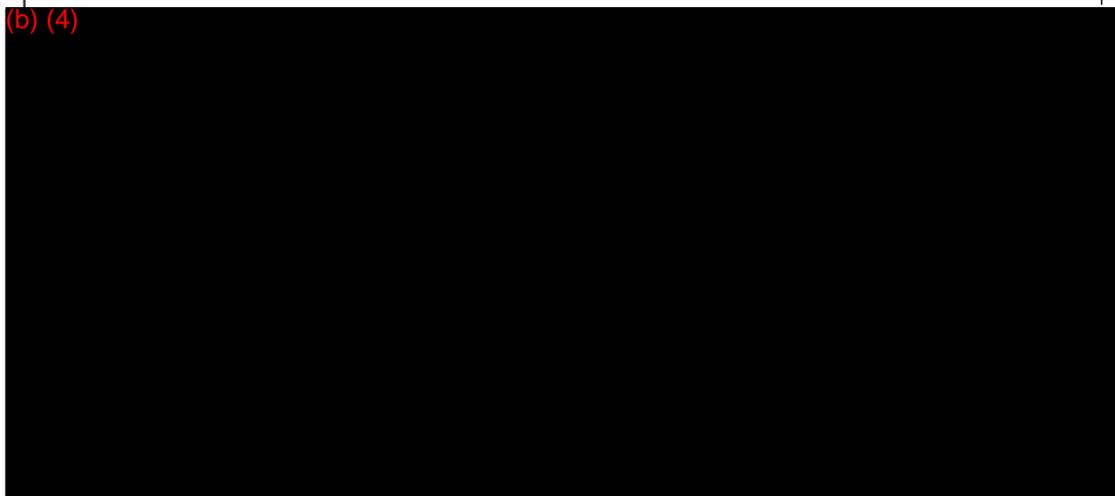
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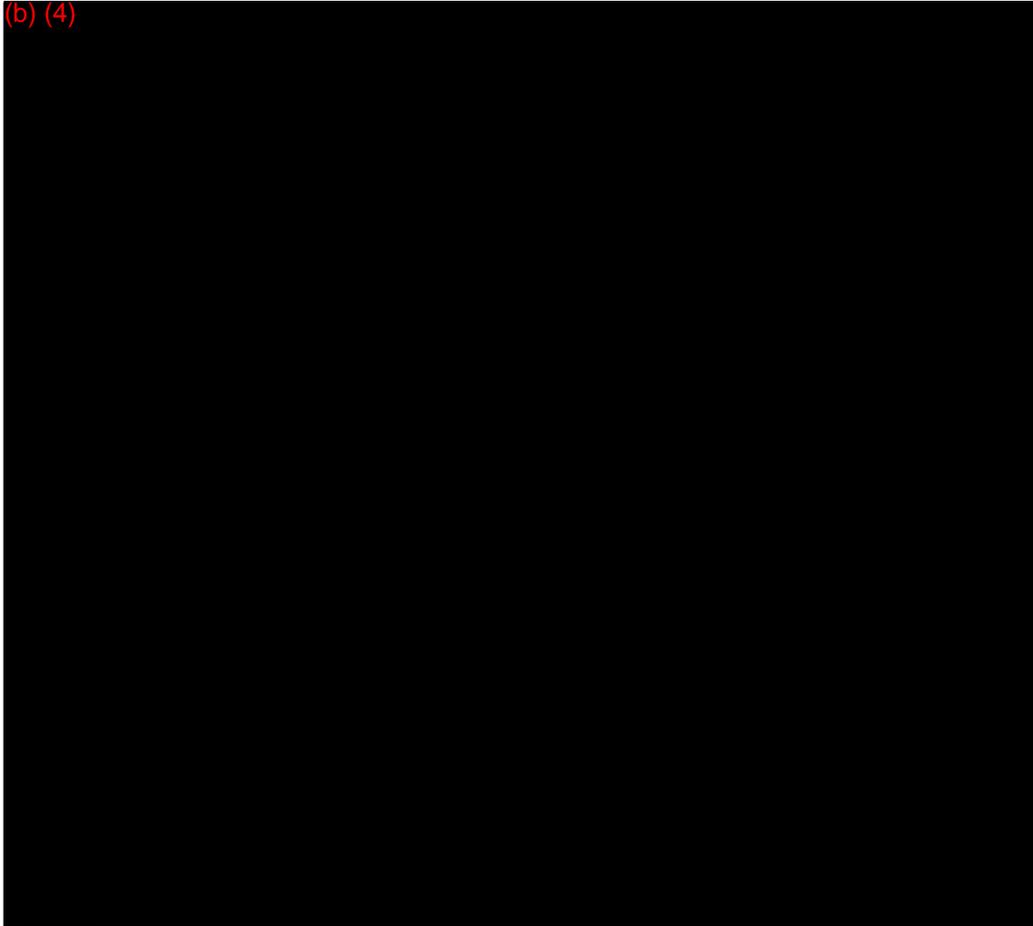
The sponsor has provided acceptable requirements specifications. The document provides information on what this acquisition device needs to do and the parameters under which it needs to operate. In addition, the sponsor has provided a top-level specification which highlights the overall functionality for this device. Both of these documents identify the Bluetooth component and the necessity to control the data flow appropriately.



x

Architecture Design Chart: *BodyGuardian Control Unit Firmware Architecture*

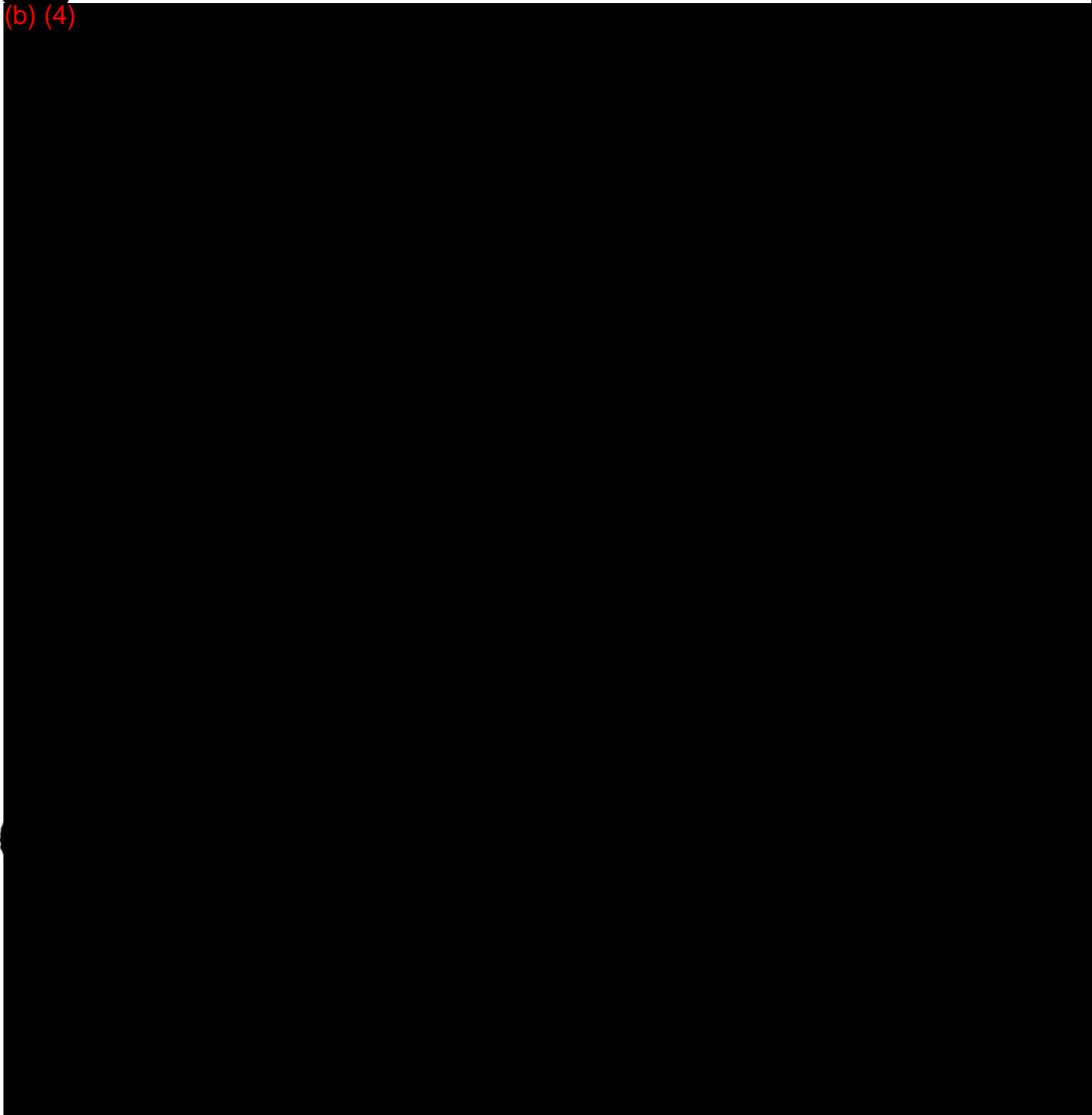




External Communication		
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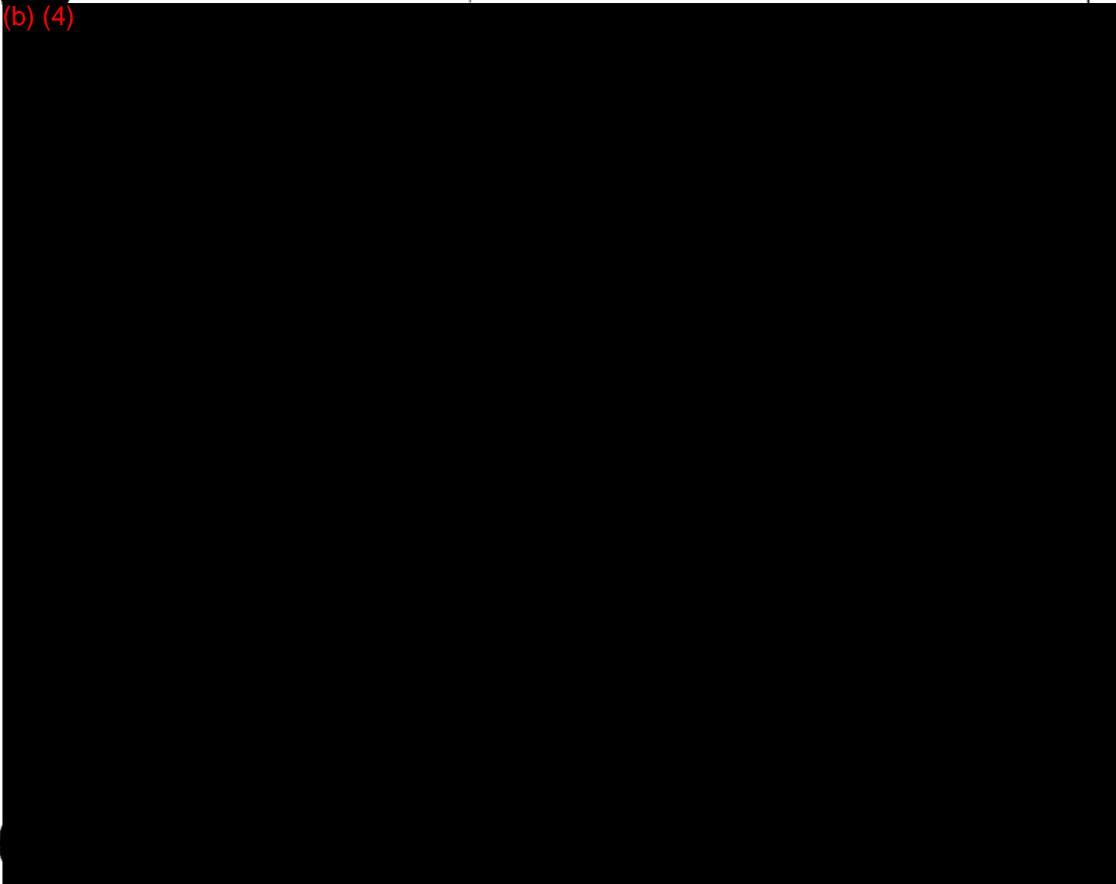
Below is a diagram of the overall BodyGuardian System Architecture

(b) (4)



	x

(b) (4)

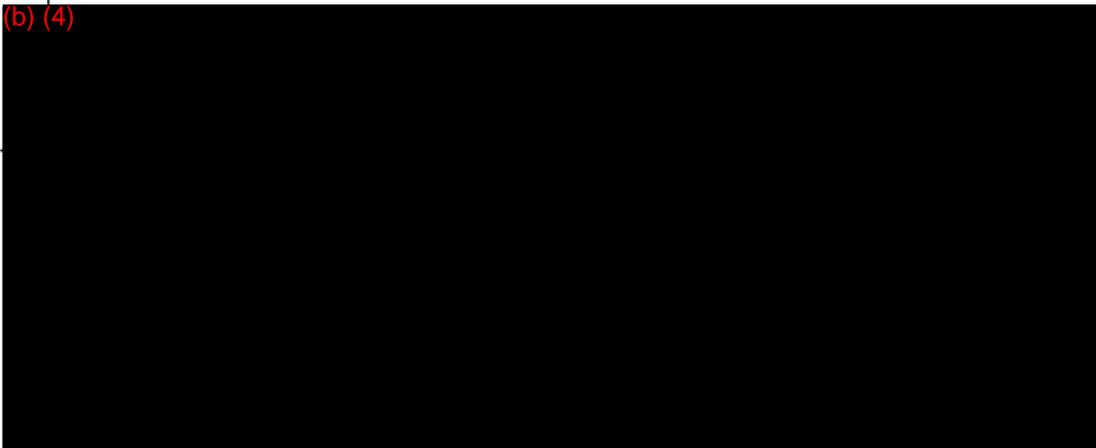


Traceability Analysis/Matrix:

The sponsor has provided an adequate traceability matrix which maps requirements to testing.

x

Development:

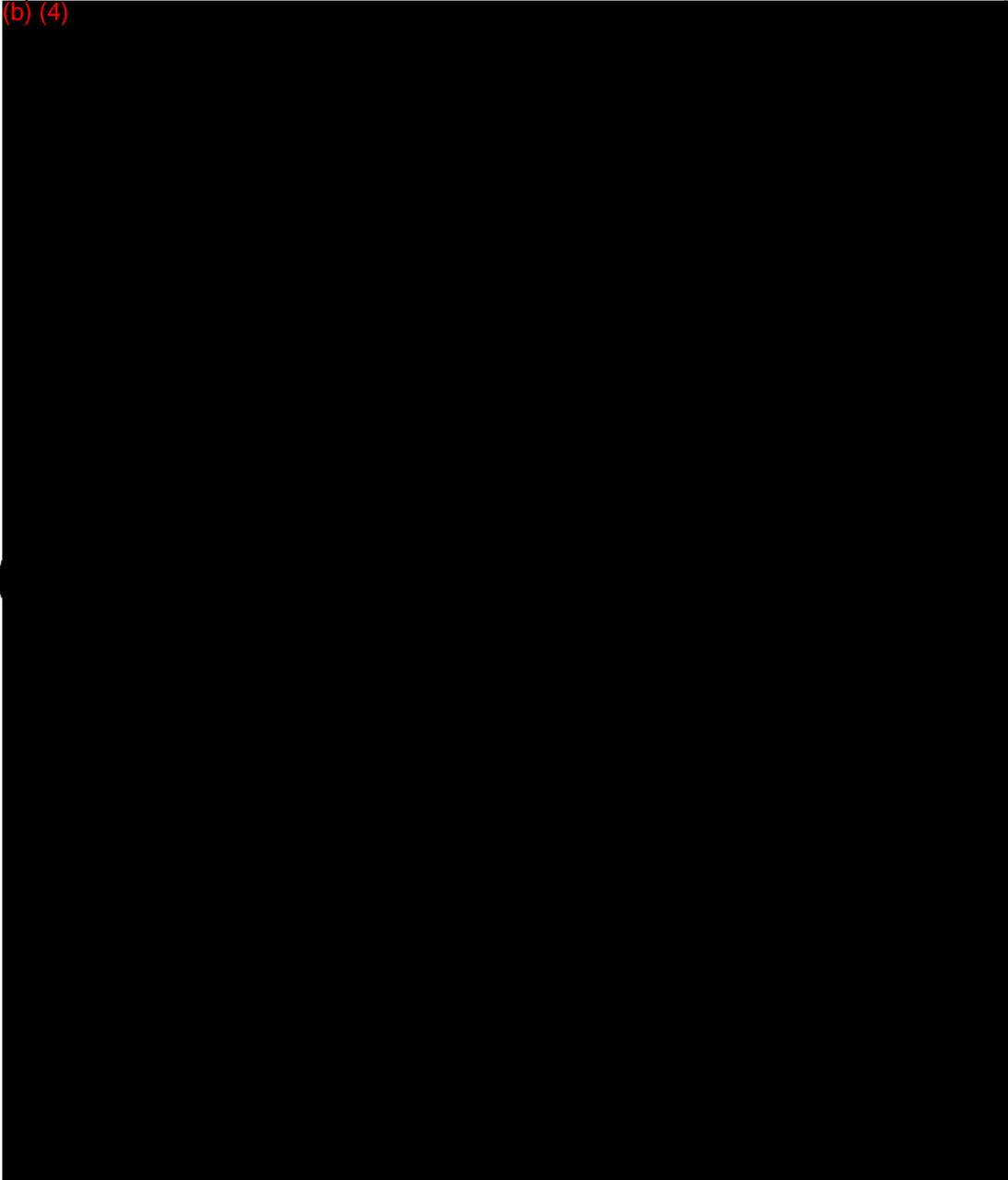


x

Verification & Validation Testing:

The sponsor has provided the protocols and test status for the software. The protocols seem to include the basic operational aspects of the device, including wireless connectivity and functionality. This set of protocols also appears to include testing of

x

<p>error conditions (low battery, low memory, lost signal) as well. The arrhythmia and respiration rate algorithms have also been tested adequately.</p>		
<p>Revision level history: The sponsor has provided an adequate revision level history which describes the versions of the software and includes the changes made at each version.</p>	x	
<p>Unresolved anomalies:</p>		
<p>(b) (4)</p> 	x	
<p><i>This reviewer believes that this type of anomaly is expected in this system. As long as it is properly disclosed, it is acceptable.</i></p>		

Reviewer's Comments:

The SW information provided by the sponsor is considered acceptable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b) (4)

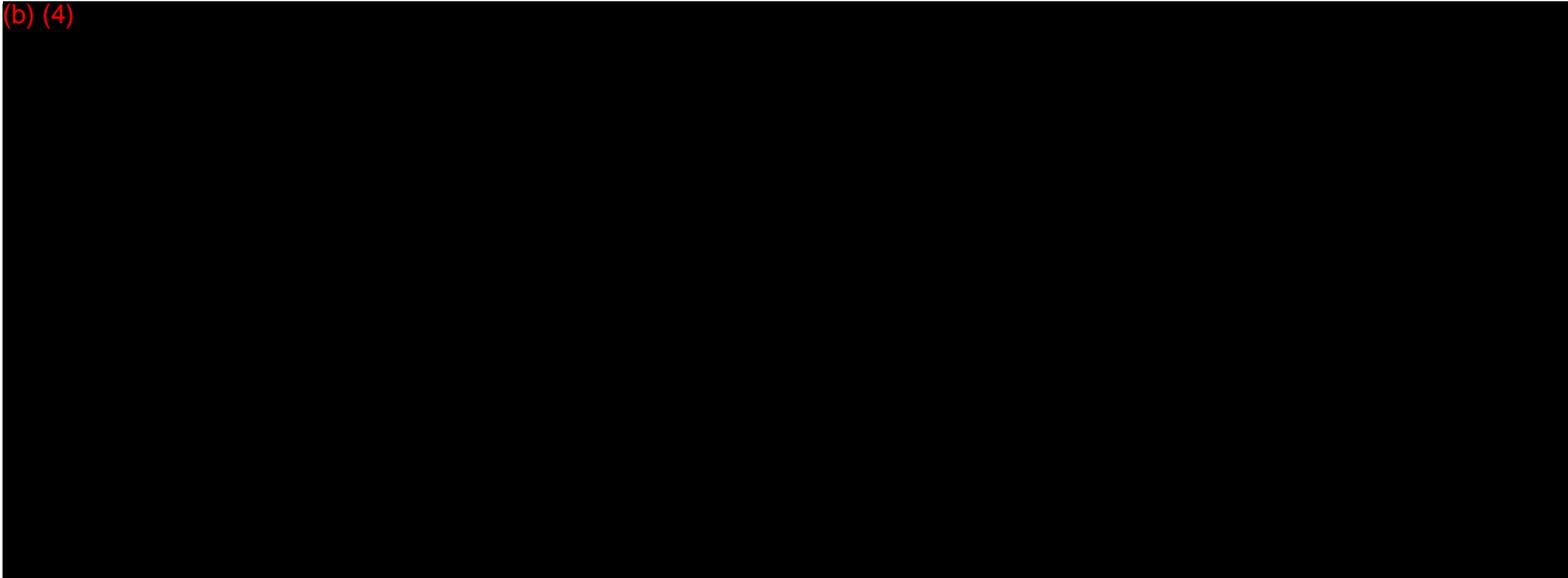


Reviewer's Comments:

The information provided by the sponsor is considered acceptable

Performance Testing – Bench

(b) (4)



BEAT-BY-BEAT COMPARISON

(b) (4)



(b) (4)



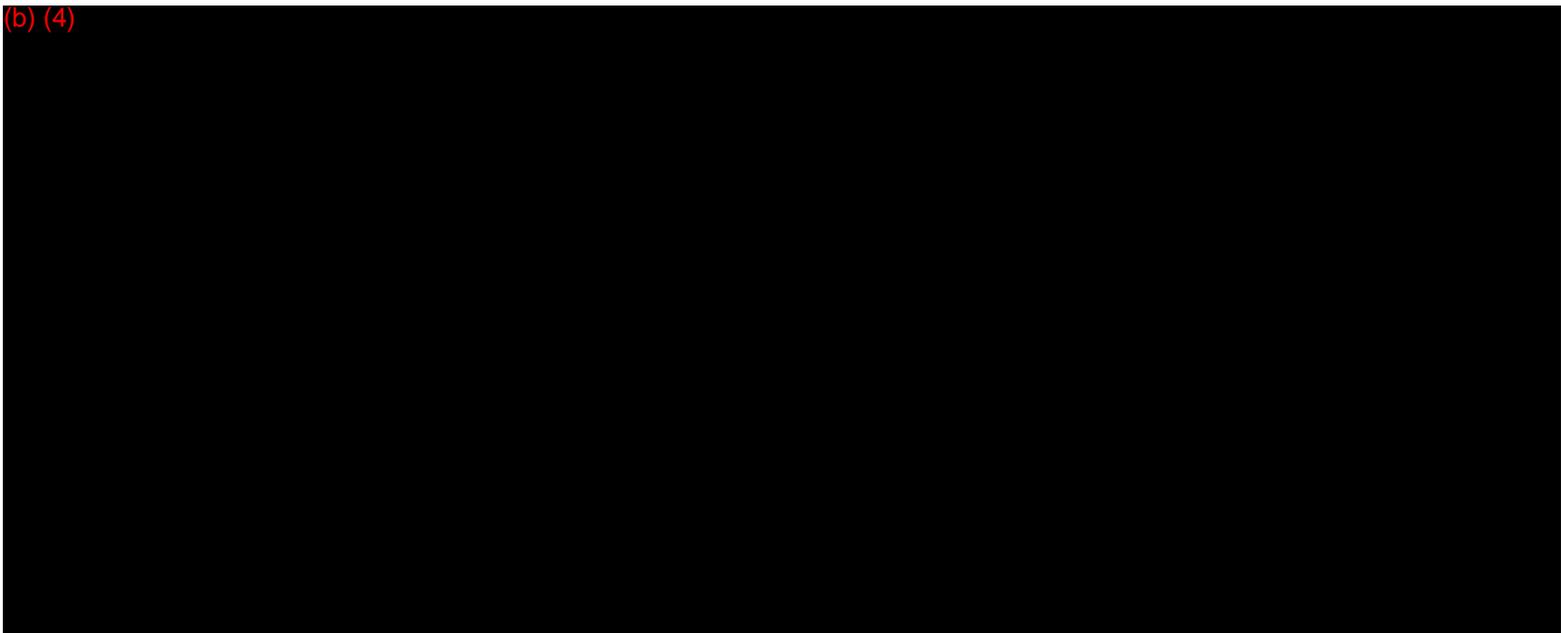
Heart rate (HR) measurement

(b) (4)

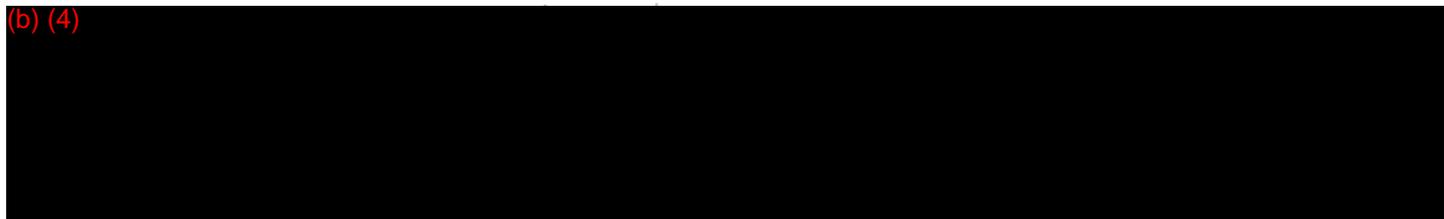


RR Interval Variability measurement

(b) (4)



(b) (4)

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RR Interval Variability measurement of test patterns

(b) (4)

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(b) (4)



ACTIVITY LEVEL

(b) (4)



RESPIRATION RATE

(b) (4)



Subjects Testing

Validation of Respiration Rate

(b) (4)

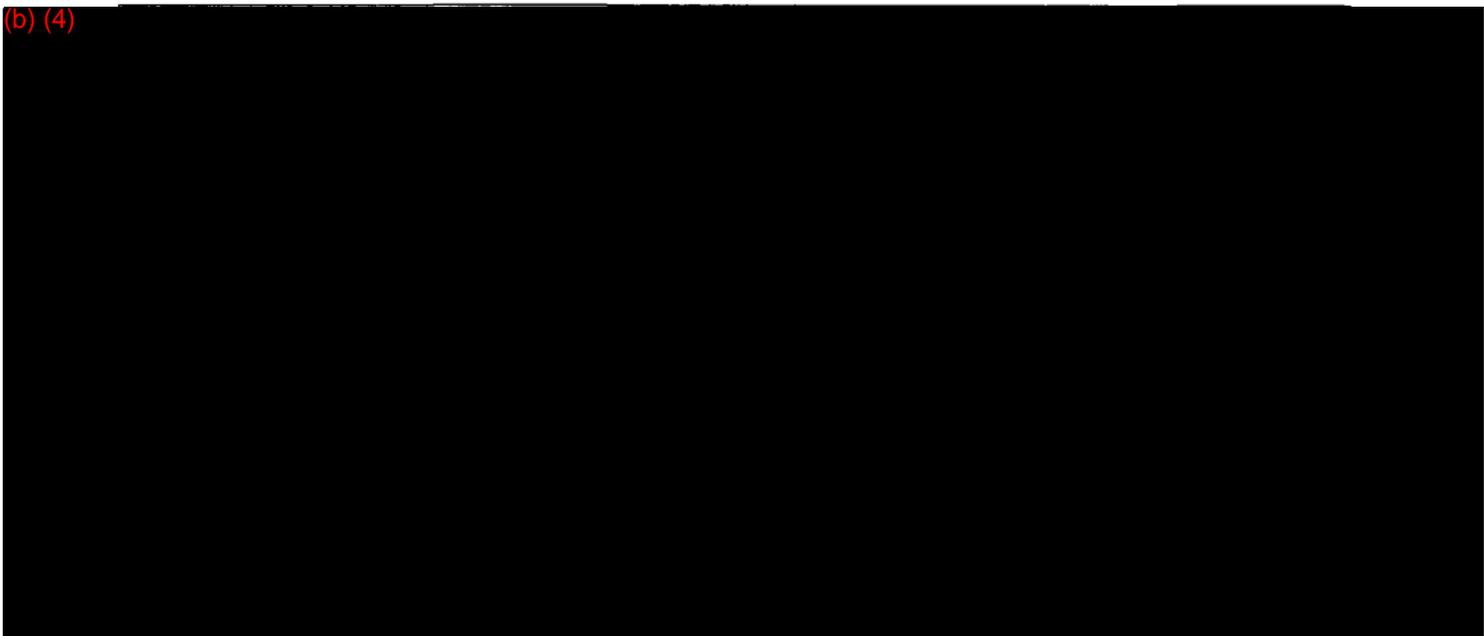


Test Results

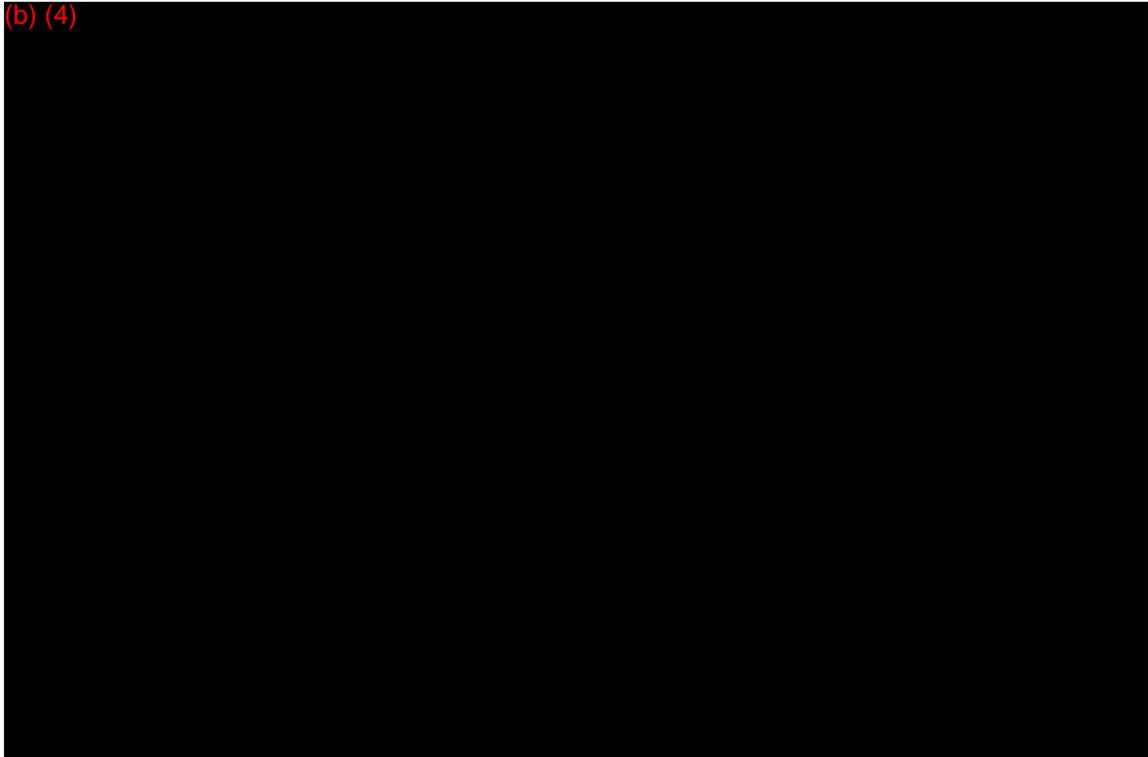
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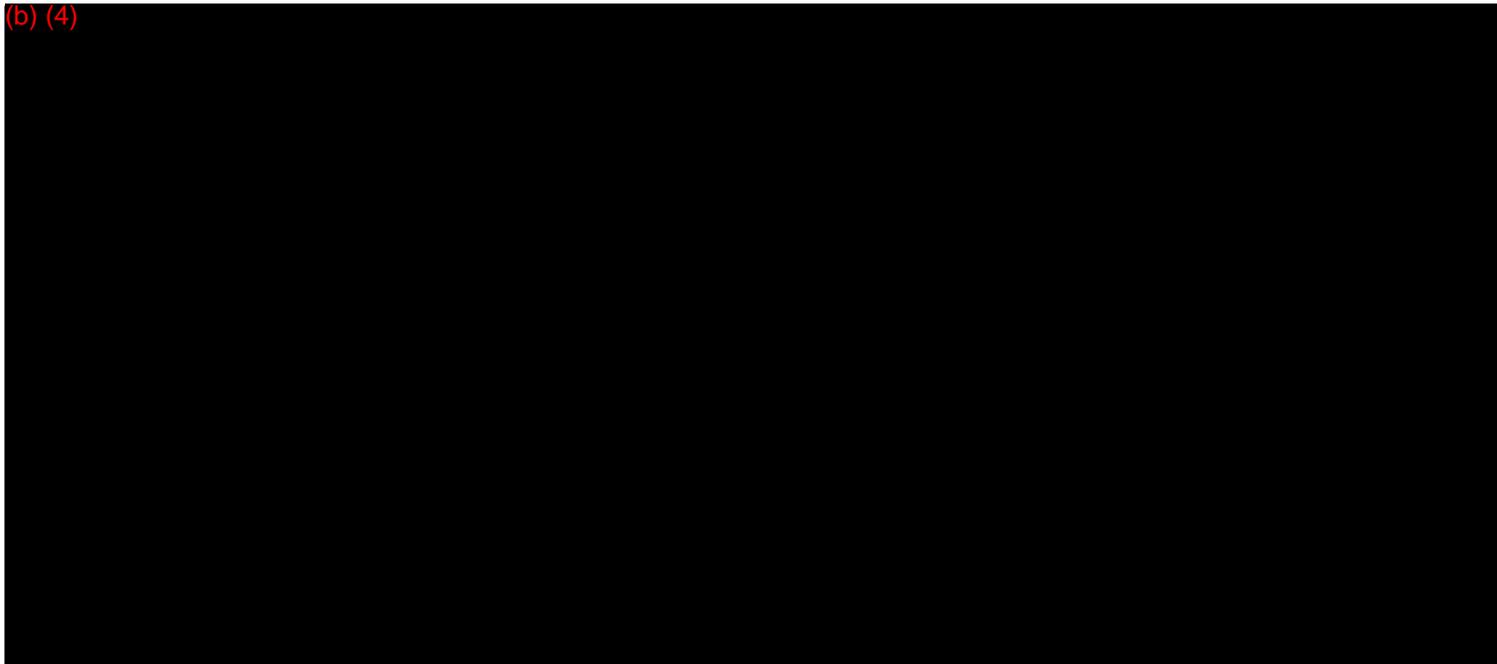


APSTRIP ELECTRODE

(b) (4)



(b) (4)





Reviewer's Comments:

The bench performance testing information provided by the sponsor is considered acceptable in this submission

XII. Performance Testing – Animal

No animal testing information was provided in this submission, which is considered acceptable.

XIII. Performance Testing – Clinical

No clinical testing information was provided in this submission, which is considered acceptable.

XIV. Substantial Equivalence Discussion

Yes No

	Yes	No	
1. Same Indication Statement?	√		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NSE
Same Technological Characteristics?	√		If YES = Go To 5
Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	√		If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NSE
7. Accepted Scientific Methods Exist?			If NO = Stop NSE
8. Performance Data Available?		√	If NO = Request Data
9. Data Demonstrate Equivalence?			Final Decision: AI

1. Explain how the new indication differs from the predicate device's indication:
2. Explain why there is or is not a new effect or safety or effectiveness issue:
3. Describe the new technological characteristics:
4. Explain how new characteristics could or could not affect safety or effectiveness:
5. Explain how descriptive characteristics are not precise enough:
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:
7. Explain why existing scientific methods can not be used:
8. Explain what performance data is needed:
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:
-The sponsor has provided acceptable supportive performance data according to required standards and FDA guidance documents to demonstrate substantial equivalence of the proposed device. Please see performance bench testing section above for summary of test results.

- However, the sponsor did not provide adequate wireless coexistence testing.
- The absence of wireless coexisting testing has been noted in the deficiency section.

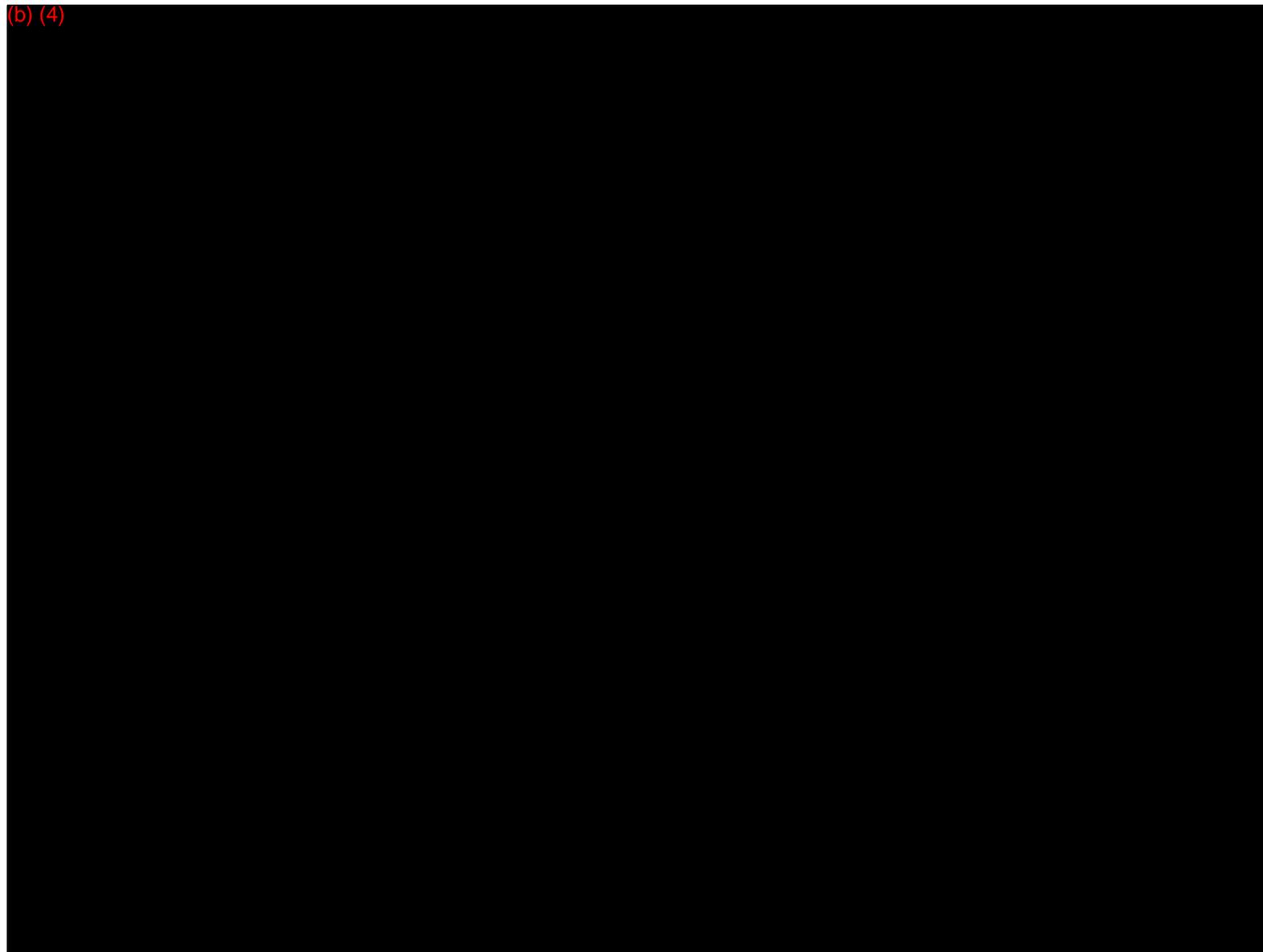
XV. Contact History

(b) (4)

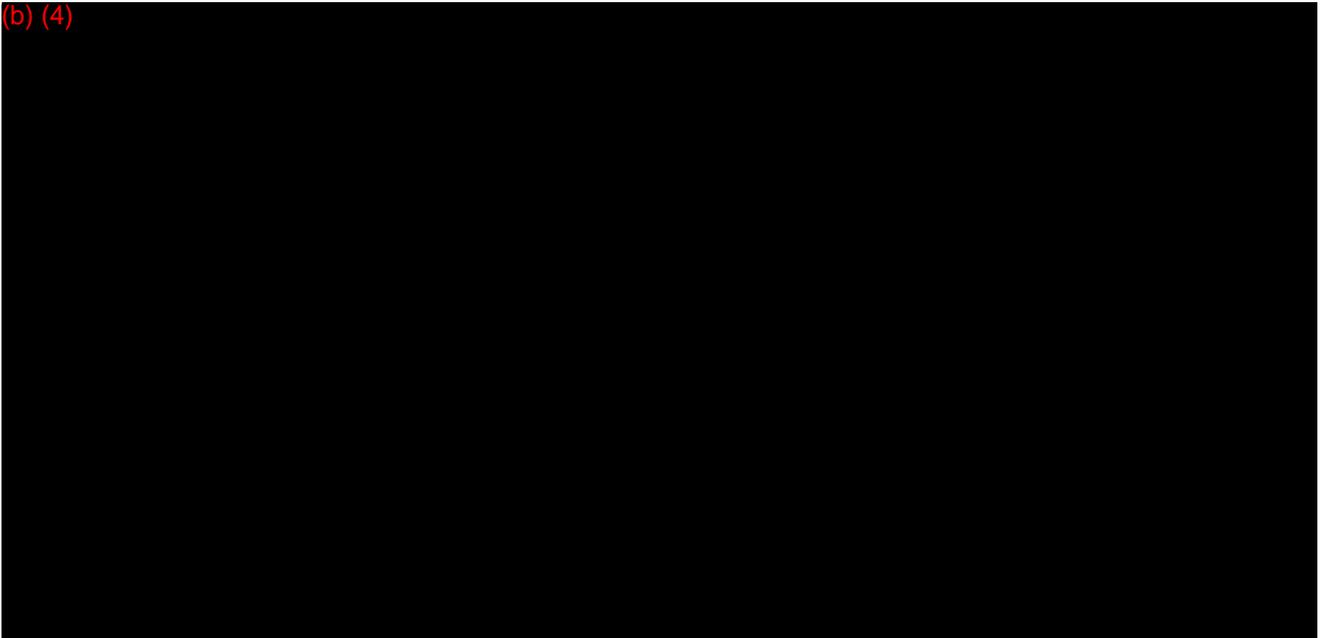
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XVI. Deficiencies

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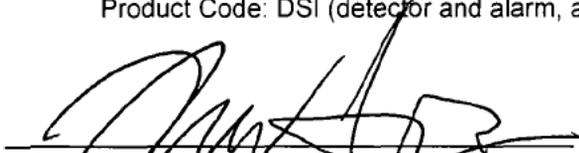
- b. (b) (4)
- c.
- d.
- e.



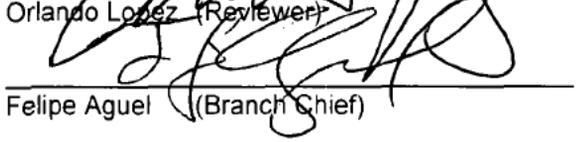
XVII. Recommendation

I recommend this submission be placed on telephone hold requesting the sponsor to provide wireless coexistence test results for the proposed device. Please see attached email with AI request sent to sponsor.

Regulation Number: 21 CFR 870.1025
 Regulation Name: (Arrhythmia detector and alarm - including ST-segment measurement and alarm)
 Regulatory Class: II
 Product Code: DSI (detector and alarm, arrhythmia)



 Orlando Lopez (Reviewer)



 Felipe Aguel (Branch Chief)

7/6/12.
 Date

7/6/2012
 Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 19, 2012

PREVENTICE, INC.
 2765 COMMERCE DRIVE NW
 SUITE 220
 ROCHESTER, MINNESOTA 55901
 ATTN: DREW PALIN

510k Number: K121197

Received: 4/19/2012

Product: BODYGUARDIAN SYSTEM
 BODYGUARDIAN

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission **MUST** be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007”

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, “Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements”. This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html>. In addition, the 510(k) Program Video is now available for viewing on line at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041, or at their internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Grayson, Giovanna *

From: Microsoft Outlook
To: 'DPALIN@PREVENTICE.COM'
Sent: Thursday, April 19, 2012 2:05 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'DPALIN@PREVENTICE.COM'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Thursday, April 19, 2012 2:05 PM
To: 'DPALIN@PREVENTICE.COM'
Subject: ack letter
Attachments: image002.png

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center W066-G619
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-4402

April 19, 2012
 PALIN
 DREW
 PREVENTICE, INC.
 7765 COMMERCE DRIVE NW
 SUITE 220
 ROCHESTER, MINNESOTA 55901
 ATTN: DREW PALIN

510k Number: K121197

Received: 4/19/2012

Product: BODYGUARDIAN SYSTEM
 BODYGUARDI

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm> for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form <http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm> accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

4/19/2012

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

Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007"
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm>. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

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Sincerely,
510(k) Staff

4/19/2012

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

Traditional 510(k) for the Preventice, Inc.

BodyGuardian System

April 18, 2012

Contact:

Drew Palin, M.D.
Medical Innovation Officer
dpalin@preventice.com
Mobile: 414-688-6858
Office: 507-322-3712

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1 Screening Checklist

Title	Related Information	Present	Inadequate	N/A
MDUFMA Cover Sheet	Medical Device User Fee Cover Sheet	X		
CDRH Premarket Review Submission Cover Sheet	CDRH Premarket Review Submission Cover Sheet	X		
510(k) Cover Letter	Appendix A of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Indications for Use Statement	Device Advice "Content of a 510(k)" Section D	X		
510(k) Summary or 510(k) Statement	Device Advice "Content of a 510(k)" Section E	X		
Truthful and Accuracy Statement	Device Advice "Content of a 510(k)" Section G	X		
Class III Summary and Certification	Class III Summary and Certification Form			X
Financial Certification or Disclosure Statement	FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators Financial Disclosure by Clinical Investigators			X
Declarations of Conformity and Summary Reports (Abbreviated 510(k)s)	Use of Standards in Substantial Equivalence Determinations FDA Standards program Declaration of conformity Required Elements for Declaration of Conformity to Recognized Standard			X
Executive Summary	See section 10 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Device Description	See section 11 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Substantial Equivalence Discussion	Guidance on the CDRH Premarket Notification Review Program 6/30/86 (K86-3)	X		
Proposed Labeling	Device Advice "Content of a 510(k)" Section H	X		
Sterilization/Shelf Life	Updated 510(k) Sterility Review Guidance (K90-1) For reuse of single use devices, see Guidance for Industry and FDA Staff – Medical Device User Fee and Modernization Act of 2002 Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices			X
Biocompatibility	FDA Blue Book Memo, G95-1, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing"	X		
Software	Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	X		
Electromagnetic Compatibility/Electrical Safety	CDRH Medical Device Electromagnetic Compatibility Program See also IEC 60601-1-2 Medical Electrical Equipment -- Part 1: General Requirements for	X		

Title	Related Information	Present	Inadequate	N/A
	Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001)			
Performance Testing – Bench	See section 18 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005	X		
Performance Testing – Animal	See section 19 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005			X
Performance Testing – Clinical	See section 20 in Chapter II of "Guidance for Industry and FDA Staff Format for Traditional and Abbreviated 510(k)s" updated November 17, 2005 FORM FDA 3454, Certification: Financial Interests and Arrangements of Clinical Investigators FORM FDA 3455, Disclosure: Financial Interests and Arrangements of Clinical Investigators			X X X
FORM FDA 3654, Standards Data Report for 510(k)s	Standards Data Report Form – Form 3654 1. No standard used - No Standards Form Required 2. Declaration of Conformity – Yes Standards Form Required 3. Standard but no declaration – Yes Standards Form Required	X		
Kit Certification	Device Advice			X

2 Medical Device User Fee Cover Sheet

Form Approved OMB No. 0910-511 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) 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/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) PREVENTICE 1652 Greenview Dr SW # 200 Rochester MN 559024219 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****4217	2. CONTACT NAME William Palin 2.1 E-MAIL ADDRESS dpalin@preventice.com 2.2 TELEPHONE NUMBER (include Area code) 888-751 5070 64 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) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice		3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input checked="" type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input type="checkbox"/> NO, I am not a small business		

3 **FDA-3674 Requirements of Clinical Trial**



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 Preventice, Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES 4/18/12
3. ADDRESS (Number, Street, State, and ZIP Code) 2765 Commerce Drive NW Suite 220 Rochester, MN 55901	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 507-322-3712 (Fax) 507 281-3630

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)

BodyGuardian System

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) W. Drew Palin	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Drew Palin, M.D. (Title) Medical Innovation Officer
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 2765 Commerce Drive NW Suite 220 Rochester, MN 559010	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 507-322-3712 (Fax)
	15. DATE OF CERTIFICATION 4/18/12

4 CDRH Premarket Review Submission Cover Sheets

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET			Form Approval OMB No. 9010-0120 Expiration Date: August 31, 2010. See OMB Statement on page 5.		
Date of Submission April 18, 2012		User Fee Payment ID Number MD6058856-956733		FDA Submission Document Number (if known)	
SECTION A TYPE OF SUBMISSION					
PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Premarket Report <input type="checkbox"/> Modular Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment <input type="checkbox"/> Licensing Agreement	PMA & HDE Supplement <input type="checkbox"/> Regular (180 day) <input type="checkbox"/> Special <input type="checkbox"/> Panel Track (PMA Only) <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 30-day Notice <input type="checkbox"/> 35-day Supplement <input type="checkbox"/> Real-time Review <input type="checkbox"/> Amendment to PMA &HDE Supplement <input type="checkbox"/> Other	PDP <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP	510(k) <input checked="" type="checkbox"/> Original Submission: <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated (Complete section I, Page 5) <input type="checkbox"/> Additional Information <input type="checkbox"/> Third Party	Meeting <input type="checkbox"/> Pre-510(K) Meeting <input type="checkbox"/> Pre-IDE Meeting <input type="checkbox"/> Pre-PMA Meeting <input type="checkbox"/> Pre-PDP Meeting <input type="checkbox"/> Day 100 Meeting <input type="checkbox"/> Agreement Meeting <input type="checkbox"/> Determination Meeting <input type="checkbox"/> Other (specify)	
IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement	Humanitarian Device Exemption (HDE) <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment	Class II Exemption Petition <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Evaluation of Automatic Class III Designation (De Novo) <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional Information	Other Submission <input type="checkbox"/> 513(g) <input type="checkbox"/> Other (describe submission):	
Have you used or cited Standards in your submission? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No (If Yes, please complete Section I, Page 5)					
SECTION B SUBMITTER, APPLICANT OR SPONSOR					
Company / Institution Name Preventice, Inc.			Establishment Registration Number (if known) Not yet obtained		
Division Name (if applicable)			Phone Number (including area code) Office : 507-322-3712, Mobile: 414-688-6858		
Street Address 2765 Commerce Drive NW, Suite 220			FAX Number (including area code) 507-281-3630		
City Rochester		State / Province MN	ZIP/Postal Code 55901	Country USA	
Contact Name Drew Palin, M.D.					
Contact Title Medical Innovation Officer			Contact E-mail Address dpalin@preventice.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/Postal Code	Country	
Contact Name					
Contact Title			Contact E-mail Address		

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

<input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or Expanded Indications <input type="checkbox"/> Request for Extension <input type="checkbox"/> Post-approval Study Protocol <input type="checkbox"/> Request for Applicant Hold <input type="checkbox"/> Request for Removal of Applicant Hold <input type="checkbox"/> Request to Remove or Add Manufacturing Site	<input type="checkbox"/> Change in design, component, or specification: <input type="checkbox"/> Software / Hardware <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Location change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager
<input type="checkbox"/> Process change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance <input type="checkbox"/> Shelf Life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below)	<input type="checkbox"/> Report Submission: <input type="checkbox"/> Annual or Periodic <input type="checkbox"/> Post-approval Study <input type="checkbox"/> Adverse Reaction <input type="checkbox"/> Device Defect <input type="checkbox"/> Amendment
<input type="checkbox"/> Response to FDA correspondence:		<input type="checkbox"/> Change in Ownership <input type="checkbox"/> Change in Correspondent <input type="checkbox"/> Change of Applicant Address
<input type="checkbox"/> Other Reason (specify):		

SECTION D2 REASON FOR APPLICATION - IDE

<input type="checkbox"/> New Device <input type="checkbox"/> New Indication <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expansion / Extension of Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Effect <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continued Access	<input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent / Applicant <input type="checkbox"/> Design / Device <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report submission: <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress Report <input type="checkbox"/> Site Waiver Report <input type="checkbox"/> Final	<input type="checkbox"/> Repose to FDA Letter Concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approved <input type="checkbox"/> Deficient Final Report <input type="checkbox"/> Deficient Progress Report <input type="checkbox"/> Deficient Investigator Report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request Extension of Time to Respond to FDA <input type="checkbox"/> Request Meeting <input type="checkbox"/> Request Hearing
<input type="checkbox"/> Other Reason (specify):		

SECTION D3 REASON FOR SUBMISSION - 510(k)

<input checked="" type="checkbox"/> New Device	<input type="checkbox"/> Additional or Expanded Indications	<input type="checkbox"/> Change in Technology
<input type="checkbox"/> Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed				Summary of, or statement concerning, safety and effectiveness information	
1	MHX	2	DSI	3	
5		6		7	
				<input checked="" type="checkbox"/> 510 (k) summary attached <input type="checkbox"/> 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	k083287	1	A VIVO Mobile Patient Management System	1	Corventis, Inc.
2		2		2	
3		3		3	
4		4		4	
Common or usual name or classification Ambulatory cardiac monitor					
	Trade or Proprietary or Model Name for This Device			Model Number	
1	BodyGuardian System			1 2000	
2	BodyGuardian Control Unit			2 2010	
3	BodyGuardian Connect			3 2030	
4	SnapStrip			4 1000	
FDA document numbers of all prior related submissions (regardless of outcome)					
1	2	3	4	5	6
	6				
	8	9	10	11	12
Data Included in Submission <input checked="" type="checkbox"/> Laboratory Testing <input type="checkbox"/> Animal Trials <input type="checkbox"/> Human Trials					
Product Codes MHX, DSI		C.F.R. Section (if applicable) 21 CFR 870.1025		Device Class <input type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified	
Classification Panel Cardiovascular					
Indications (from labeling) The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time: <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity 					

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

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

Original
 Add Delete

FDA Establishment Registration Number
 Not yet obtained

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name

(b) (4)

Establishment Registration Number
 Not yet obtained

Division Name (if applicable)

Phone Number (including area code)

(b) (4)

Street Address

(b) (4)

FAX Number (including area code)

(b) (4)

City

(b) (4)

State / Province

(b) (4)

ZIP/Postal Code

(b) (4)

Country

(b) (4)

Contact Name

(b) (4)

Contact Title

(b) (4)

Contact E-mail Address

(b) (4)

Original
 Add Delete

FDA Establishment Registration Number
 (b) (4)

Manufacturer Contract Sterilizer
 Contract Manufacturer Repackager / Relabeler

Company / Institution Name

(b) (4)

Establishment Registration Number

(b) (4)

Division Name (if applicable)

Phone Number (including area code)

(b) (4)

Street Address

(b) (4)

FAX Number (including area code)

(b) (4)

City

(b) (4)

State / Province

(b) (4)

ZIP/Postal Code

(b) (4)

Country

USA

Contact Name

(b) (4)

Contact Title

(b) (4)

Contact E-mail Address

(b) (4)

Original
 Add Delete

FDA Establishment Registration 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/Postal Code

Country

Contact Name

Contact Title

Contact E-mail Address

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,	1998; Amendment 1, 1991-11, Amendment 2, 1995	1998
			This space left blank intentionally		
2	60601-1-2	IEC	<i>Medical Electrical Equipment- Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic compatibility Requirements and Tests</i>	<i>(editor 2: 2001; Amendment 1:2004)</i>	2004
3	60601-1-4	IEC	<i>Medical Electrical Equipment- Part 1-4: General Requirements for Safety. Collateral Standard: Programmable Electrical Medical Systems</i>	<i>Edition 1.1</i>	2000
4	60601-1-6	IEC	<i>Medical Electrical Equipment. Part 1-6: General Requirement for Safety. Collateral Standard: Usability</i>	<i>Edition 1</i>	2004
	60601-2-47	IEC	<i>Medical Electrical Equipment- Part 2-47: Particular requirements for the safety including essential performance. of ambulatory electrocardiographic systems</i>	Edition 1	2001
6	60601-2-49	IEC	<i>Medical Electrical Equipment- Part 2- 49: Particular requirement for the safety of the multifunction patient monitoring equipment</i>	Edition 1	2001

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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
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

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
7	60529	IEC	<i>Degrees of protection provided by enclosures (if code)</i>	<i>Edition 2: 1989; Amend. 1: 1999</i>	1999
8	EC38	ANSI/AAMI	<i>Medical Electrical Equipment- Part 2-47: Particular requirements for the safety, including essential performances, of ambulatory electrocardiographic systems.</i>	2007	2007
9	EC57	ANSI/AAMI	<i>Testing and reporting performances results of cardiac rhythm and ST- segment measurement algorithms.</i>	2008	2008
10	EC12	ANSI/AAMI	Disposable ECG electrodes	2000/(R)2005	2005
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date
	Standards No.	Standards Organization	Standards Title	Version	Date

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

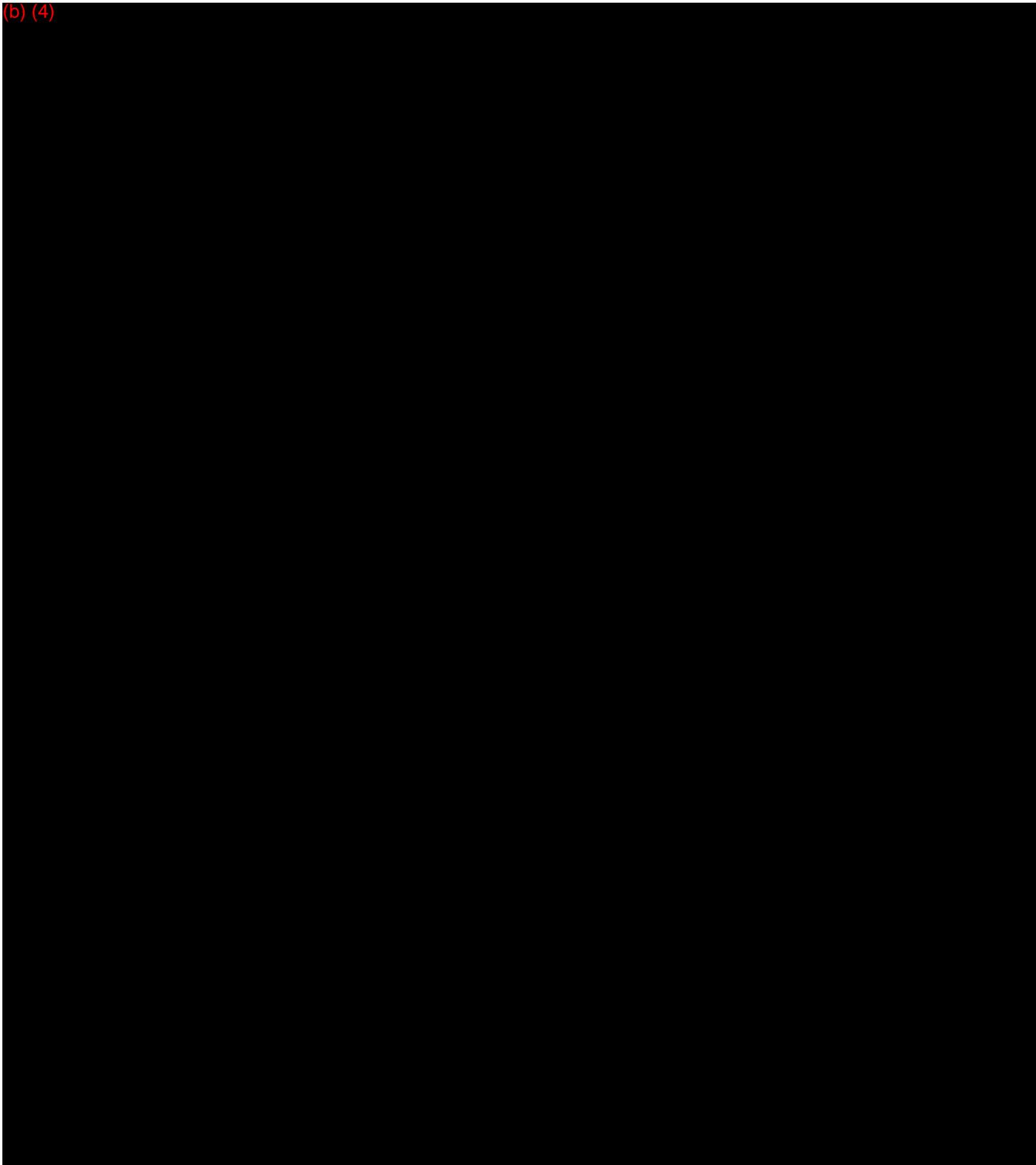
Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding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

Food and Drug Administration
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Rockville, MD 20850

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5 FDA-3654 Standards Data Reports

(b) (4)



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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ ANSI/AAMI EC12:2000/(R)2005 Disposable ECG electrodes		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#	3-52
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510 (k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/> 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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If no, include the results of testing in the 510 (k).		
Does this standard include more than one option or selection of tests?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusion from the standards?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Guidance for Industry and Food and Drug Administration Staff - Class II Special Controls Guidance Document: Electrocardiograph Electrodes		
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	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE: ANSI/AAMI EC12:2000/(R)2005 Disposable ECG electrodes		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4.2.2	SECTION TITLE Electrical Performance	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED - Only Sections 4.2.2.1, 4.2.2.2, 4.2.2.3, and 4.2.2.5 were tested against. Section 4.2.2.4 was not used as the device is not intended to be used when any defibrillation is conducted.		
DESCRIPTION See above		
JUSTIFICATION See above		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED -		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> 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.		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour 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:		
Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850		<i>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.</i>

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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>AAMI/ANSI EC38: 2007 Medical Electrical Equipment- Part 2-47: Particular requirements for the safety, including essential performances, of ambulatory electrocardiographic systems.</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510 (k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusion from the standards? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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/cddocs/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/cddocs/cfStandards/search.cfm ⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm	

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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>AAMI/ANSI EC57: 1998/ 2008, Testing and reporting performances results of cardiac rhythm and ST-segment measurement algorithms.</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#	3-73
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it Pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria? If no, include the results of testing in the 510 (k).	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusion from the standards? If yes, report these exclusions in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <i>Class II special controls: Arrhythmia Detector and Alarm; Guidance for Industry and FDA</i>		
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	

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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60529 Degrees of protection provided by enclosures (if code) Edition 2: 1989; Amend. 1: 1999</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any exclusion from the standards? If yes, report these exclusions in the summary report table.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Title of guidance: _____		
<p>¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]</p> <p>² Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm</p> <p>³ http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm</p> <p>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</p>	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. <p>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</p> <p>⁶ The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm</p>	

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE <i>IEC 60529 Degree of Protection provided by enclosures (if code)</i> <i>Edition 2: 1989; Admend 1: 1999</i>		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 5	SECTION TITLE <i>Degrees of protection against access to hazardous parts and against solid foreign objects indicated by the first characteristic numeral.</i>	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED · <i>Exclusion of section in the standard</i>		
DESCRIPTION: <i>Prescription and tests of section 5 are not applied to the equipment under test. Equipment is not classified for protection against solid foreign objects (first characteristic numeral).</i>		
JUSTIFICATION: <i>Medical Electrical Equipment standard (IEC 60601-1) requires classification of protection against ingress of water indicated by second characteristic numeral only (section 6).</i>		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ·		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
TYPE OF DEVIATION OR OPTION SELECTED ·		
DESCRIPTION		
JUSTIFICATION		
<p>* 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.</p> <p>♦ 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.</p>		
Paperwork Reduction Act Statement		
Public reporting burden for this collection of information is estimated to average 1 hour 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:		
Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer 1350 Piccard Drive, Room 400 Rockville, MD 20850	<i>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.</i>	

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 <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-1-2 Medical Electrical Equipment- Part 1-2: General Requirements for Safety. Collateral Standard: Electromagnetic compatibility Requirements and Tests (editor 2: 2001; Amendment 1:2004)</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#	5-34
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does this standard include acceptance criteria?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If no, include the results of testing in the 510 (k).		
Does this standard include more than one option or selection of tests?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report options selected in the summary report table.		
Were there any deviations or adaptations made in the use of the standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
Were deviations or adaptations made beyond what is specified in the FDA SIS?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these deviations or adaptations in the summary report table.		
Were there any exclusion from the standards?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, report these exclusions in the summary report table.		
Is there an FDA guidance ⁶ that is associated with this standard?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
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/cddocs/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/cddocs/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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TYPE OF 510 (K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-1-4: 2000 Medical Electrical Equipment- Part 1-4: General Requirements for Safety. Collateral Standard: Programmable Electrical Medical Systems (Edition 1.1)</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FDA Recognition number ³	#	5-41
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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.	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Were there any deviations or adaptations made in the use of the standard? If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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Is there an FDA guidance ⁶ that is associated with this standard? If yes, was the guidance document followed in preparation of this 510k?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Title of guidance: <i>Guidance for content of PMS of software contained in Medical Devices (May 11, 2005)</i>		
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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TYPE OF 510 (K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-1-6: 2004 Medical Electrical Equipment. Part 1-6: General Requirement for Safety. Collateral Standard: Usability (edition 1)</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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TYPE OF 510 (K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-1 Medical electrical equipment- Part 1: General requirements for safety, 1998; Amendment 1, 1991-11, Amendment 2, 1995</i>		
Please answer the following questions		
Is this standard recognized by FDA ² ?	Yes	No
.....	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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TYPE OF 510 (K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-2-47 Medical Electrical Equipment- Part 2-47: Particular requirements for the safety including essential performance, of ambulatory electrocardiographic systems (Edit. 1:2001)</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
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If yes, was the guidance document followed in preparation of this 510k?	<input type="checkbox"/>	<input type="checkbox"/>
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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TYPE OF 510 (K) SUBMISSION <input checked="" type="checkbox"/> Traditional <input type="checkbox"/> Special <input type="checkbox"/> Abbreviated		
STANDARD TITLE ¹ <i>IEC 60601-2-49 Medical Electrical Equipment- Part 2- 49: Particular requirement for the safety of the multifunction patient monitoring equipment (Ed. 1: 2001).</i>		
Please answer the following questions		
	Yes	No
Is this standard recognized by FDA ² ?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
FDA Recognition number ³	#	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510 (k)?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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If yes, were the deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?	<input type="checkbox"/>	<input type="checkbox"/>
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Title of guidance: _____		
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6 Cover Letter

K121197

D

Preventice

April 18, 2012

Office of Device Evaluation
 Document Mail Center (WO66-G609)
 Center for Devices and Radiological Health
 Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

FDA CDRH DMC

APR 19 2012

Subject: Traditional 510(k) for the BodyGuardian System

Received K45

Dear FDA:

Preventice, Inc. hereby submits 1 hard copy and 1 electronic copy of this Traditional 510(k).

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
If yes, does this device type require reprocessed validation data?		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

The existence of this 510(k) notification and the data and other information it contains are confidential and the protection afforded to such confidential information by 18 USC 1905, 21 USC 331(j), 5 USC 552 and other applicable laws is hereby claimed.

If you have any questions about this submission or require any further information, please contact me:

Email: dpalin@preventice.com

Mobile: 414-688-6858

Office : 507-322-3712

Sincerely,



Drew Palin, M.D.
 Medical Innovation Officer

7 Indications for Use Statement

510(k) Number (if known):

Device Name: BodyGuardian System

Indications for Use:

The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

Prescription Use (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Concurrence of CDRH, Office of Device Evaluation (ODE)

8 510(k) Summary

Submitter:	Preventice, Inc. 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Contact Person:	Drew Palin, M.D. Medical Innovation Officer dpalin@preventice.com Mobile: 414-688-6858 Office : 507-322-3712 FAX: 507-281-3630 Preventice 2765 Commerce Drive NW Suite 220 Rochester, MN 55901
Date Prepared:	April 18, 2012
Trade Names:	BodyGuardian System [Preventice BodyGuardian Device (BodyGuardian Control Unit and BodyGuardian SnapStrip), Preventice BodyGuardian Connect, BodyGuardian Application, Preventice PatientCare, PatientCare Portal for the Web, and PatientCare for iPad
Classification:	21 CFR 870.1025 <ul style="list-style-type: none"> • Patient Physiological Monitor (with arrhythmia detection) • Arrhythmia Detector and Alarm
Product Codes:	MHX, DSI
Predicate Device:	AVIVO Mobile Patient Management System (k083287)
Device Description:	The BodyGuardian System is an ambulatory cardiac monitoring system prescribed by healthcare providers. It monitors and records a patient's electrocardiographic (ECG) data, heart rate, respiration rate and activity level. The complete system consists of components that collect data, send the data to a remote Preventice computer server, store the data in secure databases, and present the data for review by healthcare professionals.

510(k) Summary (Continued)

Intended Use:	The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time: <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity
Comparison of Technological Characteristics:	Both the predicate system and the BodyGuardian System are small, ambulatory cardiac monitors that measure ECG, heart rate, respiration rate and activity levels. Both transmit their data to an external device which, in turn, broadcasts the data to a remote computer server that allows healthcare professionals to access and review the data. There are no fundamental differences between their technological characteristics.
Non-Clinical Testing:	The following bench testing was conducted on the BodyGuardian System: <ul style="list-style-type: none"> • EMC and electrical safety testing • ECG performance testing • Activity level measurement validation • Respiration rate measurement validation • Software verification and validation • Biocompatibility testing
Clinical Testing	Not applicable.
Conclusion:	We conclude that the results of testing show the BodyGuardian System to be substantially equivalent to the predicate device.

9 Truthful and Accurate Statement

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

(As Required by 21 CFR 807.87(k))

I certify that, in my capacity as Medical Innovation Officer at Preventice, 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.

W. Drew Palin

Drew Palin, M.D.
Medical Innovation Officer
Preventice, Inc.

4/18/12

Date: April 18, 2012

10 Class III Product Summary and Certification (Not Applicable)

Because this is not a class III device, and is not substantially equivalent to a class III device, the Literature Search and Certification requirement of the Safe Medical Devices Amendment (SMDA) of 1990 is not applicable.

11 Financial Certification / Disclosure Statement (Not Applicable)

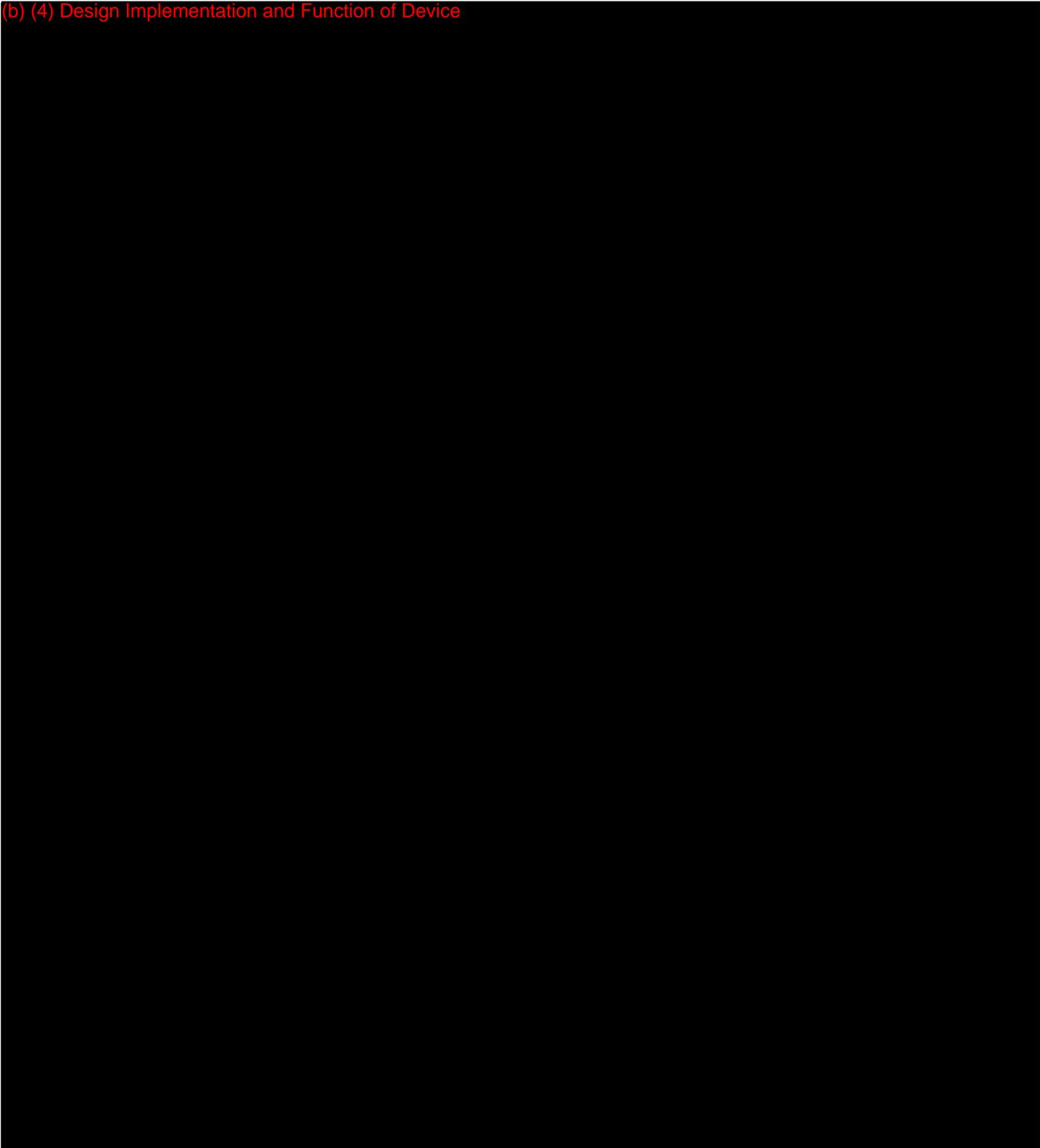
Not applicable.

12 Declarations of Conformity (Not Applicable)

Not applicable.

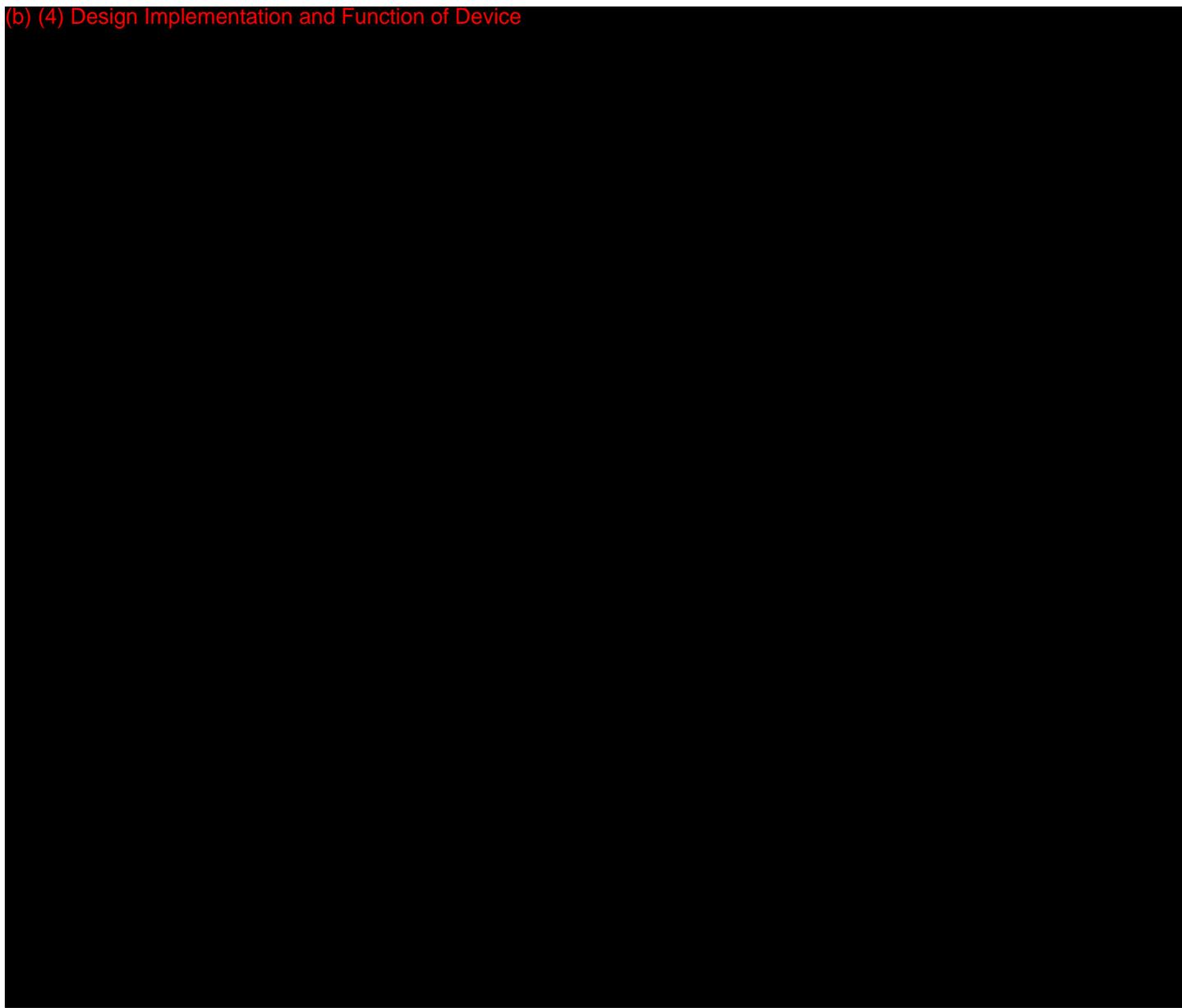
13 Executive Summary

(b) (4) Design Implementation and Function of Device



¹ “R-R” refers to the R waves of the ECG signal, this being part of the QRS complex.

(b) (4) Design Implementation and Function of Device



13.2 Indications for Use

(b) (4) Design Implementation and Function of Device



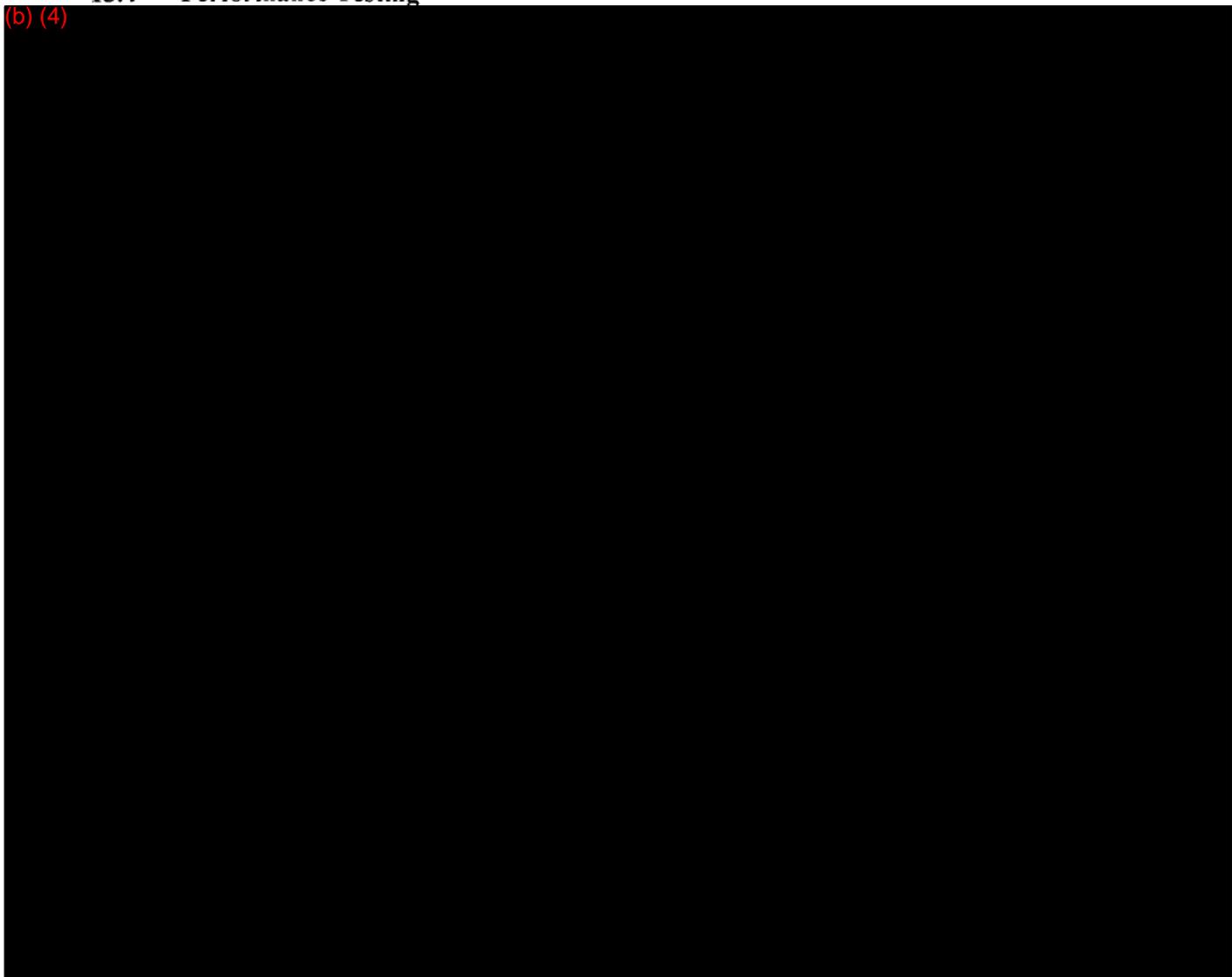
13.3 Substantial Equivalence (SE)

The BodyGuardian System is substantially equivalent to the predicate AVIVO Mobile Patient Management System by Corventis, Inc. (k083287). Both are battery-operated monitors that attach to the chest using adhesive electrodes. Similar to the predicate, the BodyGuardian System collects the following physiological data:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

13.4 Performance Testing

(b) (4)



15 Substantial Equivalence (SE)

15.1 Predicate Information

Predicate Trade Name [510(k)]: AVIVO Mobile Patient Management System

Common Names/Descriptions: Ambulatory Cardiac Monitor

Classification Names: Arrhythmia Detector and Alarm;
Patient Physiological Monitor (with arrhythmia detection)

Procodes: MHX, DSI

Manufacturer Address: Corventis, Inc.
1410 Energy Park Drive, Suite 1
Saint Paul, MN 55108

Manufacturer Registration #: 3007456577

15.2 SE Table

Table 4: SE Comparison

#	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
	Regulatory		
1	Manufacturer	Corventis Inc.	Preventice, Inc.
2	510(k) number	K083287	Not yet assigned
3	Device Class	Class II	Class II
4	Product Code(s)	MHX, DSI	MHX, DSI
5	Device Type	Arrhythmia Detector and Alarm; Patient Physiological Monitor (with arrhythmia detection)	Arrhythmia Detector and Alarm; Patient Physiological Monitor (with arrhythmia detection)
6	Regulation number	21 CFR 870.1025	21 CFR 870.1025
7	Model Name	AVIVO Mobile Patient Management System	BodyGuardian System
8	Intended Use Statement	<p>The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:</p> <ul style="list-style-type: none"> • ECG • Heart Rate (including HR variability) • Activity • Posture • Body Temperature • Respiration rate (including RR variability) • Body fluid status 	<p>The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:</p> <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity

#	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
	System Components		
9	Ambulatory Monitor (Sensor)	PiiX Adherent Device	BodyGuardian (BG) Control Unit
10	ECG/Bioimpedance Electrode	Integral to PiiX Adherent Device (disposable with PiiX ambulatory monitor)	SnapStrip (replaceable and disposable)
11	Wireless data transmission module	Zlink (custom wireless receiver/transmitter)	BodyGuardian Connect (customized, commercial smartphone)
12	Data management software	Operates on Corventis computer server	Operates on Preventice computer server
13	System Measurements	ECG Heart Rate Heart Rate Variability Respiration rate Activity Posture Body fluid status Respiration variability	ECG Heart Rate Heart Rate Variability Respiration rate Activity Heart Rate Reliability

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
	Ambulatory Monitor (Sensor)		
14	Basic Design	Disposable (built-in electrode)	Reusable (with replaceable electrode)
15	Events Monitored	<ul style="list-style-type: none"> • Patient-initiated event trigger - Patient applies a magnet to PiiX • Medical Protocol event - Thresholds for medical events are set by healthcare professionals in server software 	<ul style="list-style-type: none"> • Patient-initiated event trigger - Patient presses button on BodyGuardian Control Unit • Medical Protocol event - Physician sets parameters defining events, such as "HR >120" using server software • On regular time intervals set by physician (e.g. every 60 minutes) the BodyGuardian will record and store a random 120-second ECG
16	Communication Protocol	Two-way link with Zlink wireless data transmission module using Bluetooth V2.0 (2.402 to 2.480 GHz)	Two-way link with BG Connect wireless data transmission module using Bluetooth V2.0 (2.402 to 2.480 GHz)
17	Protocol when wireless data transmission cannot be done	Multiple readings are stored on the Ambulatory Monitor (Sensor) device and the wireless transmission module as a backup if data needs to be re-sent to the server	IDENTICAL

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
18	ECG <ul style="list-style-type: none"> • Channels • Sampling Rate • Digital Resolution • Input Dynamic Range • Input Offset Dynamic Range • Measurement Range 	Single Channel 200 Hz 10 bits ± 5 mV ± 300 mV 25 - 250 Beats per Minute	Single Channel 256 Hz 12 bits IDENTICAL IDENTICAL IDENTICAL
19	Respiration Rate (Bioimpedance subsystem) <ul style="list-style-type: none"> • Sampling rate • Measurement Range (electrical) • Measurement Range (physiological) 	4 Hz 10 - 150 Ohms 4 - 60 Breaths per Minute	32 Hz 10 - 120 Ohms 1 - 40 Breaths per Minute
20	Activity <ul style="list-style-type: none"> • Sampling Rate • Measurement Range 	0.25 Hz ± 2 g range in x, y, z direction	50 Hz IDENTICAL
ECG/Bioimpedance Electrode			

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
21	Basic Design Features	Integral to Ambulatory Monitor (Sensor) Discarded with the single-use Sensor Non-replaceable	Attached to Ambulatory Monitor (Sensor) by four snap connectors Discarded after use, separate from reusable Sensor Replaceable
22	Number of contacts	2 contacts for ECG, 2 for bioimpedance	IDENTICAL
Wireless data transmission module			
23	Module name	ZLink (Gateway)	BodyGuardian Connect
24	Data Storage	Yes, in Zlink memory	Yes, in BodyGuardian Connect memory
25	Data Transmission: Communication Protocol with Server	Cellular link between Zlink and Server Cellular frequency: GSM:850/900/1800/1950 MHz	Cellular link between BG Connect and Server Cellular frequency: GSM:850/900/1800/1950 MHz
26	Protocol when wireless data transmission cannot be done	Multiple readings are stored on the Ambulatory Monitor (Sensor) device and the wireless transmission module as a backup if data needs to be re-sent to the server	IDENTICAL
Data Management Software			
27	Location	Corventis Server	Preventice Server

	Attributes	AVIVO (Predicate Device)	BodyGuardian (New Device)
28	Functionality	<ul style="list-style-type: none"> • Display the physiological parameters in trend graphs • Display ECG waveform that corresponds to a detected arrhythmia • Provide visual notifications for the detected arrhythmia • Provide the users the ability to acknowledge or dismiss events • Provide afibrillation burden, if applicable to patient 	<ul style="list-style-type: none"> • IDENTICAL • IDENTICAL • IDENTICAL • Not provided • Not provided
29	Access	Web browser on Personal Computer (PC)	Web browser (PC) or via iPad
30	Internet Communication	Secure Sockets Layer (SSL) via HTTPS	IDENTICAL
31	Security Administration	Yes	IDENTICAL
32	Viewing Software	Web browser	Web browser, iPad

15.3 SE Discussion

The BodyGuardian System is substantially equivalent to the predicate AVIVO Mobile Patient Management System by Corventis, Inc. (k083287). Both are battery-operated cardiac monitors that attach to the chest using adhesive electrodes. Similar to the predicate, the BodyGuardian System collects the following physiological data:

- ECG
- Heart rate (including HR variability and HR reliability)
- Respiration rate
- Activity

The BodyGuardian System differs from the predicate primarily by lacking measurements of posture, temperature, respiration rate variability and body fluid status.

Both systems have a monitor and electrode that attach to the chest and transmit their data wirelessly to a separate data transmission module which in turn transmits data wirelessly to a central computer server. Both systems monitor both patient-initiated events and medical protocol events. The BodyGuardian System also can be set to transmit ECG tracings periodically independent of the other two event types. Both allow the healthcare physician to review patient data remotely, via the internet.

ECG properties are nearly identical. Both systems are single channel with similar or identical attributes such as sampling rate, digital resolution, input dynamic range, input offset dynamic range, and measurement range.

Both systems have very similar technical attributes for measurement of respiration rate. While the BodyGuardian System tops out at 40 breathes per minute versus 60 breathes per minute, this is of limited clinical import, since 40 breathes per minute is clearly serious tachypnea. For the purposes of ambulatory monitoring an upper limit of 40 breathes per minute is more than adequate.

The BodyGuardian System matches the activity measurement range of the predicate and provides a faster sampling rate which supports an accurate measurement of respiration rate.

As shown in Section 21 (page 156), bench testing has been done to show that cardiac measurements and measurements of respiration rate and activity level achieve an appropriate level of effectiveness.

15.4 SE of Indications for Use

Below we show the Indications for Use statements of the predicate and new device. They are nearly identical.

Table 5: Comparison of Indications for Use Statements

Predicate (AVIVO)	New Device (BodyGuardian)
<p>The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:</p> <ul style="list-style-type: none"> • ECG • Heart Rate (including HR variability) • Activity • Posture • Body Temperature • Respiration rate (including RR variability) • Body fluid status 	<p>The BodyGuardian System detects and monitors non-lethal cardiac arrhythmias in ambulatory patients, when prescribed by a physician or other qualified healthcare professional. The BodyGuardian System continuously records, stores and periodically transmits the following physiological data to a remote computer server for up to 30 days at a time:</p> <ul style="list-style-type: none"> • ECG • Heart rate (including HR variability and HR reliability) • Respiration rate • Activity

The BodyGuardian System differs from the predicate primarily by lacking measurements of posture, temperature, respiration rate variability and body fluid status.

15.5 SE Conclusion

We conclude that the BodyGuardian System is substantially equivalent to the predicate.

16 Labeling

16.1 Draft Labeling

See Appendix 2 for an overview of all labeling and details on labels.

NOTE: The document in Appendix 2 refers to Attachments A, B, C, D, and E. These are shown in Appendix 3 through Appendix 7, respectively and are not, as stated in the overview in Appendix 2, actually contained in Appendix 2 itself.

The documents in Appendix 3 through Appendix 7 are the five sets of instructions for use or background information available for the BodyGuardian System.

The BodyGuardian Instructions for Use are used by the patient. The other instructions for use are used by healthcare professionals.

The Flesch-Kincaid readability statistics for the BodyGuardian Instructions for Use is a grade level of 7.6 which is appropriately low for these instructions.

16.2 Predicate Labeling

See Appendix 8 for predicate labeling. The only predicate labeling document available to Preventice was the AVIVO instructions for use.

17 Sterilization and Shelf Life (Not applicable)

17.1 Sterilization (Not Applicable)

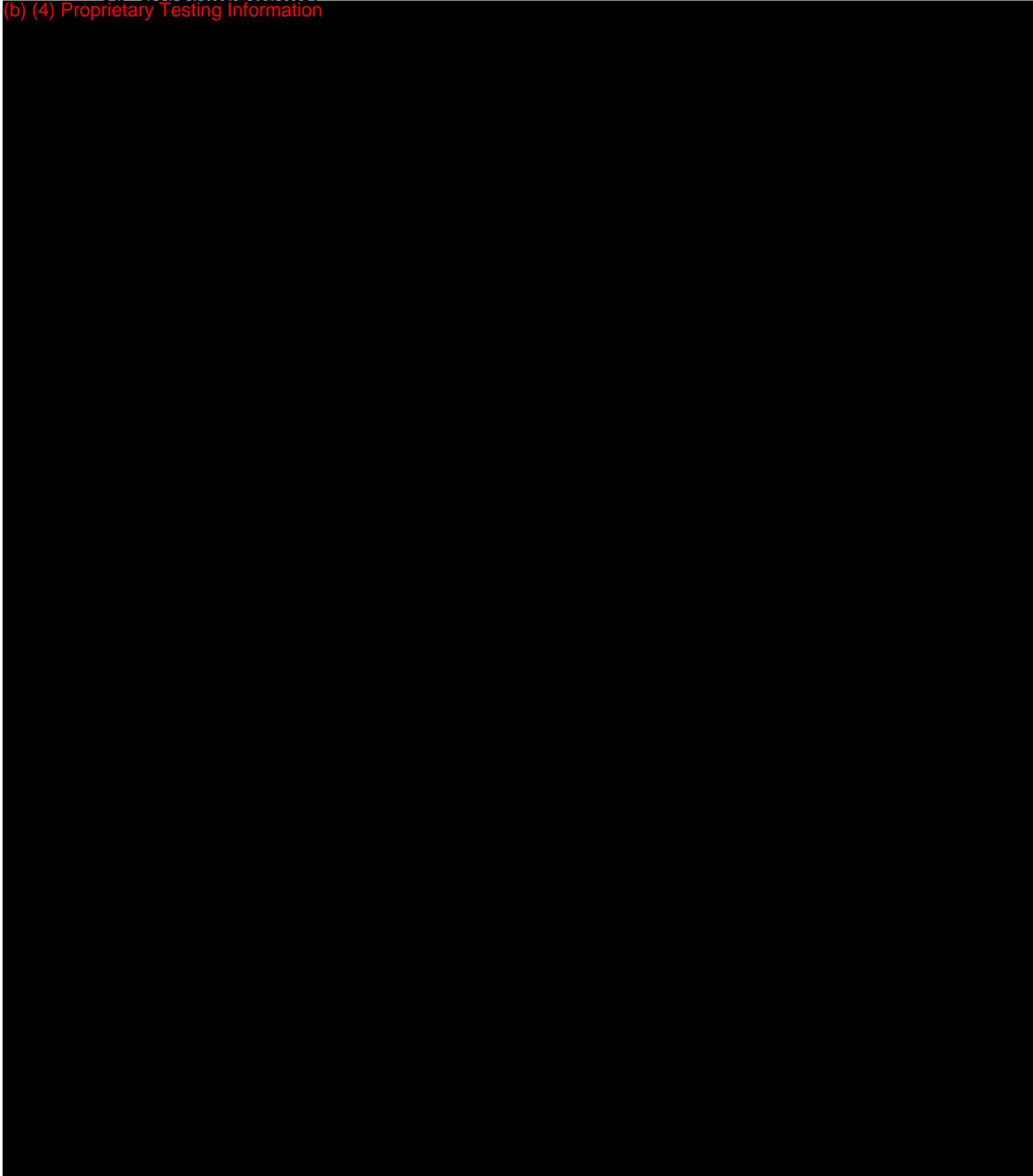
Not applicable.

17.2 Shelf Life (Not Applicable)

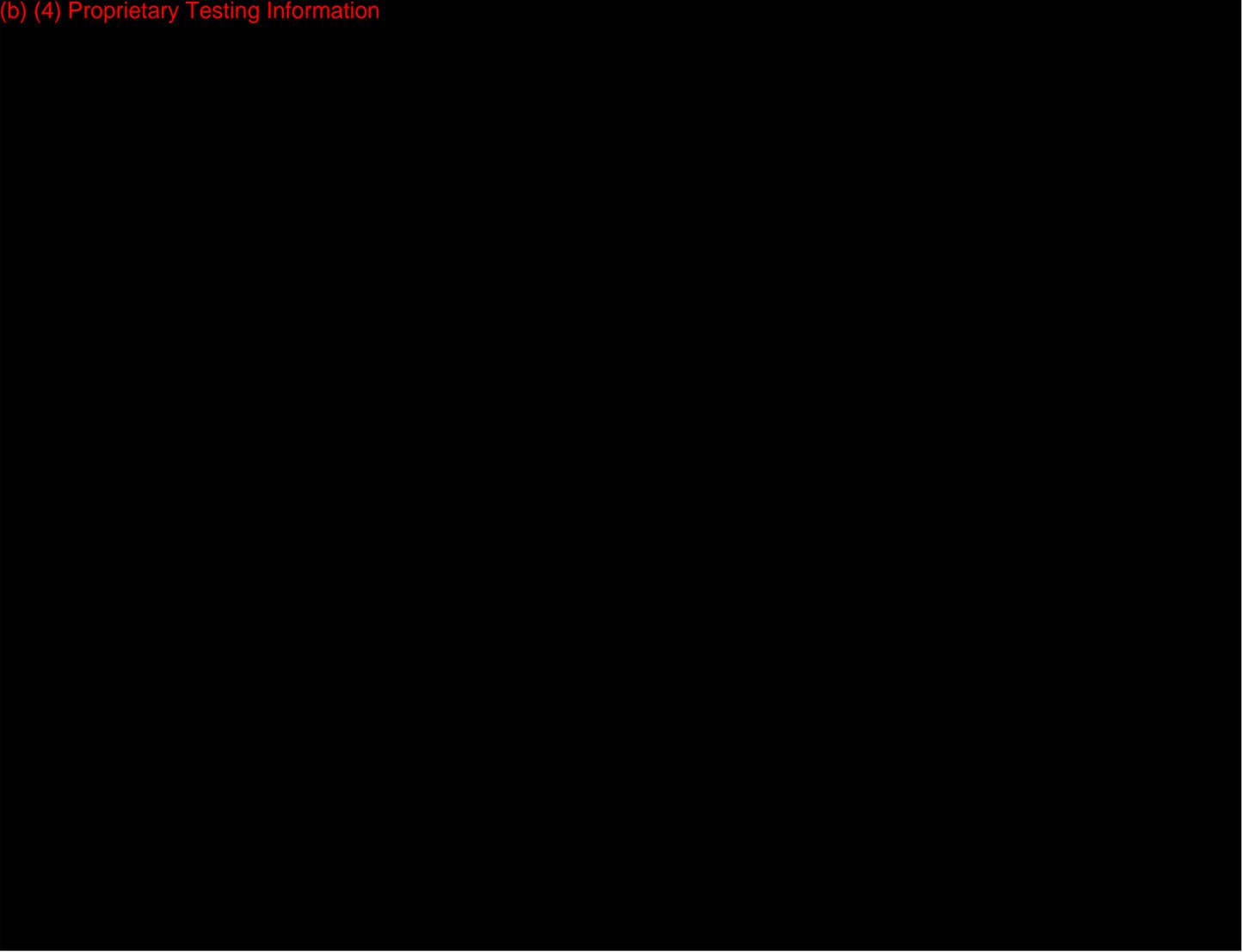
Not applicable.

18 Biocompatibility

(b) (4) Proprietary Testing Information



(b) (4) Proprietary Testing Information



(b) (4) Software Design and Architecture

19.1.1 BodyGuardian System Level of Concern

We believe the BodyGuardian System is of moderate level of concern. FDA Tables were used to help arrive at the moderate LoC self-assessment. This determination was made before the effects of mitigation per FDA guidance. As shown in Table 7 below, we respond in the negative to all of the FDA questions that indicate a device reaches a major level of concern. As an ambulatory cardiac monitor without an alarm feature, the BodyGuardian System is not intended to be used for immediate detection of cardiac arrhythmias, supporting our contention that a Major Level of Concern does not apply. We respond in the affirmative to the third question in the Moderate Level of Concern Checklist (Table 8); thereby arriving at the determination that a Moderate LoC applies. Software documentation has been provided accordingly.

Table 7: Major Level of Concern Checklist

If the answer to any one question below is Yes, the Level of Concern (LOC) for the Software Device is likely to be Major.	
1. Does the Software Device qualify as Blood Establishment Computer Software?	NO
2. Is the Software Device intended to be used in combination with a drug or biologic?	NO
3. Is the Software Device an accessory to a medical device that has a Major Level of Concern?	NO

4. Prior to mitigation of hazards, could a failure of the Software Device result in death or serious injury, either to a patient or to a user of the device? Examples of this include the following:	NO
a. Does the Software Device control a life supporting or life sustaining function?	NO
b. Does the Software Device control the delivery of potentially harmful energy that could result in death or serious injury, such as radiation treatment systems, defibrillators, and ablation generators?	NO
c. Does the Software Device control the delivery of treatment or therapy such that an error or malfunction could result in death or serious injury?	NO
d. Does the Software Device provide diagnostic information that directly drives a decision regarding treatment or therapy, such that if misapplied it could result in serious injury or death?	NO
e. Does the Software Device provide vital signs monitoring and alarms for potentially life threatening situations in which medical intervention is necessary?	NO

Table 8: Moderate Level of Concern Checklist

If the Software Device is not Major Level of Concern and the answer to any one question below is Yes, the Level of Concern is likely to be Moderate.	Preventive Answer
1. Is the Software Device an accessory to a medical device that has a Moderate Level of Concern?	NO
2. Prior to mitigation of hazards, could a failure of the Software Device result in Minor Injury, either to a patient or to a user of the device?	No
3. Could a malfunction of, or a latent design flaw in, the Software Device lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury?	Yes

22 Performance Testing - Animal (Not Applicable)

Not applicable.

23 Performance Testing - Clinical (Not Applicable)

Not applicable.

Appendix 1: Hamilton and Tompkins Publication

Quantitative Investigation of QRS Detection Rules Using the MIT/BIH Arrhythmia Database

PATRICK S. HAMILTON AND WILLIS J. TOMPKINS, SENIOR MEMBER, IEEE

Abstract—We have investigated the quantitative effects of a number of common elements of QRS detection rules using the MIT/BIH arrhythmia database. A previously developed linear and nonlinear filtering scheme was used to provide input to the QRS detector decision section. We used the filtering to preprocess the database. This yielded a set of event vectors produced from QRS complexes and noise. After this preprocessing, we tested different decision rules on the event vectors. This step was carried out at processing speeds up to 100 times faster than real time. The role of the decision rule section is to discriminate the QRS events from the noise events. We started by optimizing a simple decision rule. Then we developed a progressively more complex decision process for QRS detection by adding new detection rules. We implemented and tested a final real-time QRS detection algorithm, using the optimized decision rule process. The resulting QRS detection algorithm has a sensitivity of 99.69 percent and positive predictivity of 99.77 percent when evaluated with the MIT/BIH arrhythmia database.

INTRODUCTION

SOFTWARE QRS detectors are an integral part of modern computerized ECG monitoring systems. Perhaps the most critical use of QRS detection occurs in intensive care unit arrhythmia monitoring systems where the algorithm must run in real time. However, there are many other instruments that use such real-time algorithms. These include ECG machines, operating room monitors, and ECG stress test systems. In an arrhythmia monitoring system, significant false negative and false positive rates can result from faulty QRS detection [1]. As yet, no one has developed a perfect real-time QRS detection algorithm.

Pahlm and Sommo [2] observe that most QRS detectors are divided into two sections. The preprocessor section performs linear and nonlinear filtering of the ECG signal and produces a set of periodic vectors that describe events. The decision rule section operates on the output of the preprocessor, classifies each event as either a QRS complex or noise, and saves the temporal location of each of the identified QRS complexes.

The decision rules for a QRS detector are generally built from a number of components each having experimentally determined parameters. The most important task of the decision rule section is the determination of detection thresholds. Other common components of QRS decision

rules are blanking, where events immediately following a QRS detection are ignored for a set time, search back, where previously rejected events are reevaluated when a significant time has passed without a detection, and use of slope to distinguish between T waves and early occurring ectopic beats.

Decision rule components have generally been assembled in ad hoc fashion. Little has been done to attach quantitative significance to different decision rule components. Fig. 1 shows our experimental approach for examining the effects of different decision rules. We used the preprocessor developed by Pan and Tompkins [3], with slight modifications, to process the MIT/BIH database. The preprocessor produced event vectors consisting of peak heights from the processed ECG signal and time of peak occurrence. These vectors were recorded along with annotation as to whether the event resulted from a QRS complex or noise. Progressively more complex decision rules were applied to the event vectors to evaluate the quantitative effects of different decision rule components. At each stage we optimized the decision rules. We implemented the resulting rules in a real-time QRS detector together with a derivative algorithm used to discriminate between T waves and early ectopic beats.

When designing QRS or PVC detectors around a given data set, there is some concern that the detector will be tuned to the database used for development. Small improvements in detector performance on a given database may not reflect significant improvement in real-world performance. Moody and Mark [4] have discussed how well real-world performance can be predicted from performance on a given database. Such performance can only be judged by the clinician with long-term clinical trials. Detection of rare events such as ventricular tachycardia and the effects of noise under different conditions cannot be accurately judged with limited databases. The general consensus is that databases such as the MIT/BIH yield the best indication of arrhythmia detector performance available without extensive clinical trials.

PREPROCESSOR

The preprocessor does linear and nonlinear digital filtering and peak detection.

Filtering

Fig. 2 illustrates the filter stages of the preprocessor. See Pan and Tompkins [3] for further details. The low-

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The authors are with the Department of Electrical and Computer Engineering, University of Wisconsin-Madison, Madison, WI 53706.
IEEE Log Number 8611199.

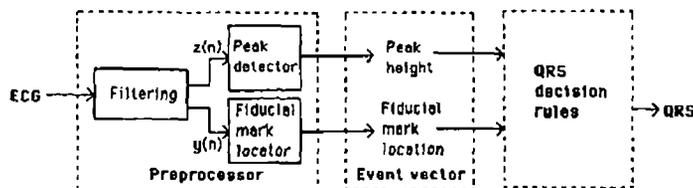


Fig. 1. Block diagram of QRS detector algorithm. The preprocessor does linear and nonlinear digital filtering and peak analysis to produce event vectors. The vectors are processed by decision rules to locate QRS complexes.

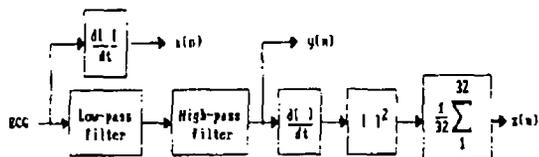


Fig. 2. Filter stages of the QRS detector. $z(n)$ is the time-averaged signal, $y(n)$ is the bandpassed ECG, and $x(n)$ is the differentiated ECG.

pass and high-pass filters together form a bandpass filter that can be implemented with integer arithmetic to provide for real-time operation. This is followed by differentiation, squaring, and time averaging of the signal. A separate derivative of the original ECG is used for T wave discrimination.

The low-pass filter is one of a class of filters described by Lynn [5], implemented with the difference equation

$$y(nT) = 2y(nT - T) - y(nT - 2T) + x(nT) - 2x(nT - 6T) + x(nT - 12T)$$

where T is the sampling period and n is an arbitrary integer. The high-pass filter is implemented with the difference equation

$$y(nT) = y(nT - T) - x(nT)/32 + x(nT - 16T) - x(nT - 17T) + x(nT - 32T)/32.$$

The difference equation for the derivative is

$$y(nT) = (2x(nT) + x(nT - T) - x(nT - 3T) - 2x(nT - 4T))/8.$$

The nonlinear squaring function squares each output data point. Time averaging is done by adding together the 32 most recent values from the squaring function and dividing the total by 32.

Fig. 3 shows a typical ECG and the resulting output signals after each of the processing steps.

Peak Detection

Fig. 4 shows a typical large waveform produced by the time-averaged window for a QRS complex. Although it is easy to visually identify one large peak, simple peak detection algorithms falsely detect multiple peaks due to ripples in the wave. A simple local maxima peak detector has the liability of detecting many small-amplitude peaks. Although both peaks result from the same QRS complex, one peak is classified as resulting from a QRS complex,

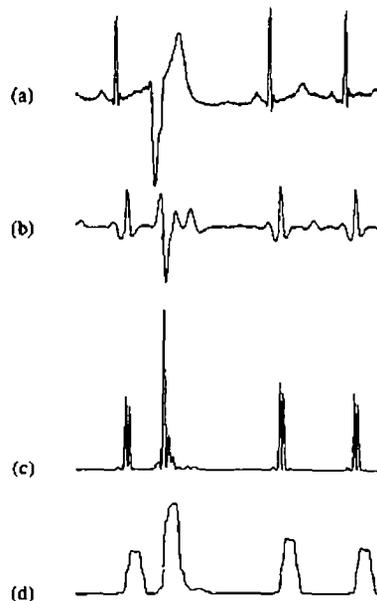


Fig. 3. Outputs of filters in the QRS detector. (a) Unfiltered ECG. (b) Output of bandpass filter. (c) Output after the bandpass, differentiation, and squaring processes. (d) Final time-averaged signal.

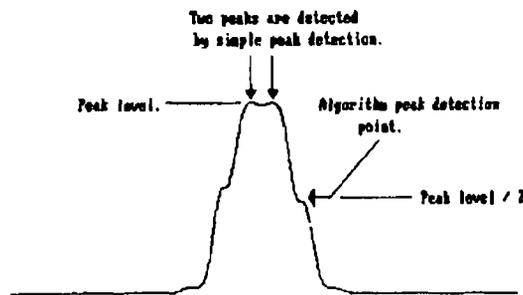


Fig. 4. Typical waveform of time-averaged signal during the QRS complex.

the other is classified as noise. This can bias the noise level estimate on the high side. In contrast, ripples in the baseline of the signal can bias the noise estimate on the low side.

Murthy and Rangaraj [6] proposed a time-averaged, first difference signal having somewhat similar characteristics to our bandpassed, differentiated, squared, time-averaged signal. They advocated low-pass filtering of the time-averaged signal to reduce ripples and multiple peaks before peak detection. However, instead of adding such an additional filter stage, we developed a peak detection al-

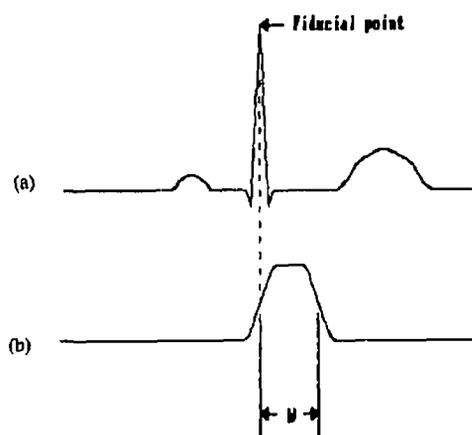


Fig. 5. Idealized relationship between the QRS complex and the time-averaged waveform. (a) Unfiltered ECG. (b) Time-averaged signal. Interval W equals the width of the averaging window.

gorithm that eliminates detection of both ripples on large waves and also very small noise peaks.

The peak detector finds peaks in the final output of the filtering stages. A detected peak defines an event. The detector algorithm stores the maximal levels encountered in the signal since the last peak detection. A new peak is defined only after a level is encountered that is less than half the height of the maximal, or peak, level. Detection occurs halfway down the back side of the peak. This approach eliminates multiple detections from ripple around the wave peak.

When ECG signals have prominent T waves, the time-averaged waveform for a heart cycle sometimes appears as one long wave formed from the combination of waves produced by the QRS complex and the T wave. The time of occurrence of the peak detected in the preprocessed signal is important for placing the fiducial mark. With a prominent T wave, the detection may be delayed by the duration of the lengthened wave. To avoid this delay, in addition to the previously stated conditions for detection, a QRS is detected by the peak detector if 175 ms elapses from the occurrence of the maximal positive slope in the time-averaged signal. The reasons for this detection condition will become clearer to the reader later in the discussion on the fiducial mark.

FIDUCIAL MARK

Fig. 5 shows an idealized relation between the QRS complex and the time-averaged signal. The peak of the R wave occurs in the middle of the rising slope of the time-averaged signal. As already discussed, the peak detection algorithm does not establish that a valid peak has occurred until the middle of the falling slope when the level drops below half the distance from the maximal value to the base point. Because the time between the middle of the rising slope and the middle of the falling slope is equal to the duration of the averaging window, ideally the fiducial mark representing the time of occurrence of the peak of the R wave is located with a fixed delay of one window's

width (i.e., 160 ms) back in time from the point of peak detection.

For a more consistent location, the fiducial mark is set to the location of the largest peak in the bandpassed signal in an interval from 225 to 125 ms preceding a peak detection in the time-averaged signal. We use peaks in the signal from the bandpass filter only for location of the fiducial mark, so a simple three-point scheme is used for detection of peaks in this signal. To compensate for late detection, when a peak detection occurs with a long wave in the bandpassed signal, the valid fiducial interval is from 250 to 150 ms preceding the peak detection.

DECISION RULE OPTIMIZATION

We preprocessed all the MIT/BIH tapes with the filters and peak detector. For each detected peak, we determined and saved a two-dimensional event vector composed of the peak signal level of the preprocessed waveform and the elapsed time from the last fiducial mark. We also saved a flag that notes whether the vector resulted from noise or from a QRS complex. All the event vectors for the entire database require about 700 kbytes for storage. We used these digital recordings of the event vectors to optimize the decision rules. Even with complicated decision rule schemes, we were able to run as many as 100 trials on an IBM PC in the time required for one real-time analysis of the entire set of analog tapes in the database.

We analyzed the effects of different parts of the decision rule stage by constructing and testing an increasingly complex decision rule scheme. As we added new rules, we varied their parameters along with detection threshold parameters to produce optimal performance. Initially we examined different peak level estimation schemes and set the detection threshold as a percentage of the QRS peak level estimate. After determining the best method for estimating peak levels, we applied the method to a scheme where the detection threshold is set between the noise level estimate and the QRS peak level estimate. Next, we introduced 200 ms refractory blanking to eliminate both false detection on the T wave and also multiple detection of the QRS complex. Finally, we introduced search back and optimized the relative search back and normal thresholds.

QRS detectors may be optimized with respect to the number of false positive and false negative detections. The relative cost of false detections varies from application to application. Thakor *et al.* [7] used receiver operating characteristic (ROC) curves to analyze the performance of QRS detectors. They chose the "knee" of each curve as the point of optimal detector performance. If the probability of a noise occurrence and the probability of a QRS occurrence are approximately the same, then a detector operating at the optimal or "knee" point will produce the minimal total number of false positive and false negative detections. In our case, we optimized the decision rules for QRS detection to minimize the sum of false negative and false positive detections.

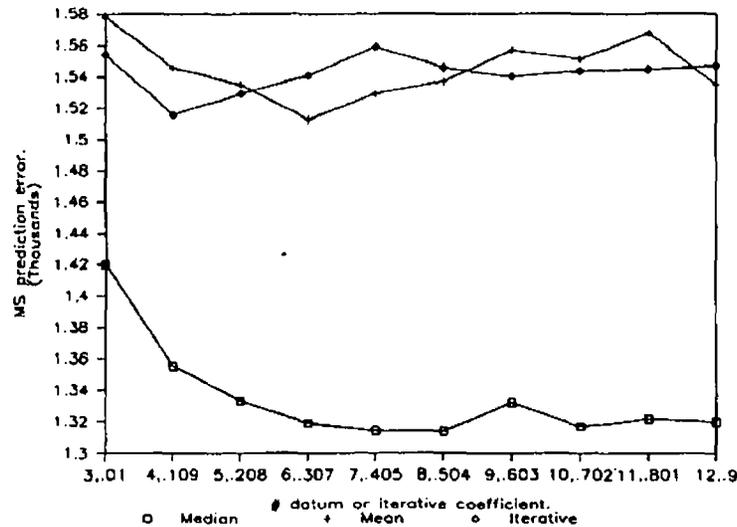


Fig. 6. Mean square prediction error for the mean, median, and iterative signal peak estimators applied to the time-averaged signal.

PEAK LEVEL ESTIMATION

The method of local peak level estimation is an important performance factor in the QRS detection algorithms that use adaptive detection thresholds. We examined the relative performance of mean, median, and iterative peak level estimators. The mean estimator determines the local peak level as the mean of a specified number of past peaks whereas the median estimator uses the median peak level. The first-order iterative estimator has the general form

$$\text{Estimate}(n) = (1 - A) \times \text{Estimate}(n - 1) + A \times \text{Peak}(n)$$

where *A* is a positive coefficient less than one.

Mean Square Prediction Error

The peak level estimator may also be considered a predictor, predicting the value of the next QRS peak based on the previous QRS peaks. If the estimator were perfect, the detection threshold could be set just below the predicted peak level. We applied the three estimators to the peaks derived from the time-averaged signal and tabulated the mean square prediction errors. For the mean and median estimators, we performed trials with different numbers of data points used in the calculation of the peak level estimate. For the iterative estimator, we did trials with ten coefficient values ranging from 0.01 to 0.9.

Fig. 6 illustrates the relative performance of the three predictors applied to QRS peaks. The median predictor has a lower prediction error than either the mean or iterative predictor. Its minimal error occurs when seven or eight previous data points are used for level prediction. The performance of the mean and iterative predictors is about equal.

Fig. 7 shows the performance of the mean and median predictors as applied to the noise peaks of the bandpassed signal. The iterative predictor is not shown because its mean square prediction error is generally much larger than

Noise Peak Predictor Comparison

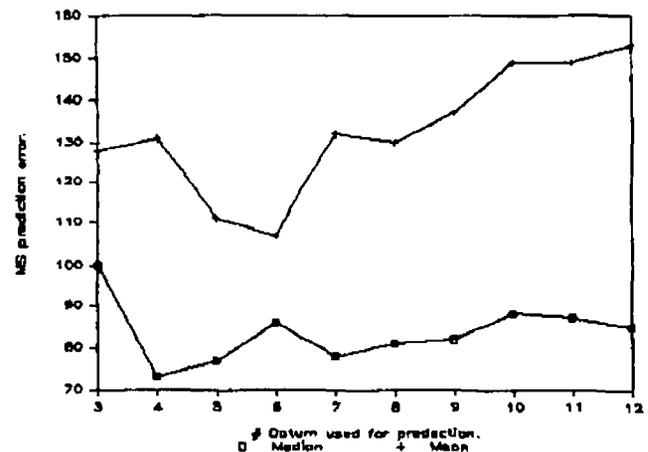


Fig. 7. Mean square prediction error for the mean and median noise peak estimators applied to the time-averaged signal. Most trials of the iterative estimator had too large an error to plot on this scale.

the other two for the range of coefficient values that we tested. For example, with a coefficient of 0.5044, the iterative predictor produced a mean square prediction error of 3116. However, a coefficient of 0.9 reduced the error to only 93.

As with the QRS peaks, the median predictor appears to be the best predictor of noise peaks, producing a minimal mean square error using only four data points. However, it is possible that iterative predictors with coefficients higher than 0.9 could do better.

Peak Estimator Performance

For our application, the ultimate performance measure of a peak estimator is its effect on QRS detection. One estimator may yield a consistently low peak prediction, and another with a better mean square error might give inconsistent predictions. The consistent predictor is preferable because it will produce fewer false positive and

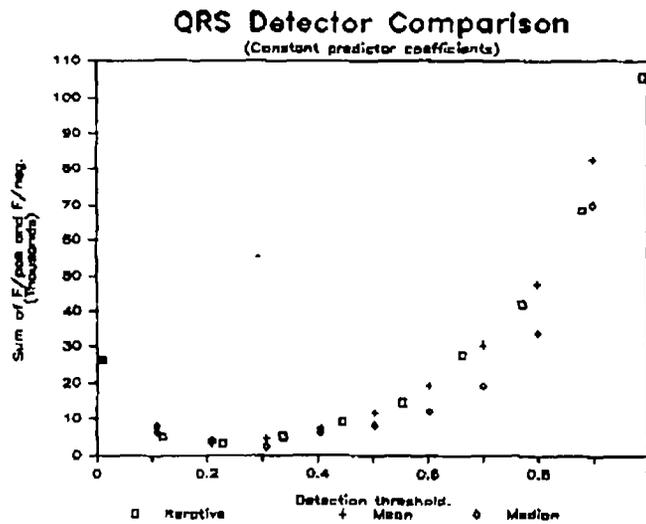


Fig. 8. False detections as a function of detection threshold level for QRS detectors based on mean, median, and iterative estimators.

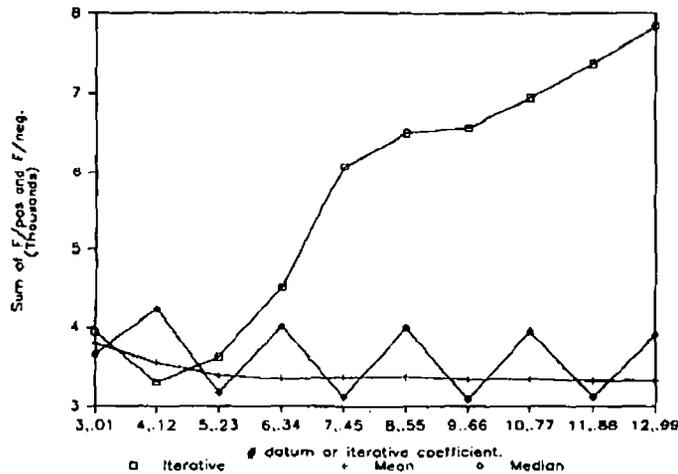


Fig. 9. False detections for QRS detectors as a function of parameter changes of the mean, median, and iterative predictors. The mean and median predictors are plotted as a function of the number of data points in the calculation. The iterative predictor coefficients are shown.

false negative detections if the proper relative detection threshold is used.

We tested a simple QRS detector to compare peak level estimator performance. We set the detection threshold to be a percentage of the QRS peak level estimate.

$$\text{Detection threshold} = B \times \text{Peak level estimate.}$$

The detection threshold coefficient B is set to values between zero and one. Any peaks larger than the detection threshold are classified as QRS complexes and are used to update the detection threshold. Noise peaks are ignored.

We performed trials with mean, median, and iterative peak level estimators. For the mean and median estimators, we varied both the detection threshold coefficient B and also the number of data points used for estimation. For the iterative estimator, we varied both the iterative coefficient and also the detection threshold, each throughout the range from 0.01 to 0.99. In our initial trials

of the mean and the median estimators, we used ten different groups of 3-12 data points. We applied ten detection threshold coefficient levels ranging from 0.01 to 0.9 for a total of 100 trials. We did a second set of trials using thresholds approximately equal to those that performed best in these first trials.

Fig. 8 shows the general performance of the three QRS detectors as a function of the detection threshold level. For each estimator, the sum of the false negative and false positive detections is plotted as a function of the detection threshold. The median estimator provided the minimal number of false detections and fewer false detections than the others for most of the detection threshold range. In general, all the QRS detectors work best with detection threshold coefficients between 0.15 and 0.4.

Fig. 9 illustrates the performance of the three QRS detectors tested with similar detection threshold coefficients. The QRS detectors with the mean and median peak

200 ms Blanking Performance Comparison

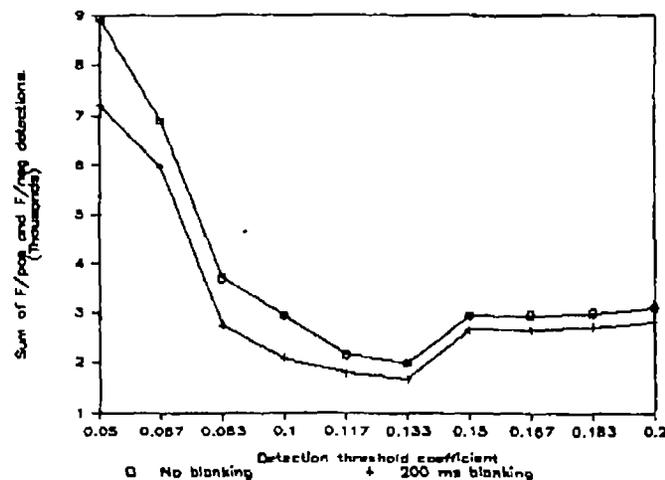


Fig. 10. Influence of blanking on false detections for a QRS detector with a median peak level estimator.

level estimators have detection threshold coefficients of 0.208. The QRS detector with the iterative estimator has a detection threshold of 0.228. The iterative estimator works best with an iterative coefficient of 0.119, and its performance deteriorates for larger iterative coefficients. The performance of the mean estimator improves slightly as more data points are used for estimation. The median estimator oscillates with odd and even numbers of data points used in the median, but tends to improve with larger numbers of data points. This oscillation probably results because we chose the lower of the middle two numbers to be the median for an even number of data points. Thus, statistically, the median of an even number of data points produces a lower estimate than the median of an odd number of points. With a detection coefficient of 0.208, the median estimators using an odd number of data points perform better than those using an even number. For a detection coefficient of 0.307, the performance switches, such that the even-median estimators are better.

We performed a second set of trials to determine the number of data points and coefficients for each estimator that produce the fewest number of false detections. The iterative estimator has a minimum of 2564 false detections when using an estimator coefficient of 0.043 with a detection threshold coefficient of 0.211. The mean estimator has a minimum of 3147 false detections using 15 data points in the mean and a detection threshold coefficient of 0.167. Although it is possible that using more than 15 points for the mean would improve performance, we did not test this possibility. The median estimator produces the minimal number of false detections of the three techniques with 2088 false detections for a median of 12 data points and a detection threshold coefficient of 0.283.

The median estimator performs better than either the mean or iterative estimator as a predictor of peak levels for both QRS and noise and as a peak level estimator for QRS detection. Therefore, we used the median estimator in all the following QRS detector trials.

DETECTION THRESHOLD

In our tests of peak level estimators, we used a simple detection threshold scheme which relied only on the QRS peak level estimate. Both QRS peak and noise peak level estimates may be used to determine the detection threshold. The threshold equation

$$DT = NPL + TC \times (NPL - QRSPL) \quad (1)$$

has been used [3] where DT is the detection threshold, NPL is the noise peak level, TC is the threshold coefficient, and $QRSPL$ is the QRS peak level. We tested this method for calculating detection thresholds with median peak level estimators. Prediction performance of the median estimator for noise and QRS peaks was similar, so we used the same number of data points for calculating both.

We performed trials with peak estimators using from 3 to 12 previous-peak data points and detection threshold coefficients from 0.01 to 0.9. A QRS detector with a 10 data-point median and a detection threshold of 0.133 gave the minimal number of 1974 false detections.

Some improvement can be obtained by including a noise peak estimate in calculation of detection threshold, but the median estimator must be adjusted or only very slight improvement is made in the overall QRS detection. The adjustment to the estimator is probably a compromise between the optimal number of data points for noise peak estimation and the optimal number needed for QRS peak estimation. Ideally, different estimators might be used for noise and QRS peaks. For simplicity, in the following QRS detection trials, we used the same estimator for noise and QRS estimation.

REFRACTORY BLANKING

After a QRS complex occurs, there is a physiological refractory period of about 200 ms before another can occur. Fig. 10 shows that the performance of a QRS detector with median peak level estimation and a threshold be-

RR Predictor Comparison

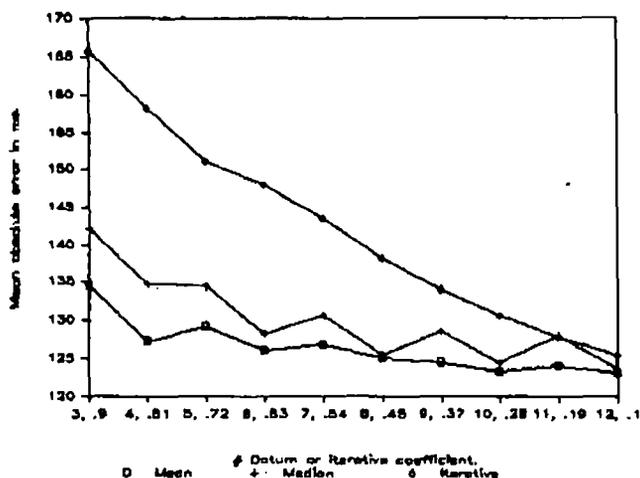


Fig. 11. Performance of RR interval predictors based on mean, median, and iterative estimators.

tween the noise and peak estimate is improved for all threshold levels when 200 ms blanking is used. A minimal number of false detections of 1622 was obtained with an eight-point median and a threshold coefficient of 0.133.

SEARCH BACK

Optimization of the search back feature requires analysis of RR interval prediction and the relative levels of the normal and search back detection thresholds.

RR Interval Prediction

As with the peak level estimator, we examined mean, median, and iterative prediction of the RR interval. Fig. 11 shows the relative performance of the three methods. The mean absolute prediction errors of the three RR predictors are plotted as functions of the number of data points or the iterative coefficient used for prediction. For all values, the mean predictor has a smaller prediction error than either the median or iterative predictor, but the performance of all the predictors is comparable for large numbers of data points and small iterative coefficients.

Chernoff *et al.* [8] examined the mean predictor and the iterative predictor in the context of beat classification. They tested mean (or moving average) predictors on the MIT/BIH database with 1-6 data points used for prediction calculation. They tested iterative predictors with coefficients of 0.1, 0.3, and 0.5. They concluded that the iterative method performs better than the mean method of RR interval prediction. These results agree with ours, but do not go far enough toward our conclusion that the mean predictor performs better than the iterative when more than six data points are used.

The median and mean predictors perform comparably when using eight data points in the median. Thus, we used the median predictor with eight data points in subsequent search back testing.

Search Back Detection Threshold

We examined the effect of relative normal and search back thresholds on QRS detection. The QRS detector used eight-point median peak level estimators, a detection threshold calculated according to (1), a 200 ms refractory period, and a median RR interval predictor. If no QRS complex was detected within 150 percent of the latest RR interval, then we applied the search back detection threshold to the peaks previously classified as noise in that range.

We tried two methods of calculating the search back threshold. One method used a new threshold coefficient. The other calculated the search back threshold as a percentage of the normal detection threshold. For the first method we did trials with ten values for the normal threshold coefficient from 0.1 to 0.5. We tested ten levels of search back detection coefficients from 0.01 to 0.1 for each normal threshold coefficient. With the second method we used the same normal coefficients but varied search back thresholds from 0.05 to 0.5 times the normal threshold.

Both methods of calculating the search back detection threshold yielded a minimum of 1422 false detections. The first method produced the minimum with a normal threshold coefficient of 0.189 and a search back detection threshold coefficient of 0.02. The second method produced the minimum with the same normal threshold and a search back threshold 0.3 times the normal.

DISCUSSION

More complete algorithm testing can be done with more information from the preprocessor stage. Practical constraints limited us to the recording of levels and arrival times of peaks from the time-averaged signal. More complete testing would include all factors used by the Assembly language algorithm decision rule, peak values of the bandpassed signal, and maximal derivative values as well as the peak values of the time-averaged signal and fiducial point arrival times. Experiments could show whether or not performance can be improved by using peak data from the bandpassed signal.

Fig. 12 summarizes the quantitative effect of different decision rule components on QRS detection. The total false detections are shown for the optimal performance of different stages of QRS detector development. Of greatest importance is the selection of a peak level estimator. Including the noise peak estimate in the calculation of the detection threshold results in only a small performance improvement. The addition of 200 ms of refractory blanking contributes more to the algorithm's performance than the introduction of search back. The effects of the different sections on performance are probably not independent. We suspect that details of the algorithm such as search back may be able to compensate for suboptimal performance of other algorithm factors. It is even possible that poorer estimators might yield better detector performance when other algorithm improvements are added.

QRS Detector Performance

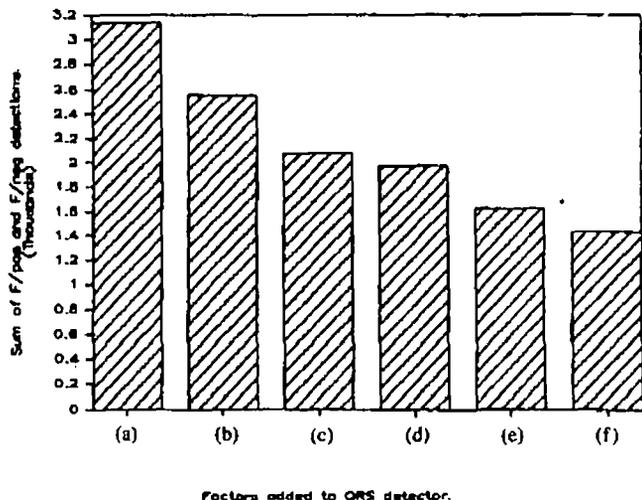


Fig. 12. Influence of processing techniques on performance of the QRS detector. (a) Iterative peak level estimator. (b) Mean peak level estimator. (c) Median peak level estimator. (d) Detection threshold that includes the noise peak estimate. (e) 200 ms refractory blanking. (f) Search back.

Further tests could establish the relative independence of different algorithm components.

REAL-TIME IMPLEMENTATION

We implemented the final optimized QRS detection algorithm in real time with the C language. The decision rule section uses an eight-point median peak level estimator, a detection threshold coefficient of 0.1825, a search back threshold of half the normal threshold, an eight-point median RR interval estimator, and a 200 ms refractory blanking period. Although the best detector tested had a normal threshold coefficient of 0.189, not 0.1825, and a search back threshold 30 percent of the normal detection threshold rather than 50 percent, we chose coefficients for this real-time implementation that are easily calculated with power-of-two arithmetic. We also added to the real-time implementation the maximal derivative for T-wave discrimination. The T-wave discriminator rejects any detections between 200 and 360 ms following a QRS detection, unless the complex has a maximal derivative in its unfiltered ECG greater than half that of the previous QRS.

QRS DETECTOR PERFORMANCE

Table I lists the tape-by-tape performance of the new QRS detector on the MIT/BIH database. The detector produces 340 false negative detections and 248 false positive detections for a sensitivity of 99.69 percent and a positive predictivity of 99.77 percent. This excludes episodes of ventricular flutter that occur on tape 207.

SUMMARY

We used the MIT/BIH arrhythmia database to quantitatively examine relative importance of commonly used QRS detection decision rules. We concluded that the QRS

TABLE I
RESULTS OF REAL-TIME EVALUATION WITH QDES SYSTEM

Tape (#)	Total (beats)	FP	FN	Failed detection (FP + FN)	Failed detection (FP + FN)/Total
100	2267	2	0	2	0.09
101	1859	3	1	4	0.22
102	2181	0	0	0	0.00
103	2081	0	1	1	0.05
104	2224	3	7	10	0.45
105	2564	53	22	75	2.95
106	2024	1	2	3	0.15
107	2131	0	3	3	0.14
108	1757	50	47	97	5.67
109	2526	0	1	1	0.04
111	2120	3	2	5	0.24
112	2536	0	0	0	0.00
113	1791	2	1	3	0.17
114	1872	5	7	12	0.64
115	1945	0	0	0	0.00
116	2409	4	25	29	1.22
117	1532	10	3	13	0.85
118	2273	2	2	4	0.18
119	1985	2	0	2	0.10
121	1858	1	0	1	0.05
122	2471	0	0	0	0.00
123	1514	0	0	0	0.00
124	1613	0	0	0	0.00
200	2595	3	2	5	0.19
201	1946	3	19	22	1.14
202	2134	0	3	3	0.14
203	2976	14	61	75	2.57
205	2650	1	4	5	0.19
207*	1856	5	5	10	0.54
208	2953	9	19	28	0.95
209	2999	2	2	4	0.13
210	2645	2	41	43	1.65
212	2746	0	0	0	0.00
213	3245	0	1	1	0.03
214	2235	2	6	8	0.37
215	3357	0	0	0	0.00
217	2202	2	4	6	0.27
219	2150	1	1	2	0.09
220	2041	0	0	0	0.00
221	2422	1	1	2	0.08
222	2492	40	37	77	3.14
223	2603	0	2	2	0.08
228	2048	19	6	25	1.22
230	2252	0	1	1	0.04
231	1566	0	0	0	0.00
232	1719	0	0	0	0.00
233	3135	0	3	3	0.10
234	2747	0	0	0	0.00
TOTALS:	109267	248	340	588	0.54

* Episodes of ventricular flutter excluded from counts.

peak estimation component of the QRS detector is of primary importance, with a median estimator performing better than either iterative or mean peak estimators. Based on the experimental studies, we developed a real-time QRS detection algorithm in the C language from the optimized set of decision rules together with added T-wave discrimination. The QRS detection algorithm uses integer arithmetic, making it particularly suitable for real-time implementation. The algorithm's performance is comparable to other algorithms evaluated with the MIT/BIH database. Extensive clinical testing would be required of all available algorithms to differentiate significant performance differences between this one and others.

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[8] D. Chernoff, T. Lee, G. Moody, and R. Mark, "Evaluation of *R-R* interval predictors using an annotated ECG database." *Comput. Cardiol.*, pp. 359-362, 1981.

William J. Tompkins (S'61-M'66-SM'77), for a photograph and biography see this issue p. 1140.



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Preventive 510(k)

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Appendix 2: Draft Labeling - Overview and Labels

Preventice BodyGuardian System

Device Labeling

April 15, 2012



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Introduction

This document provides a single reference point for all the labeling that is a part of the Preventice BodyGuardian system. It includes all the labels that are on the components (physical labels), documents seen by the patients using BodyGuardian and the healthcare provider who prescribe BodyGuardian, manage patients using BodyGuardian, and assess the data collected by BodyGuardian.

Most of the documents referenced herein are Attachments to this document. Those attachment references correlate to file names on the softcopy submission. For example, a reference to *Attachment A. BodyGuardian Instructions for Use* resolves to a file with the name '**Attachment A BodyGuardian Instructions for Use**'



Packaging

Figure 1 shows the assembly of the BodyGuardian kit package.



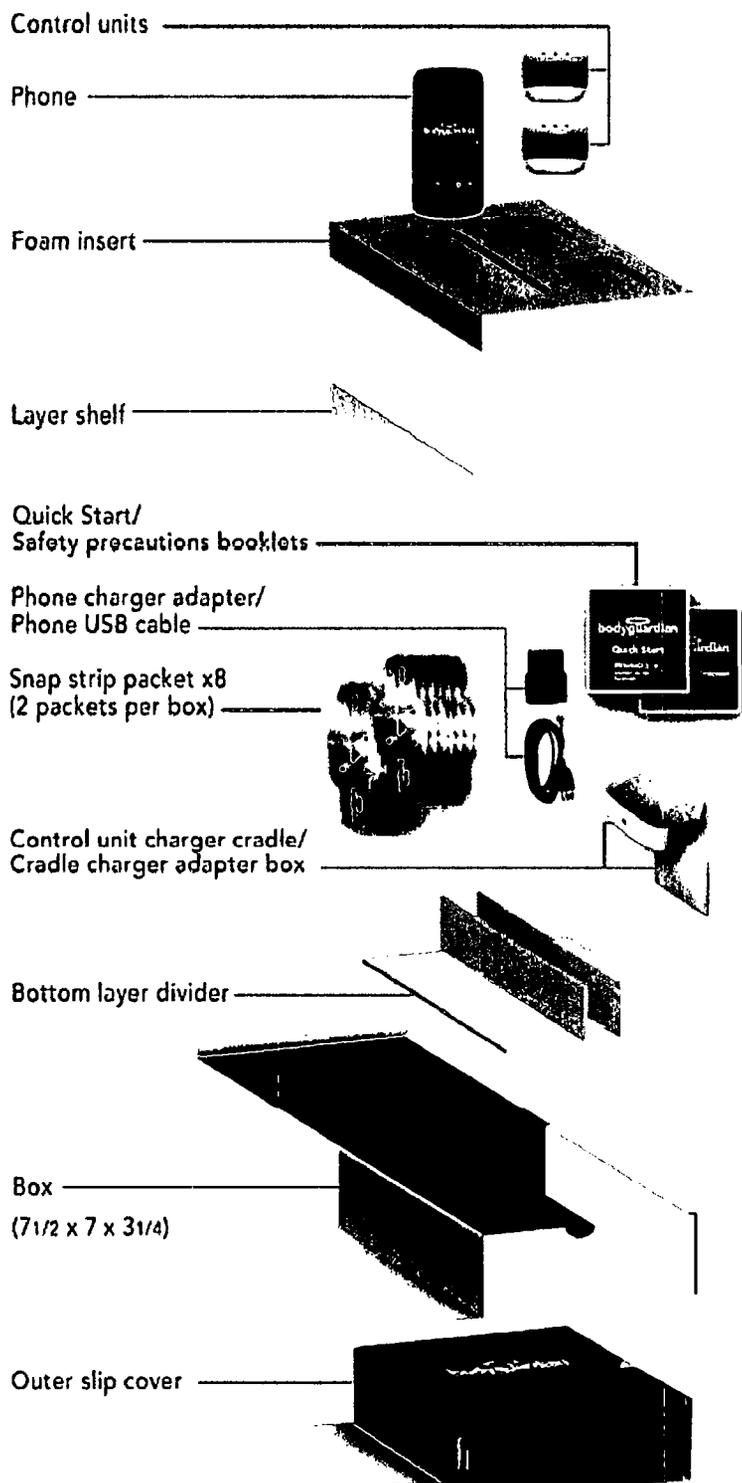


Figure 1 BodyGuardian Kit Pack Out



BodyGuardian Kit

The health care provider gives a BodyGuardian System Kit to each patient prescribed a BodyGuardian System. Each kit contains

- Two BodyGuardian Control Units (Figure 5 on p. 10)
- A box containing (see *BodyGuardian Charging Cradle and Adapter Packaging* on p. 7) :
 - One BodyGuardian Charging Cradle (Figure 6 on p. 10)
 - One BodyGuardian Charger Adapter (Figure 7 on p. 10) and power cord
- One BodyGuardian Connect Smartphone (Figure 8 on p. 11)
- One BodyGuardian Connect Smartphone Charger (Figure 9 on p. 12) and cord
- One package of BodyGuardian SnapStrips (*BodyGuardian SnapStrip Labeling* on p. 12)
- One *BodyGuardian Instructions for Use* (p. 14)

BodyGuardian Charging Cradle and Adapter Packaging

The BodyGuardian Charging Adapter and cord are in a box placed in the BodyGuardian Kit Package.

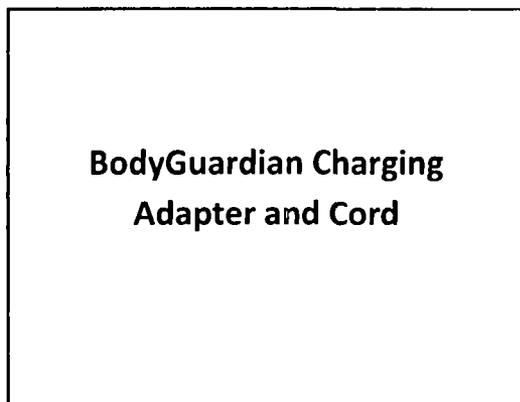


Figure 2 Box Containing BodyGuardian Charger



BodyGuardian SnapStrips Packaging

SnapStrips are packaged in a re-sealable plastic pouch. The package has the following printed on it:

SnapStrip

This package includes:

8 Disposable Single-Use Self-Adhering Hydrogel Electrodes.

For single patient use only.

Storage: Reseal the pouch after opening and removing a SnapStrip. See Instructions for Use for detailed skin preparation, application and removal.

Limit of Application: Change the SnapStrip once daily or when it loses its adhesive quality.

CAUTIONS:

- CAUTION: Federal law (USA) restricts the device to sale by or on the order of a licensed practitioner or therapist.
- Should only be used by or in consultation with a healthcare provider familiar with their proper placement and use;
- May damage the skin if removed carelessly;
- Should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas).

Precautions:

The Snap Strip should be replaced if it no longer sticks firmly to the skin.

Lot Number: _____

Use before date: __/__/__

Made in USA

Rev. _____

Figure 3 Labeling on SnapStrip Package

Sufficient SnapStrips for the prescription are included in the Kit box. If additional SnapStrips are required for the patient (for example, if their prescription is extended), additional packages are sent to the patient. When additional SnapStrips are required (for example, when a prescription is extended), additional packages are sent. See *SnapStrip Instructions for Use* on p. 14.



Physical Labels

There are labels on the individual components of BodyGuardian.

Label on the Bottom of the BodyGuardian Control Unit

Symbols and text are imprinted on the bottom of the BG Control Unit. See Figure 4. The *Instructions for Use* on p. 14 defines these symbols for the patient.

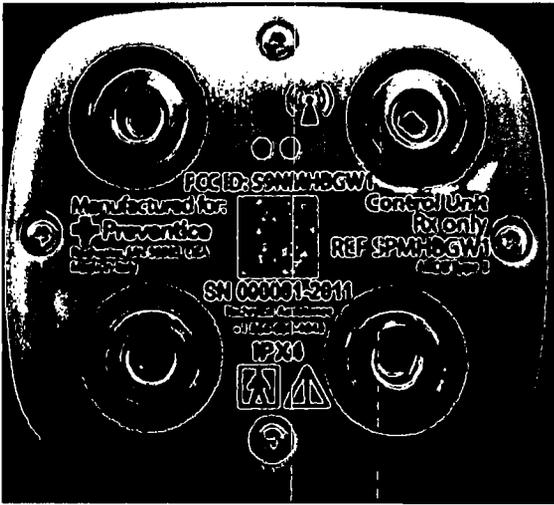


Figure 4 BG CU Label - Bottom

Labeling on the Top of the BG Control Unit

Symbols and text are imprinted on the top of the BG Control Unit. See Figure 5. The *Instructions for Use* on p. 14 defines these symbols for the patient.

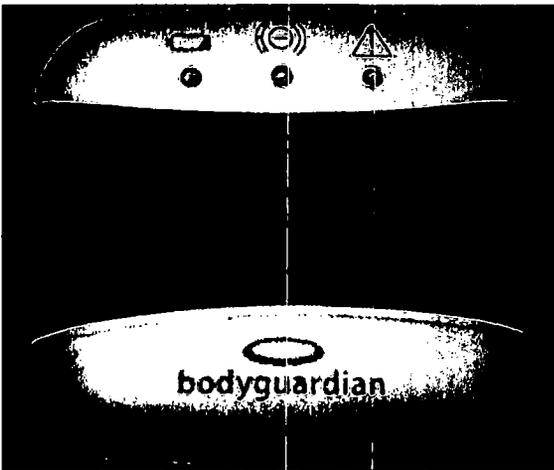


Figure 5 BG CU Label - Top

Label on Bottom of the BodyGuardian Charger Cradle

Symbols and text are imprinted on the top of the BG Control Unit. See Figure 6. The *Instructions for Use* on p. 14 defines these symbols for the patient.

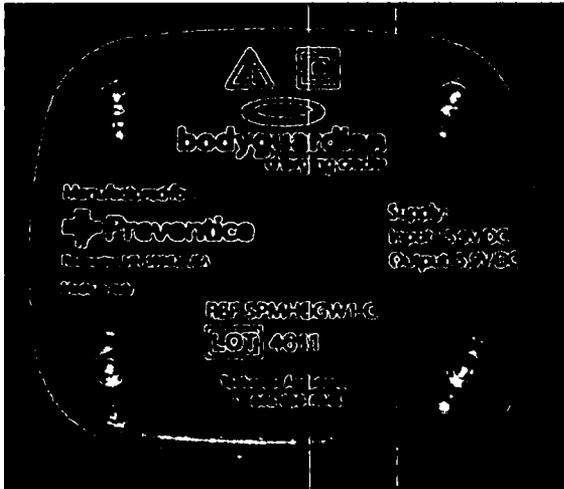


Figure 6 BG CU Charger

Label on BodyGuardian Charger Adapter

Figure 7 shows the labeling on the top of the adapter used for the BodyGuardian Charging Cradle. Symbols and text are imprinted on the top of the adapter. The *Instructions for Use* on p. 14 defines these symbols for the patient.



Figure 7 BodyGuardian Charger Adapter

Label on Inside of the Lid of the Kit Box

A Serial Number imprinted on the bottom of the Control Unit (see Figure 4 on p. 9) identifies each BodyGuardian Control Unit. Preventice provides a label that associates the correct Device Pairing ID (used for associating the Control Unit with



the BodyGuardian Connect Smartphone) and a Media Access Control address (identifies the Control Unit to the PatientCare software on the Preventice computer servers). The integration vendor places a label for each Control Unit on the inside of the lid of the kit box.

Table 1 In-Kit Label for BodyGuardian Control Units

Customer Identifier	
BodyGuardian Control Unit Serial Number	123456-1234
Media Access Control Address (MAC)	00:80:E1:FC:nn:nn
Device Pairing ID	xxxx

Label on BodyGuardian Connect Smartphone

There is no labeling on the Smartphone. Figure 8 shows the back and front views of the Smartphone. Note that the screen on the Smartphone shows the BodyGuardian application initial screen (



Figure 8 BodyGuardian Connect Smartphone

Label on BodyGuardian Connect Smartphone Charger

Figure 9 shows the labeling on the Smartphone Charger. This charger is in the kit box (Figure 1 on p. 6).



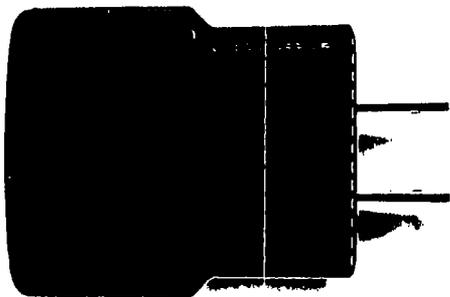


Figure 9 Smartphone Charger

BodyGuardian SnapStrip Labeling

Positioning information is imprinted on the BodyGuardian SnapStrips that attach the BG Control Unit to the patient's skin. See Figure 10.

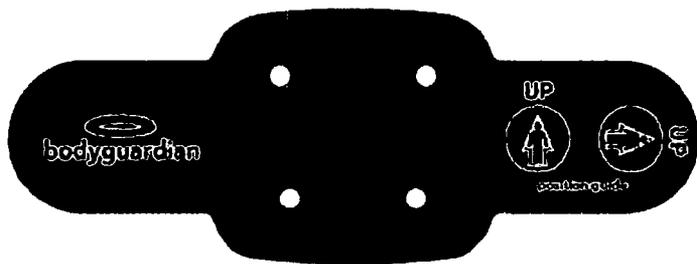


Figure 10 BodyGuardian SnapStrip Labeling



Documents and Screens

Seven documents are a part of the BodyGuardian System. In addition, some instructions are a part of the BodyGuardian Application on the BodyGuardian Connect Smartphone. Only the *BodyGuardian Instructions for Use* is in printed form; all other documents are available from the Preventice Help and Support web site as downloadable PDF files.

Table 2 Documentation Table

Attach-ment	Item	Audience	Format	Distribution
A	<i>BodyGuardian Instructions for Use</i>	Patient	Paper booklet	Printed in BodyGuardian Kit
N/A	<i>BodyGuardian Connect Smartphone screens</i>	Patient	Loaded on the Smartphone	Part of the BodyGuardian Connect Application on the Smartphone
B	<i>BodyGuardian General Information</i>	Health Care Providers	Electronic PDF document	Online: PatientCare Help and Support page (must log in)
C	<i>PatientCare Administrator's Guide</i>	Institution Administrator	Electronic PDF document	Online: PatientCare Help and Support page (must log in)
D	<i>PatientCare Managing Patients</i>	Physician Assistant/Managing Physician	Electronic PDF document	Online: PatientCare Help and Support page (must log in)
E	<i>PatientCare Viewing Patient Data</i>	Physicians, Physician Assistant, ECG Technician	Electronic PDF document	Online: PatientCare Help and Support page (must log in)

The following sections separate those documents into those used by patients and those intended for healthcare providers. There is also one set of screens used internally by Preventice to create profiles for licensed institutions.

Used by Patients

As a part of the BodyGuardian Kit, the patient is provided with a *BodyGuardian Instructions for Use* document. In addition, application (from the BodyGuardian Connect application) screens loaded on the Smartphone direct the user is setting up their BodyGuardian, including attaching the BG CU to a SnapStrip and placing the SnapStrip on their chest.



Instructions for Use

The *BodyGuardian Instructions for Use* is in the kit box with the BodyGuardian Control Units and the BodyGuardian Connect Smartphone. This printed document tells the patient how to use the BodyGuardian and is in booklet (5"x7") format. Some instructions are on-screen displays on the BodyGuardian Connect Smartphone and are referenced from the *Instructions for Use* (see SnapStrip Instructions for Use

Sufficient SnapStrips for the original prescription are provided in the Kit box. However, if the physician extends the prescription, additional SnapStrips are sent to the patient separately. The SnapStrips are packaged in a re-sealable plastic pouch (see *BodyGuardian SnapStrips Packaging* on p.8). The *Instructions for Use* tells the patient to press a control on the phone, which takes them to screen 3 (see Figure 11 on p. 17) to guide them through using the new SnapStrip.

BodyGuardian Connect Smartphone Instruction Screens on p. 14). The *BodyGuardian Instructions for Use* lists the Warnings, Cautions and Precautions for the BodyGuardian Device and explains the icons and symbols that are on the BodyGuardian Control Unit and charger. The *BodyGuardian Instructions for Use* is Attachment A.

SnapStrip Instructions for Use

Sufficient SnapStrips for the original prescription are provided in the Kit box. However, if the physician extends the prescription, additional SnapStrips are sent to the patient separately. The SnapStrips are packaged in a re-sealable plastic pouch (see *BodyGuardian SnapStrips Packaging* on p.8). The *Instructions for Use* tells the patient to press a control on the phone, which takes them to screen 3 (see Figure 11 on p. 17) to guide them through using the new SnapStrip.

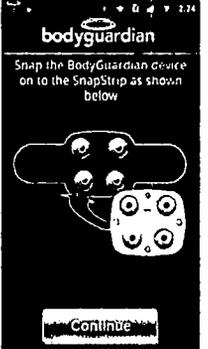
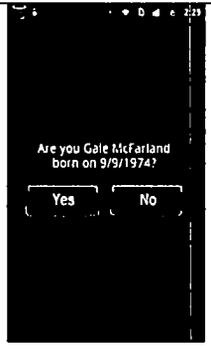
BodyGuardian Connect Smartphone Instruction Screens

The BodyGuardian Connect Smartphone provides instructional screens to assist the user in:

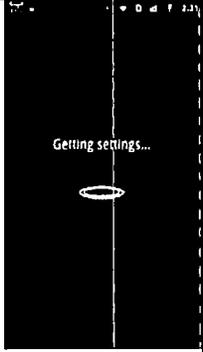
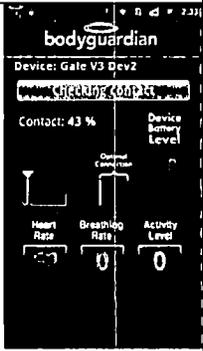
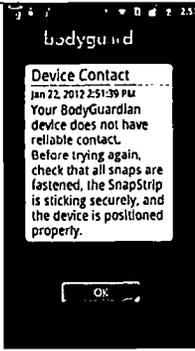
- Attaching the BodyGuardian Control Unit to the BodyGuardian SnapStrip
- Determining where to wear the BodyGuardian
- Attaching the BodyGuardian to the skin
- Connecting with the BodyGuardian Connect Smartphone

Figure 11 on p. 17 shows the screens seen by the patient during initial startup (the first time the patient uses BodyGuardian.) Some screens show only if there is a problem, including some seen only when directed by Preventice Support. During normal operation, the patient sees the Status screen (screen 23). Note that the text shown with the screens in Figure 11 is not part of the screen interface; it is here for reference purposes only.



<p>1 Logo Screen. No action</p>		<p>2 Instructions only. Patient taps continue</p>		<p>3 Instructions only. Patient taps continue</p>	
<p>4 Instructions only. Patient taps continue</p>		<p>5 Instructions only. Patient taps continue</p>		<p>6 Instructions only. Patient taps continue</p>	
<p>7 Patient turns on BG Control Unit and taps continue</p>		<p>8 Progress screen. No action</p>		<p>9 Only seen if no BG Control Units are found. Make sure Control Unit is turned on and tap okay</p>	
<p>10 Found device, getting data. Progress only. No action</p>		<p>11 Confirm identity. Tap Yes or No</p>		<p>12 Problem connecting to Preventice server. OK takes back to identity screen (11)</p>	



<p>13</p> <p>Identity confirmed. Progress screen, no action. Thresholds being loaded.</p>		<p>14</p> <p>Initial screen once thresholds loaded to Control Unit. No action.</p>		<p>15</p> <p>Checking the reliability of the Control Unit electrodes' contact with the patient's skin. No action.</p>	
<p>16</p> <p>Continue contact check, no action.</p>		<p>17</p> <p>Continue contact check, no action.</p>		<p>18</p> <p>Cannot establish reliable contact with the skin. Follow instructions, tap OK.</p>	
<p>19</p> <p>Retrying checking contact. No action.</p>		<p>20</p> <p>checking contact. No action.</p>		<p>21</p> <p>Checking contact. No action.</p>	



<p>22</p> <p>Contact established. Starting monitoring.</p> <p>No action.</p>		<p>23</p> <p>Monitoring. No action but can tap Refresh to updated status (Heart Rate, Breathing Rate, Activity Level)</p>		<p>24</p> <p>Only seen when directed by Preventice support to unlock the phone to access phone settings.</p>	
<p>25</p> <p>When support directed actions complete, this returns to BG app.</p>					

Figure 11 BodyGuardian Connect Smartphone Screens Seen by Patient

Used by Providers

Several documents are for the healthcare providers who prescribe and support BodyGuardian. With the exception of the *General Information* manual, each document supports a specific set of tasks. Those task sets and the intended users are:

- Managing healthcare providers and provider licenses: Institution Administrator
- Managing patient profiles and licenses: Physician Assistant and Managing Physician
- Viewing patient data: Physicians, ECG Technicians and Physician Assistants

These documents contain the screens (either for the PatientCare Web Portal of the PatientCare for iPad application) used by the Health Care providers to manage patients and providers and to view the patient medial data.



BodyGuardian General Information Manual

The *BodyGuardian General Information* manual contains an overview of the BodyGuardian System and is for the healthcare providers. It also contains the technical specification for the BodyGuardian Control Unit and charger. It is available only on the Preventice Help and Support site as a PDF (Portable Document Format) file. All registered providers have access to this site.

The *BodyGuardian General Information* manual is Attachment B.

PatientCare Administrator's Guide

The *PatientCare Administrator's Guide* is used by the person(s) designated by their institution as being the administrator for PatientCare. This person creates the profiles for healthcare providers who will use the system and manages provider license assignments for BodyGuardian. The institution administrator has no authorization to view patient data or patient profiles. It is available only on the Preventice Help and Support site as a PDF (Portable Document Format) file. All registered providers have access to this site.

The *PatientCare Administrator's Guide* is Attachment C.

When the Institution Administrator creates a provider profile, that provider receives an email from Preventice. Within the email is an encrypted link to the Preventice site. The provider takes that link to a) accept the end user license agreement, b) set the password for their user profile and c) verify the contents of their user profile.

Figure 12 shows the screens the provider goes through when verifying their provider profile. The text accompanying the screens is for reference purposes only.



<p>1</p> <p>Email sent to provider when profile created</p>	<p>Preventice +</p> <p>-----</p> <p>Congratulations, Gerald Barry!</p> <p>Your institution's administrator requested a HealthGuardian account for you to access HealthGuardian PatientCare on the web and your iPad.</p> <p>The User Name already created for you is GEBTest.</p> <p>To complete the registration process and begin using PatientCare, simply click on the link below to validate your profile.</p> <p style="text-align: center;"><u>Click here to validate your profile!</u></p> <p>If you are not able to successfully click on the link directly from this e-mail message, cut and paste the following URL into the address field of your Firefox or Internet Explorer browser: http://bpfda.gov/id-62.boosti.com/modules/open/provideractivate.aspx?u=GEBTest&h=aa6fad24ef86d4384a475d245c871e92</p>
<p>2</p> <p>End User License Agreement seen when following the link in 1</p>	 <p>Preventice Home</p> <p>ACCOUNT VALIDATION</p> <p>Preventice End User License Agreement</p> <p><u>Preventice End User License Agreement</u></p> <p>Please read the following Preventice End User License Agreement ("Agreement") carefully before continuing. This is a legal contract between Preventice, Inc. ("Preventice") and you ("you" or "User"). Preventice is willing to license the software provided to you, whether by download, via the Internet, as part of a device or piece of equipment, or on software media, including all databases, data, and documentation contained therein or provided therewith (the "Software") to you only upon the condition that you accept all of the terms and conditions contained in this Agreement. By clicking on the "Accept" button, or otherwise accessing or using Software, you accept all of the terms and conditions of this Agreement and agree to be bound by its terms. If you do not accept the terms of this Agreement, you are not permitted to use the Software. Please click the "Cancel" button and do not download, access or use the Software. By downloading, accessing or using the Software, you agree with Preventice to be bound by this Agreement. Preventice is willing to license the Software to you only upon the condition that you accept all of the terms contained in this Agreement.</p> <p>1. License. Preventice grants, and the User hereby accepts, a non-exclusive, nontransferable, revocable license to use the Software on the terms and conditions set forth in this Agreement. Except as provided in a separate, signed license agreement, the license granted in this Agreement is only for the personal use of individual healthcare providers or consumers. License agreements for all other professionals and organizations must be arranged through Preventice. Please contact us at (866) 830-4043 or e-mail us at support@preventice.com. You may not do any of the following yourself, or through any third party, and you may not permit any third party with whom you have a business or personal relationship to do any of the following: (A) copy the Software; (B) modify or create derivative works based upon the Software; (C) decompile, disassemble, or reverse engineer the Software in whole or in part; (D) defeat, disable, or circumvent any protection mechanism related to the Software; (E) sell, license,</p> <p style="text-align: center;">I Agree To These Terms</p>



<p>3</p> <p>Set and confirm a password</p>	 <p>Preventice Home</p> <p>ACCOUNT VALIDATION</p> <p>Provider Account Validation</p> <p>Welcome to HealthGuardian Provider Validation. Please submit the requested information to complete your validation.</p> <p>Choose password: <input type="text"/></p> <p>Retype Password: <input type="text"/></p> <p style="text-align: center;">Next</p> <p style="text-align: center; font-size: small;">Copyright © Preventice 2011 All Rights Reserved Contact Us Privacy Policy</p>												
<p>4</p> <p>Verify profile</p>	 <p>Preventice Home</p> <p>ACCOUNT VALIDATION</p> <p>Provider Account Validation</p> <p>Welcome to HealthGuardian Provider Validation. Please submit the requested information to complete your validation.</p> <p><i>* indicates required field</i></p> <table border="0"> <tr> <td>* First Name: <input type="text" value="Gerald"/></td> <td>* Last Name: <input type="text" value="Bary"/></td> </tr> <tr> <td>* Email Address: <input type="text" value="gebary@mchsi.com"/></td> <td>Gender: <input type="text" value="Select gender"/></td> </tr> <tr> <td>Address: <input type="text"/></td> <td>City: <input type="text"/></td> </tr> <tr> <td>State: <input type="text" value="Select state"/></td> <td>Postal Code: <input type="text"/></td> </tr> <tr> <td>Country: <input type="text" value="Select country"/></td> <td>Cell Phone: <input type="text"/></td> </tr> <tr> <td>Office Phone: <input type="text"/></td> <td></td> </tr> </table> <p style="text-align: center;">Back Next</p> <p style="text-align: center; font-size: small;">Copyright © Preventice 2011 All Rights Reserved Contact Us Privacy Policy</p>	* First Name: <input type="text" value="Gerald"/>	* Last Name: <input type="text" value="Bary"/>	* Email Address: <input type="text" value="gebary@mchsi.com"/>	Gender: <input type="text" value="Select gender"/>	Address: <input type="text"/>	City: <input type="text"/>	State: <input type="text" value="Select state"/>	Postal Code: <input type="text"/>	Country: <input type="text" value="Select country"/>	Cell Phone: <input type="text"/>	Office Phone: <input type="text"/>	
* First Name: <input type="text" value="Gerald"/>	* Last Name: <input type="text" value="Bary"/>												
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Address: <input type="text"/>	City: <input type="text"/>												
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Country: <input type="text" value="Select country"/>	Cell Phone: <input type="text"/>												
Office Phone: <input type="text"/>													



5 Review and Finish	 Preventice Home												
	ACCOUNT VALIDATION												
<h3 style="margin: 0;">Provider Account Validation</h3> <p style="font-size: small; margin: 5px 0;">Welcome to HealthGuardian Provider Validation. Please submit the requested information to complete your validation.</p> <h4 style="margin: 0;">Review</h4> <hr/> <p>Provider Profile</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; border-bottom: 1px solid black;">First Name: Gerald</td> <td style="width: 50%; border-bottom: 1px solid black;">Last Name: Barry</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Email Address: gebarry@mchsi.com</td> <td style="border-bottom: 1px solid black;">Gender:</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Address:</td> <td style="border-bottom: 1px solid black;">City:</td> </tr> <tr> <td style="border-bottom: 1px solid black;">State:</td> <td style="border-bottom: 1px solid black;">Postal Code:</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Country:</td> <td style="border-bottom: 1px solid black;">Cell Phone:</td> </tr> <tr> <td style="border-bottom: 1px solid black;">Office Phone:</td> <td></td> </tr> </table> <div style="text-align: center; margin-top: 10px;"> Back Finish </div>		First Name: Gerald	Last Name: Barry	Email Address: gebarry@mchsi.com	Gender:	Address:	City:	State:	Postal Code:	Country:	Cell Phone:	Office Phone:	
First Name: Gerald	Last Name: Barry												
Email Address: gebarry@mchsi.com	Gender:												
Address:	City:												
State:	Postal Code:												
Country:	Cell Phone:												
Office Phone:													
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Figure 12 Verifying Provider Profile

PatientCare Managing Patients Guide

Every institution using PatientCare must have at least one physician assistant or managing physician role defined. The institution administrator creates the profile for a physician assistant or managing physician, who manages those patients prescribed the BodyGuardian. The physician assistant or managing physician creates profiles for each patient that identifies the patient, the healthcare providers authorized to that patient, and the BodyGuardian Control Units assigned to the patient. Under the direction of a physician, the physician assistant can also set and change medical event thresholds. It is available only on the Preventice Help and Support site as a PDF (Portable Document Format) file. All registered providers have access to this site.

The *PatientCare Managing Patients Guide* is Attachment D.

PatientCare Viewing Patient Data

BodyGuardian collects medical data from patients and stores that data in a secure database. Healthcare providers access and view that data using standard web browsers (Internet Explorer 7 and 8 or Firefox Version 10) and accessing the PatientCare Web Portal or they use the PatientCare® for iPad® app to download and view the data. *Viewing Patient Data* provides instruction on using both the web version and the iPad application. It is available only on the Preventice Help and Support site as a PDF (Portable Document Format) file. All registered providers have access to this site.

The *PatientCare Viewing Patient Data Guide* is Attachment E.



Help and Support Web Site

Registered healthcare providers have access to the Preventice Help and Support site. The site has two pages; one is the support page that provides the phone numbers to call for support and to report an adverse event. The second page is the resources page, which contains links to the following PDF documents:

- *BodyGuardian General Information*
- *PatientCare Administrator's Guide*
- *PatientCare Managing Patients Guide*
- *PatientCare Viewing Patient Data*

Preventice Internal Use – Create Institution Administrator

When the institution contracts with Preventice for BodyGuardian, the institution identifies the person who is to be the administrator. Preventice creates a profile for that person and sends a validation email. Once the administrator accepts the license agreement and sets a password, they can sign on to PatientCare and create healthcare provider profiles. See Figure 13 for the screens used by Preventice to create the Institution Administrator profile. Healthcare providers or patients do not see these screens; they are for Preventice internal use only.

CREATE NEW INSTITUTION WIZARD [X]

Step 1 - Create Institution
* Indicates Required Field

* Institution Name:

* Address: * City:

* Country: * State/Province:

* Postal Code: * Phone Number:

Cancel Next

1



CREATE NEW INSTITUTION WIZARD
X

Step 2 - Assign Provider and Patient Licenses

** Indicates Required Field*

* Provider License:

* Patient License:

Back
Next

CREATE NEW INSTITUTION WIZARD
X

Step 3 - Create Institution Administrator

** Indicates Required Field*

* First Name:

* Last Name:

* Email:

* Phone Number:

Back
Finish

CREATE NEW INSTITUTION WIZARD
X

Review Institution Information

Institution Information

Institution Name: Male	City: Houston
Address: Douglas	State/Province: Texas
Country: dougskjervin@mayoclinic.com	Phone Number: 306-444-4000
Postal Code: 52369-9653	

License Information

Provider License: HG67889PO9090	Patient License: PT6785U99044
---------------------------------	-------------------------------

Institution Administrator

First Name: Jason	Last Name: Anderson
Email: jasonanderson@houstongeneral.com	Phone Number: (306) 444-4444

Back
Finish

Figure 13 Screens for Creating an Institution and Institution Administrators Profile



Re: [REDACTED] process [REDACTED]

Appendix 3: Draft Labeling - BodyGuardian Instructions for Use



Instructions for Use

Rochester, MN 55901
Corporate Office: 800 509 0503

BodyGuardian® (BG) is a remote cardiac monitoring system prescribed by your healthcare provider to assess your recorded ambulatory ECG data correlated with other physiological information (breathing rate, heart rate, and activity level). The BodyGuardian System includes the BodyGuardian Control Unit (BG CU), a cellular phone and adhesive electrode strips. The BG CU is a wearable device.

Note: BodyGuardian does not summon physicians or emergency assistance (911) and does not replace direct communication with your healthcare providers.

BodyGuardian Kit

Ensure the BodyGuardian kit contains (see Figure 1):

- A. BodyGuardian Control Unit (BG CU), two in the kit
- B. BodyGuardian Charger cradle and power adapter
- C. BodyGuardian Connect Smartphone (phone) and charger
- D. BodyGuardian SnapStrips (SnapStrip) for the length of your prescription

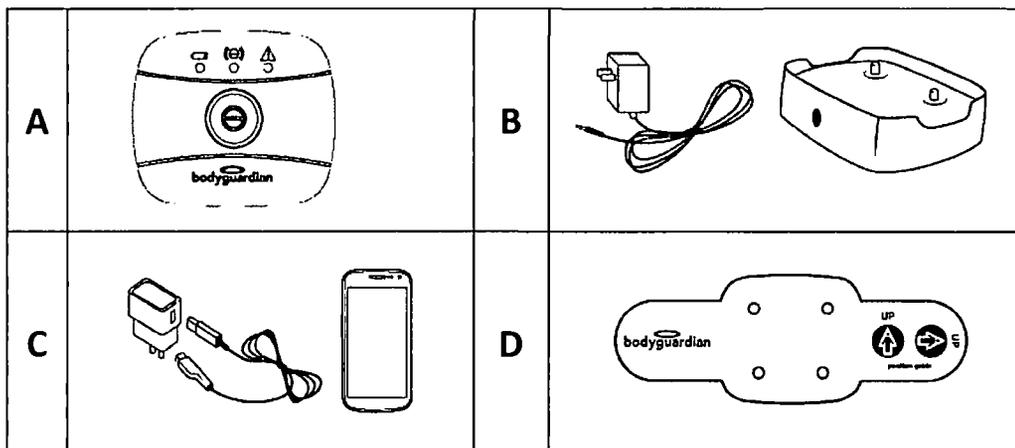


Figure 1 BodyGuardian Kit Contents

BodyGuardian® is a registered trademark of Preventice



BodyGuardian Control Unit

Figure 2 describes the indicator lights and the single button on the BG CU. During normal operation, the center light (green) is slowly flashing, indicating the BG CU is monitoring your heart.

1. Battery - Amber

- When BG CU is on charger, **on** when charging, **off** when fully charged
- When in use, normally **off**, **flashes slowly** when battery is low and needs charging. A message displays and an audible alarm sounds on the phone when the BG CU battery is low.

2. Monitoring – Green

Flashes slowly when the BG CU is monitoring your heart

3. Information – Amber

- When the light is **on**, a message may appear on the phone screen (some conditions are handled automatically).
- If there is a message on the phone, follow the directions in the message. If the light stays on, call Preventice Support at **866-830-4043**

4. Button in center

Power On/Off: Press and hold for 15-seconds

Symptom: Press and release



Figure 2 BG CU Lights and Button

BodyGuardian Connect Smartphone

Figure 3 shows the status bar on the phone at the top of the phone display. During normal operation, you need to make sure the battery is charged and a cellular signal is available.



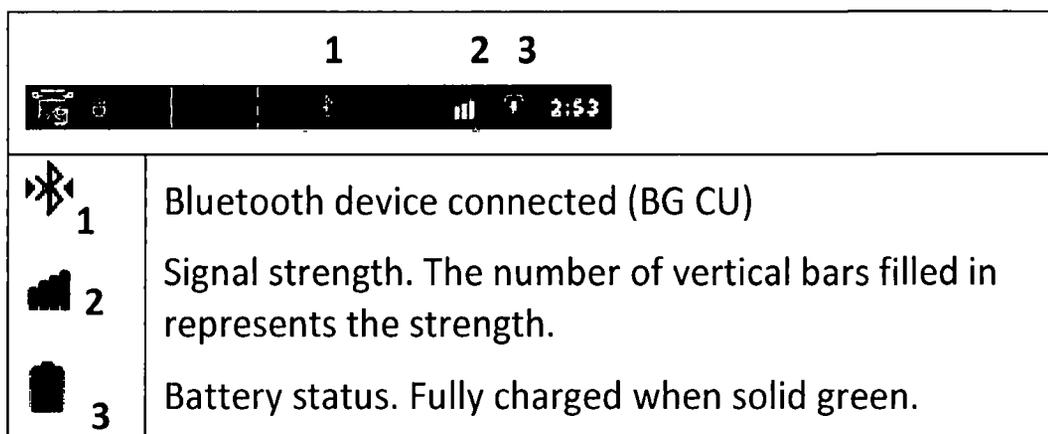
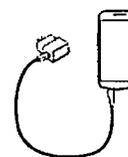


Figure 3 Phone Status Bar

Before Using BodyGuardian

When you receive your BodyGuardian:

1. Remove one BG CU, the BG charging cradle and adapter, the phone and the phone charger
2. Set up the BG Charger in a dry location.
3. Plug in the power adapter in to the cradle and a power outlet
4. Place the BG CU on the cradle (it fits in one way only)
5. Fully charge the BG CU (about 4-hours). All lights go out when charged.
6. Plug the phone charger in to the phone and a wall outlet.
7. The phone is charged when the battery indicator is completely green (about 4-hours)



Charge the phone every night. You can continue using BodyGuardian while the phone charges.

Android System Updates: Do **not** update the Android System if a message appears on the phone asking whether you want to. Tap the back key  to dismiss the message or tap **'Install Later'**.

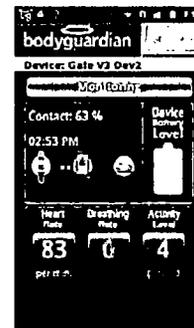


To Use BodyGuardian

Warning: Do not directly expose the BG CU to water. A damaged or cracked BG CU can short if water enters the unit; this can cause serious harm.

Caution: Do not use the BodyGuardian if you have broken, damaged or irritated skin on your chest where you place the device. Contact your healthcare provider for options.

1. Prepare your skin before you attach the BodyGuardian. Be sure skin is clean and dry with no lotions or oils. Shave chest hair regularly
2. Press the power button on the top right of the phone; touch the displayed padlock and move your finger to the right to unlock the phone. Wait for the phone to show “**Welcome to BodyGuardian**”.
3. Tap **Continue** and follow the directions on the phone.
4. The status screen shows your information and status of the BG CU (battery level and skin contact). The screen changes as it receives new information from the BG CU.
5. The status screen tells you when skin contact is poor or the BG CU battery is low. A message shows on the screen and an audible notification sounds. Follow the directions on the phone screen.
6. Keep the phone in the same room with you when wearing BodyGuardian.



If You Have Symptoms

Your healthcare provider has told you what symptoms to watch for. If you have any of those symptoms, briefly press the center button on the BG CU to record your current medical information.



If You Have Trouble

Contact your healthcare provider with any questions. Contact Preventice at **866-830-4043** if your BodyGuardian System is not operating properly or if you have any questions about using the system.

Removing BodyGuardian

Remove the BG CU from the SnapStrip.

1. Use finger pressure to hold the SnapStrip against your skin and gently lift a corner of the BG CU. Keep lifting the BG CU until all four snap connectors release.
2. Place the BG CU in the BodyGuardian charger.
3. Gently peel the edge of the SnapStrip away from the skin; roll the edge toward the other end of the SnapStrip. For fragile or sensitive skin, use a moist cloth or gauze to dampen the edge of the SnapStrip as it peels away from the skin.
4. Discard the SnapStrip.

Daily Maintenance

- Charge the BodyGuardian Connect Phone every night.
- You can change BG CUs without removing the SnapStrip from your body. Unsnap the BG CU and place it on the charger. Snap on the new BG CU and press and hold the power button. The Phone will find the new BG CU and continue monitoring.
- Replace the SnapStrip at least once a day. This is also a good time to replace the BG CU with a fully charged unit.

Note: For instructions on attaching a new SnapStrip, tap the  BodyGuardian box at the upper left of the status screen.

- The BG CU is not waterproof but the SnapStrip is. When you shower or bathe, remove the BG CU from the SnapStrip.



- The adhesive on the SnapStrip may break down if you perspire heavily.
- You may have to replace the SnapStrip if it loses stickiness

Cleaning the Control Unit

If you see visible dirt on the BG CU:

1. Use a sterile 70% Isopropyl Alcohol (IPA) pad and thoroughly wipe in a circular motion, for a minimum of 30 seconds, all outer surfaces of the BG CU. Pay close attention to seams and crevices in the device. Ensure excess IPA does not run into or collect in device seams or crevices.
2. Allow the device to air dry.
3. Inspect the device to be sure that it is visibly clean, pay close attention to the seams and crevices in the device.
4. If visible soil remains, repeat Steps 1 through 3 using a new sterile IPA pad until the device is visibly clean

Precautions

- Federal law (USA) restricts the device to sale by or on the order of a licensed practitioner or therapist. ✓
- Remove the SnapStrip slowly. Improper removal of the SnapStrip can cause skin irritation or tearing. ✓
- This device is for single patient use only. ✓
- Do not dispose of the BG CU. Return BG CUs to your healthcare provider ✓
- Remove the BG CU and SnapStrip before undergoing an MRI. ✓
- Do not use the BG CU if the casing is broken or damaged. ✓
- Do not disassemble the BG CU. ✓
- Do not wear BodyGuardian while traveling on aircraft. ✓
Remove and turn off the BG CU (press and hold the center button for 15-seconds) and ensure the phone is off. ✓
- The BodyGuardian is for use within the United States only.



Indications for Use:

Physicians prescribe the BodyGuardian System for patients who require monitoring for cardiac events. The BodyGuardian monitors:

- Patients with non-lethal cardiac arrhythmias ✓
- Sinus bradycardia and sinus tachycardia ✓
- Patients at risk for stroke from cardiac arrhythmias ✓

Using collected data, the BodyGuardian allows the healthcare provider to:

- Assess supraventricular arrhythmias to include atrial fibrillation
- Assess cardiac contributions to syncope and dizziness

Contraindications for Use

Patients with any of the following conditions should not use the BodyGuardian:

- Known skin allergies or sensitivities to acrylic, hydrogel or silicone adhesives
- Fragile skin
- Pregnancy
- An implantable device or a bed partner with an implantable device.

Note: The BodyGuardian system does not replace direct communication with healthcare providers. The BodyGuardian **does not** alert physicians or summon emergency assistance (911).



Specifications for BG CU

Shelf Life	6-months
Battery Capacity	350mAh minimum, 380mAh typical
Battery Charger Power Requirement	100-240 VAC, 50-60 Hz
Battery Type	Rechargeable Li-ion
Battery Voltage	3.7 VDC
Operating Temperature	+5°C to +40°C
Maximum Temperature of the Applied Part	
Storage Temperature (Power Off)	+5C to +40C
Operating Humidity	30% to 75%
Storage Humidity	30% to 75% (excluding condensation)
ECG <ul style="list-style-type: none"> • Sampling Rate • Digital Resolution • Input Dynamic range • Input Offset Dynamic Range 	256Hz 12 bit ±10mV ±300mV
Sampling Rate <ul style="list-style-type: none"> • ECG • Impedance • Accelerometer 	256Hz 32Hz 50Hz
Measurement Ranges <ul style="list-style-type: none"> • Heart Rate • Impedance • Respiration • Activity 	25 to 240 bpm 0 to 120 Ohms 0 too 30 breaths/min ±2b range in x,y,z direction
Data Storage <ul style="list-style-type: none"> • Capacity • Type 	24 hour continuous Internal NAND Flash
Weight	35g
Communications Type	Bluetooth between CU and phone



Symbols

	Caution: consult accompanying documents
	Type BF applied part; Denotes device is not in direct contact with cardiac muscle
	Wireless transmission symbol
	Lot number
SN	Serial number
REF	Catalogue reference
IPX4	Water splashing against the enclosure from any direction shall have no harmful effect.
Rx Only	Federal law (USA) restricts the device to sale by or on the order of a licensed practitioner or therapist.
	For Indoor use only
	Class II equipment

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First Edition

March 2012



Appendix 4: Draft Labeling - BodyGuardian General Information



BodyGuardian System

General Information

March 2012



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Preventice Confidential and Proprietary

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First Edition

March 2012



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Preventice BodyGuardian General Information

Preventice BodyGuardian® is an EC38¹ compliant remote cardiac monitoring system prescribed by healthcare providers to assess a patient's recorded ambulatory ECG data correlated with other physiological information. Remote monitoring enables collecting cardiac data in the patient's normal environment as they go about their day-to-day activities.

The complete system, as shown in Figure 1, consists of components to monitor and collect physiological data, send the data to a remote Preventice server on the Internet, store the data in secure databases on the Preventive server, and display data for review by healthcare professionals.

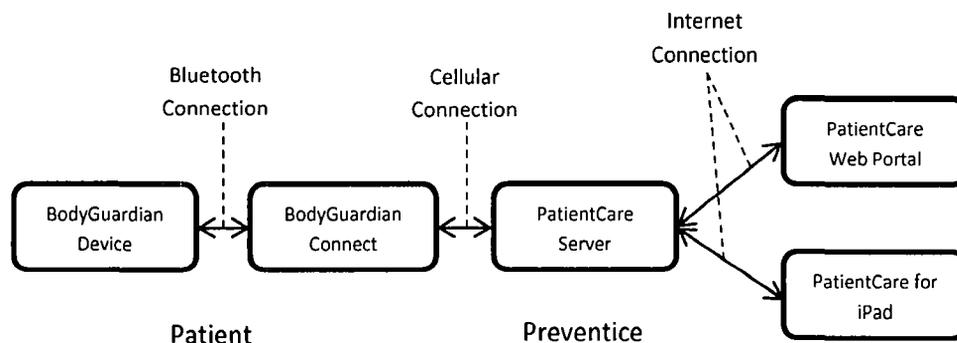


Figure 1 BodyGuardian System Components

The components of BodyGuardian are those used by the patient, those maintained by Preventice, and those used by the healthcare providers.

The patient uses the following components:

- The **Preventice BodyGuardian Device** (BG Control Unit), worn by the patient, consists of a **BodyGuardian Control Unit** (BG Control Unit) and a **BodyGuardian SnapStrip** (BG SnapStrip). The BG Control Unit is an electronic sensor that monitors and records patient cardiac (ECG) and other physiological data (respiration rate, level of patient activity, heart rate). The BG Control Unit connects to a BG SnapStrip using snap connectors. The BG SnapStrip has an adhesive backing that attaches to the patient's chest. Integrated in the BG SnapStrip are the electrodes for reading electrical signals from the patient's skin. The BG Control Unit communicates with BodyGuardian Connect using wireless Bluetooth communications.
- The **Preventice BodyGuardian Connect** (BG Connect) is an Android-based smartphone that runs the **BodyGuardian Application** (BG App). The BG App is the gateway between the PatientCare software and the BG Control Unit. It establishes a connection with the BG Control Unit, confirms the patient identity, gets device and prescription configuration data from PatientCare and sends

¹ American National Standard ANSI/AAMI EC38:1998. Ambulatory electrocardiographs
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that to the BG Control Unit. The BG App shows a status screen and lets the patient know when the BG Control Unit battery is low or if contact with the skin has degraded. BG Connect communicates with the BG Control Unit using a Bluetooth communications link and with PatientCare over a cellular network connection.

Preventice hosts and maintains the following component on its servers:

- **Preventice PatientCare (PatientCare)** is a set of databases and software applications running on a remote Preventice server that collect data relayed by the BG Connect, sends the data to the BG Connect, and stores clinical data in a secure database. The clinical data database keeps all of the medical information about a patient in a de-identified format (there is no patient identifying information stored with the clinical data); the patient profile (in the separate user profile database) contains the identifiable information about a patient. This mechanism supports the privacy requirements for medical information. PatientCare also manages patient and healthcare provider profiles. Each patient has a patient profile on PatientCare in a secure database (user profile database); each healthcare provider who uses PatientCare has a provider in that same database.

Healthcare providers access and view patient cardiac data using standard web browsers and accessing PatientCare remotely over an internet connection or with an application (app) that runs on an Apple® iPad®. The components are:

- **PatientCare Portal for the Web (PatientCare Portal)** enables providers, using standard web browsers such as Internet Explorer 7 or 8 or Firefox Version 10, to access PatientCare Portal remotely over an internet connection and to view or print visualizations (ECG strips, heart rate graphs, respiration rate graphs, activity level graphs) of the patient clinical data. Providers use a standard internet browser to manage patient and provider profiles.
- **PatientCare for iPad** allows providers to download patient data from PatientCare and to analyze that data on an Apple™ iPad™ tablet computer using the PatientCare for iPad application. Using the downloaded data, the application generates visualizations (ECG strips, heart rate graphs, respiration rate graphs, activity level graphs) of the patient data so that providers can analyze the data. The PatientCare for iPad application does not provide print capability. If desired, a provider can capture an image of the displayed clinical data by simultaneously pressing the iPad home and power buttons. This captures and stores the screen image as a photo on the iPad.

Note: The visualization and analysis tools do not contain diagnostic interpretation. The reported analysis is provided for review by qualified professionals to render a diagnosis based on clinical judgment and experience.

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Physicians prescribe the BodyGuardian System for patients who require monitoring for cardiac events. The BodyGuardian monitors:

- Sinus bradycardia and sinus tachycardia
- Arrhythmias and respiratory rates in cardiac patients
- High-risk cardiac patients in the hospital and after discharge
- Patients at risk for stroke from cardiac arrhythmias
- Chronically ill cardiac patients
- Post cardiac ablation and cardioversion patients

Using collected data, the BodyGuardian also allows the healthcare provider to:

- Assess supraventricular arrhythmias to include atrial fibrillation
- Assess cardiac contributions to syncope and dizziness with patient initiated event capture

Indications for Use

The BodyGuardian System includes the BodyGuardian Control Unit, a cellular phone, and data management software. The BodyGuardian Control Unit is a wearable device that collects the following physiological data:

- ECG
- Heart rate (including HR variability)
- Respiratory rate
- Activity

The BodyGuardian System is used for ambulatory cardiac event monitoring. The BodyGuardian Control Unit can be worn intermittently or continuously for up to 30 days. Recorded information is stored on the BG Control Unit, wirelessly transmitted to a phone, and then transmitted by cellular networks to data management software on a remote computer server. The data management software displays the data and is accessible by internet connection.

Contraindications for Use

Patients with any of the following conditions should not use the BodyGuardian:

- Potentially life-threatening arrhythmias requiring hospitalization
- Patients with implantable devices or bed partners with implantable devices
- Pregnancy
- Known skin allergies or sensitivities to acrylic, hydrogel or silicone adhesives
- Fragile skin

Note: The BodyGuardian system does not replace direct communication with healthcare providers. The BodyGuardian *does not* alert physicians or summon emergency assistance.



Data Collected by BodyGuardian

BodyGuardian collects data and sends it to the PatientCare Web Portal. The data sent includes ECG and physiological data associated with a Medical Protocol event, a Patient Initiated (by pressing the button on the BG Control Unit) or random data. Using the tools provided by PatientCare, you view visualizations of the collected data.

Medical Protocol Event

When a Physician Assistant or Managing Physician creates a Patient Profile (see the *PatientCare Managing Patients* document), they specify thresholds that define when a Medical Protocol event occurs. When a Medical Protocol Event occurs, the BG Control Unit immediately collects and sends ECG and physiological data from 60-seconds before to 60-seconds after the event occurs.

A complete profile of the patient's heart rate, respiration rate and activity level information is also collected along with the medical protocol event (30-minute summary graphs of these physiological data are shown).

Heart Rate Thresholds

The BG Control Unit gathers a single-channel ECG using electrocardiogram front-end support (signal acquisition, amplification, signal conditioning). The BG Control Unit calculates heart rate by sampling the number of R wave peaks in a preset time interval (10-seconds) and extrapolating that to beats per minute.

Bradycardia threshold defines the minimum acceptable heart rate for the patient. If the heart rate drops below this threshold, the BG Control Unit marks it as a medical protocol event (of type Bradycardia).

Tachycardia While at Rest threshold defines the point at which the heart rate is too high for the level of activity. When the patient's heart rate exceeds the Tachycardia While at Rest threshold (while the patient activity level is at or below the At Rest Activity Level threshold), the BG Control Unit marks a Tachycardia While at Rest medical protocol event.

Note: You can set the thresholds to monitor for tachycardia. Set the **Activity Level Threshold** to its maximum and the **Tachycardia While at Rest** threshold to the desired Tachycardia threshold.

Heart Rate Variability (HRV) threshold defines the maximum acceptable variance in patient heart rate. When the calculated heart rate varies by more than this, a Heart Rate Variability medical protocol event is marked. The BG Control unit marks R-R variability events using the Heart Rate Variability threshold defined in the patient profile. The threshold is in beats per minute, but the BG Control Unit marks a variability event based on a preset time interval of 10-seconds. The BG App on the Smartphone uses the R-R variability to derive the HRV over a full minute.

For example, when the threshold is 30-bpm (the default) a variance of more than five bpm over a 10-second interval triggers an HRV medical protocol event. The change measured here selects ECG



tracings that are more likely to indicate arrhythmia (based on dropped beats or increased heart rate) for physician review.

Respiration Rate Thresholds

The BG Control Unit determines the patient's respiration rate using bio-impedance. The BG Control Unit injects a low voltage charge to the patient's skin from one electrode and measures the change in voltage over a fixed distance to the receiving electrode, which reads the voltage. The BG Control Unit uses those changes to determine when a breath occurs. The voltage drops slightly when the patient inhales because of the increased distance between electrodes (caused by chest expansion). Using averages of these collected data, the BG Control Unit determines when a breath occurs by comparing the current voltage reading against the average.

Bradypnea threshold defines the minimum acceptable respiration rate for the patient. If the respiration rate drops below this threshold, the BG Control Unit marks it as a medical protocol event (of type Bradypnea).

Tachypnea While at Rest threshold defines the point at which the respiration rate is too high for the level of activity. The BG Control Unit triggers a medical protocol event when the patient's respiration rate exceeds the Tachypnea While at Rest threshold (while the patient activity level is at or below the At Rest Activity Level threshold).

Note: You can set the thresholds to monitor for Tachypnea (abnormally rapid breathing). Set the **Activity Level Threshold** to its maximum and the **Tachypnea While at Rest** threshold to the desired tachypnea threshold.

Activity Level Threshold

The BodyGuardian Control Unit contains a three-axis (vertical, horizontal, and side-to-side) accelerometer to detect movement in three directions. The BG Control Unit uses the data from the accelerometer to measure patient activity. The threshold specified in the patient profile defines when the patient is 'at rest'. Activity level can range from zero to 100, with 100 being high activity. The default threshold is 10.

Patient Initiated event Data

When a physician prescribes BodyGuardian, they tell the patient what symptoms to watch for, such as dizziness. When these symptoms occur, the patient presses the button on the BG Control Unit. The BG Control Unit collects and sends ECG and physiological data from 60-seconds before to 60-seconds after the button is pushed. The BG Control Unit marks the data as being from a patient-initiated event.

Random Event Data

When the Physician Assistant or Managing Physician creates a Patient Profile, (see the *PatientCare Managing Patients* document), they specify a **Communications Interval** (normally 60-minutes). When this time interval expires, the BG Control Unit marks and sends one random 120-second ECG strip. This



random strip is in addition to any Medical Protocol or Patient Initiated events. The random event data provides a view of the patient's normal ECG data.

Data Reliability

The BodyGuardian Control Unit assesses the reliability of ECG signals and respiration rate signals.

ECG and Heart Rate Reliability

The BG Control Unit assesses the reliability of the ECG signal by measuring the signal to noise ratio of the signal used to calculate the Heart Rate. Noise can come from movement artifact, muscle contractions, ambient electrical signals and poor electrode contact. As BodyGuardian users are ambulatory and active, signal noise will vary significantly. If the signal used to calculate the Heart Rate includes too much noise, the data is less reliable. When the Heart Rate reliability falls below a threshold the ECG and Heart Rate data is rejected and not used as data for Medical Thresholds. This implementation increases the specificity of Medical Thresholds in the ambulatory setting for BodyGuardian as a remote cardiac event monitor.

Respiratory Rate Reliability

The BodyGuardian determines respiratory rate by measuring the bio-impedance and measuring the change in charge as the chest wall moves with respiration. Body movement, body position, muscle contractions and most importantly electrode contact can influence noise in the signal. The BodyGuardian measures both the charge change and the noise. If the noise exceeds a level the data for respiratory rate is rejected and respiratory rate is reported as not a valid value. If the respiratory rate is not valid it is not used in medical threshold calculations. This method is designed to report respiratory rate that has high reliability.



Usage Overview

Once BodyGuardian is prescribed for a patient, the healthcare provider uses a standard web browser (Microsoft® Internet Explorer version 7 or 8 or Firefox version 10) to create a profile on the PatientCare site for the patient.

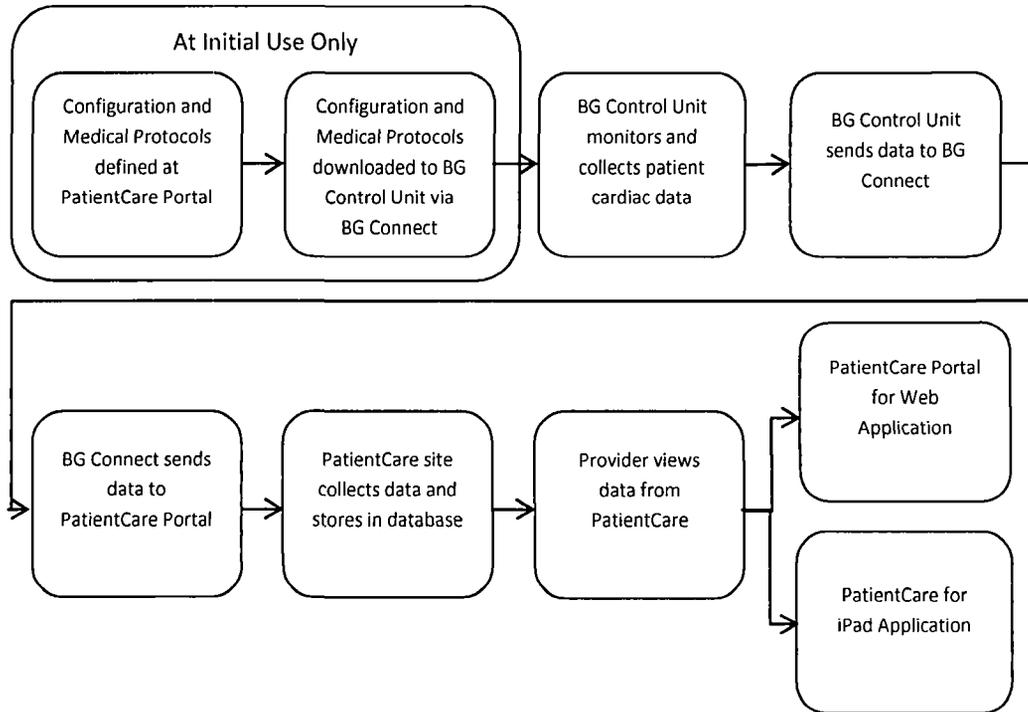


Figure 2 Flow of Data with BodyGuardian

When active and monitoring, the BG Control Unit captures and sends data at random intervals. The BG Control Unit immediately collects and sends data for the 60-second periods before and after a medical event occurs (an asymptomatic event). The healthcare provider defines the thresholds for these events when creating the patient profile at the PatientCare Portal. Medical events include:

- Bradycardia
- Tachycardia while at rest
- Bradypnea
- Tachypnea while at rest
- Heart rate variability

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Figure 3 is an example of the screen used at PatientCare Portal to define the medical event thresholds for a patient.

Note: To monitor for Tachycardia, set the **Activity Level Threshold** to its maximum and the **Tachycardia While at Rest** threshold to the desired Tachycardia threshold. To monitor for Tachypnea, set the **Activity Level Threshold** to its maximum and the **Tachypnea While at Rest** threshold to the desired Tachypnea threshold

ADD NEW PATIENT PROFILE
X

Step 6 - Device Thresholds

Heart Rate Thresholds (beats/min)

40 Bradycardia

120 Tachycardia While At Rest

30 Heart Rate Variability

Activity Level Thresholds

10 At Rest

Respiration Thresholds (breaths/min)

6 Bradypnea

24 Tachypnea While At Rest

Device Thresholds

85 Reliability

50 Sensitivity

60 Communication Interval

Back
Next

Figure 3 Setting Medical Event Thresholds

When a patient experiences symptoms (typically including such conditions as dizziness or a light headed feeling), they push the center button on the BG Control Unit. The device collects and sends ECG trace and physiological data from the interval 60-seconds before and 60-seconds after the time of the button push. This, along with the ability to detect asymptomatic events, allows the device to act as event monitoring device.

The BodyGuardian Control Unit monitors the quality of the ECG signals. Based on the threshold defined for **Reliability**, the Control Unit determines when the signal is reliable. Reliability is determined by percentage of good signals received during a time interval; if the percentage is greater than the threshold, the signal quality is considered good.



Viewing Patient Cardiac Data

A healthcare provider uses either the PatientCare Web Portal (using Internet Explorer 7 or Firefox Version 4.5) or the PatientCare for iPad® App to view cardiac data. Both allow the healthcare provider to select a specific event on a specific day and to view the data for that event.

Tools are available to assist the healthcare provider in analyzing the data for an event. For example, the ECG strip can be zoomed (magnified) for close inspection on either the time or the millivolts measurement axis.

A tool called **eCaliper** allows the healthcare provider to select segments of the ECG strip to get precise measurements of either time or voltage changes. On the iPad, those measurement segments can be saved and recalled.

Figure 4 is an example of using eCaliper on the PatientCare Portal.

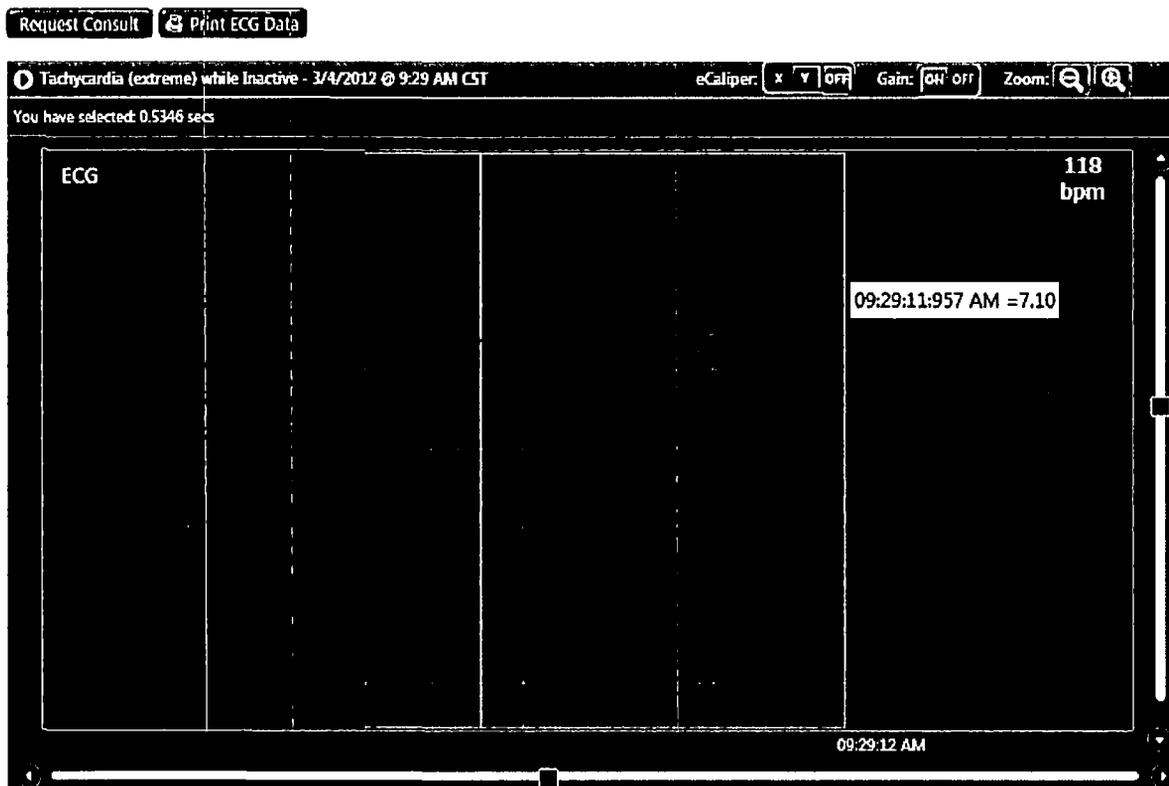


Figure 4 eCaliper Use on PatientCare Portal

Figure 5 is an example of using eCaliper on the PatientCare for iPad app.



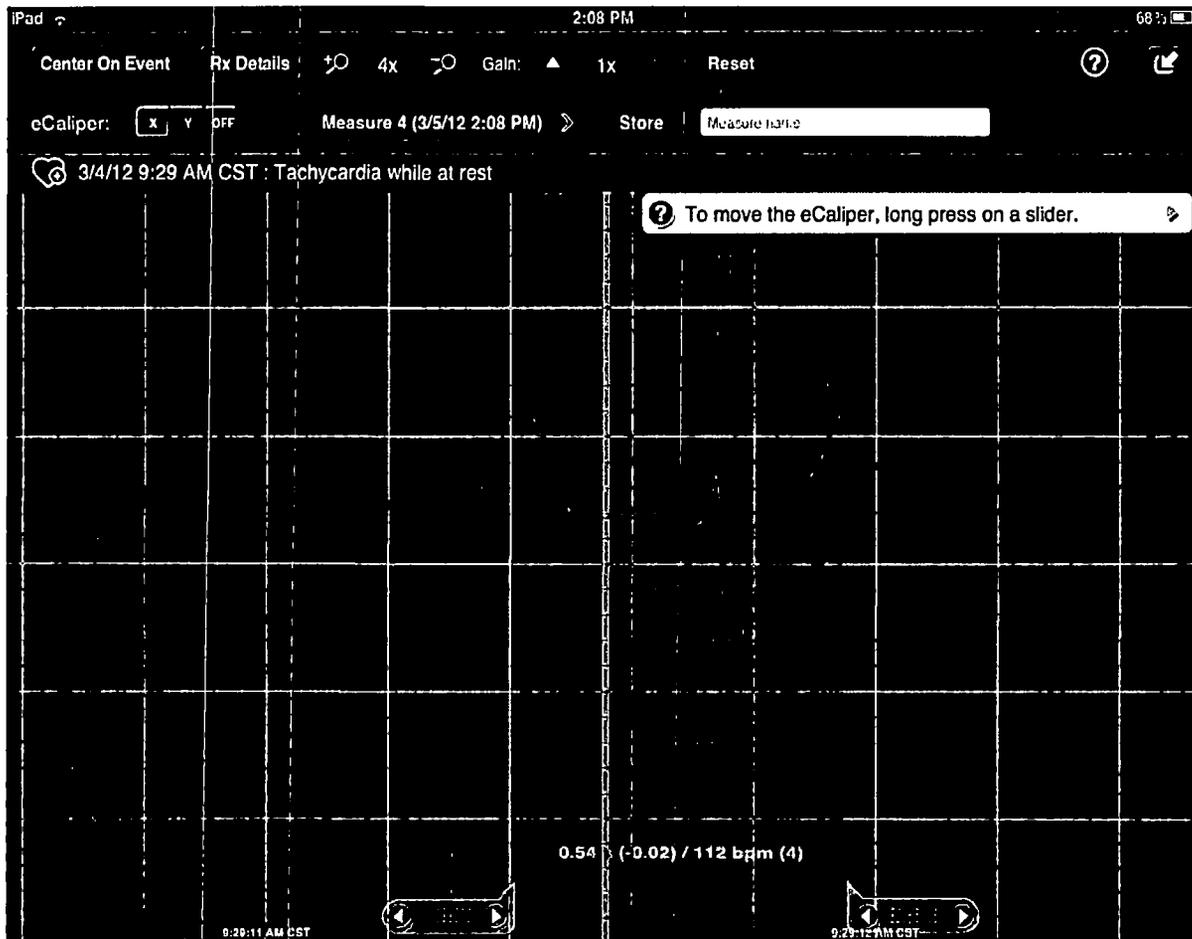


Figure 5 eCaliper Use on PatientCare for iPad App

Resources

The following documents are available on the PatientCare Help and Support page. You can access this page from any PatientCare screen.

- *PatientCare Administrator's Guide*
- *PatientCare Managing Patients*
- *BodyGuardian Instructions for Use*
- *PatientCare Viewing Patient Data*



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Appendix A. Technical Specifications

BodyGuardian Control Unit Safety Standards

Standard	Edition / year	Description
IEC 60601-1	Ed. 2 + A1 + A2 + Deviation UL/CSA	Medical Electrical Equipment – General requirement for safety
IEC 60601-1-1	Ed. 2	Collateral standard: Safety requirements for medical electrical systems
IEC 60601-1-2	Ed. 2 + A1	Collateral standard: Electromagnetic compatibility requirements and tests
IEC 60601-1-4	Ed. 1	Collateral standard: Programmable electrical medical systems
IEC 60601-1-6	Ed. 1	Collateral standard: Usability
IEC 60601-2-47	Ed. 1	Particular requirements for safety, including essential performance, of ambulatory electrocardiographic systems
IEC 60601-2-49	Ed 1 + Ec1	Particular requirements for safety of multifunction patient monitoring equipment
IEC 60529	Ed. 2 + A1	Degrees of protection provided by enclosures (IP Code)
EC38	2007	Particular requirements for safety, including essential performance, of ambulatory electrocardiographic systems
EC57	Ed. 2	Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms
UL 60601-1	Ed. 1	Safety of Medical Electrical Equipment Part 1 – General requirements for Safety
CAN/CSA 22.2	Ed. 2 + A1 + A2	Medical Electrical Equipment Part 1 – General requirements for Safety

Figure 6 BodyGuardian Control Unit Applicable Safety Standards



BodyGuardian Control Unit Technical Specifications

Environmental conditions for use	
Temperature	+5°C to +40°C
Relative humidity	30% to 75%
Atmospheric pressure	700hPA to 1060hPA
Environmental conditions for storage (max. 6 months)	
Temperature	-10°C to +35°C
Relative Humidity	30% to 75% RH (excluding condensation)
Atmospheric pressure	500hPA to 1060hPA
External dimensions and weight	
Width	17mm
Height	60mm
Depth	50mm
Weight	35g
Case Material	Polycarbonate (PC)
Control Unit Battery	
Capacity	350mAh minimum, 380mAh typical
Battery type	Rechargeable built-in Lithium Battery
Battery charger input requirement	100-240 VAC, 50-60 Hz
Battery charger output requirement	6 VDC @ 200mA
Battery voltage	3.7 VDC
Power consumption while charging	<600mW
ECG	
Sampling rate	256Hz
Digital resolution	12 bit
Input dynamic range	±10mV
Input offset dynamic range	± 300mV
Bio Impedance	
Injection	300µA @ 50KHz
Sampling	32/second
Impedance	0 to 120 Ohms
Maximum allowed load	7K Ohms
Accelerometer	
Activity sampling	50/second
Accelerometer	3 axis 12 bit
Sampling Rates	
ECG	256Hz
Bio Impedance	32 Hz
Accelerometer	50 Hz
Measurement Ranges	



Heart rate	25 to 240 BPM
Respiration	0 to 30 Breathes/minute
Activity	$\pm 2b$ range in x,y,z direction

Figure 7 BodyGuardian Control Unit Technical Specifications



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AC/DC medical power supply

Manufacturer	FRIWO
Model	FW7662M/06
Input	100-240 VAC – 50-60 Hz
Output	5.9VDC @ 1A
Safety standards	Fulfills Class II SELV for IEC 60601-1, UL 2601, VDE, CE label, SIQ Fulfill medical application class B / BF / CF
Electrical protection level	Class II
Case Material	Plastic
Case Dimensions	52 x 52 x 35.5 mm

Figure 8 AC/DC Power Supply Technical Specifications

BodyGuardian Charging Cradle

Technical Specifications	
Input/Output	Operative 5.9VDC/6VD nominal
Input connector	THT Power Supply Jack 4.4mm opening diameter
Output connector	Spring-Loaded Contacts Pins
Case Material	PC (Polycarbonate)
Case Dimensions	63 x 54 x 21 mm
Operational mode	Continuous
Operating Environment	
Temperature	+5°C to +35°C
Relative humidity	30% to 75% RH(excluding condensation)
Atmospheric pressure	500hPA to 1060hPA
Storage Environment	
Temperature	-10°C to +35°C
Relative humidity	30% to 75% RH(excluding condensation)
Atmospheric pressure	500hPA to 1060hPA

Figure 9 BodyGuardian Charging Cradle Technical Specifications



Appendix 5: Draft Labeling - PatientCare: Administrator's Guide



PatientCare

Administrator's Guide

March 2012



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Overview: Licenses and Provider Roles

Licenses and Authorities control access to the Preventice PatientCare portal. Patients and providers require licenses; different provider types have authority to access different parts of the system.

BodyGuardian Licenses

When an institution contracts for a BodyGuardian® system, the contract defines how many providers can use the system and the number of patient prescriptions available. If the institution assigns more licenses than are available, Preventice notifies the institution administrator. The institution can purchase additional licenses or ask Preventice to remove providers or patients from the system.

Provider Licenses

Each provider uses one of the available provider licenses. The institution administrator assigns a provider license when creating the provider profile. Only providers with an assigned license can view patient data. The institution administrator can deactivate a provider, which means the provider can no longer log on to the PatientCare Portal.

Note: An institution administrator does not use a license.

Patient Licenses

Each patient uses one of the available patient licenses. The physician assistant or managing physician assigns a patient license when creating the patient profile. Only Preventice can remove a patient from the system.

PatientCare Roles and Authorities

For the PatientCare portal, specific roles define what each health care provider can do. For example, an institution administrator can add a physician to the system but cannot view any data related to a patient; or, only a physician assistant or managing physician can create a patient profile. Figure 1 summarizes these roles and authorities.



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Role	Default Authorities					
	Create Provider Profile	Create Patient Profile	Assign Device/ Device Configuration	Medical Protocol Configuration	View Data	Request Consult
Institution administrator	x					
Prescribing physician				x	x	x
ECG tech					x	
Physician assistant		x	x	x	x	x
Managing physician		x	x	x	x	x

Figure 1 PatientCare Roles and Authorities

PatientCare provider roles are:

Institution administrator: When an institution contracts with Preventice for the BodyGuardian system, Preventice creates an institution administrator profile for one individual at the institution. The institution administrator creates profiles and assigns license seats for health care providers (physicians, ECG technicians and physician assistants) within the institution. The institution administrator cannot view patient data.

Prescribing physician: The prescribing physician prescribes a BodyGuardian for one or more patients. The prescribing physician uses the PatientCare portal or the PatientCare for Apple® iPad® app to review patient data collected by the BodyGuardian (E.g., ECG data, heart rate, respiration rate, activity level). The prescribing physician can also set medical protocol thresholds that define when an event is recorded (such as bradycardia threshold) by the BodyGuardian. The Request Consult option is available to a prescribing physician when viewing patient data.

ECG technician: An ECG technician is only able to view patient data.

Physician assistant: A physician assistant manages certain aspects related to patients who use BodyGuardian. The physician assistant creates profiles for each patient, assigns patient licenses and BodyGuardian devices to patients, and authorizes physicians and ECG technicians who can work with patient data. At the direction of a physician, the physician assistant can set medical protocol thresholds that define when an event is recorded (such as low heart rate threshold) by the BodyGuardian. The Request Consult option is also available to the physician assistant when viewing patient data.

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Managing physician: A managing physician manages certain aspects related to patients who use BodyGuardian, such as:

- Create profiles for patients
- Assign patient licenses
- Assign BodyGuardian devices to patients
- Authorize other providers to work with the patient data
- Set medical protocol thresholds that define when an event is recorded (such as Bradycardia) by the BodyGuardian
- Request a consult option when viewing patient data

Note: The PatientCare for iPad application does not use roles and does not have the capability of managing patients or providers. The iPad application is only for viewing data. However, anyone using the iPad application must have a provider profile and be authorized to view patient data.

Managing Provider Profiles

Each institution has one institution administrator. Preventice creates the profile for the institution administrator and sends a validation email. Follow the secure link in the email to accept the end user license for the PatientCare platform, set a password and verify content of the institution administrator profile.

Figure 2 is what you see in your inbox; Figure 3 is an example of the email contents. Your User Name for PatientCare is in the email (Provider964 in this example).

 account Your PatientCare registration is nearly complete

Figure 2 Inbox View of Validation email

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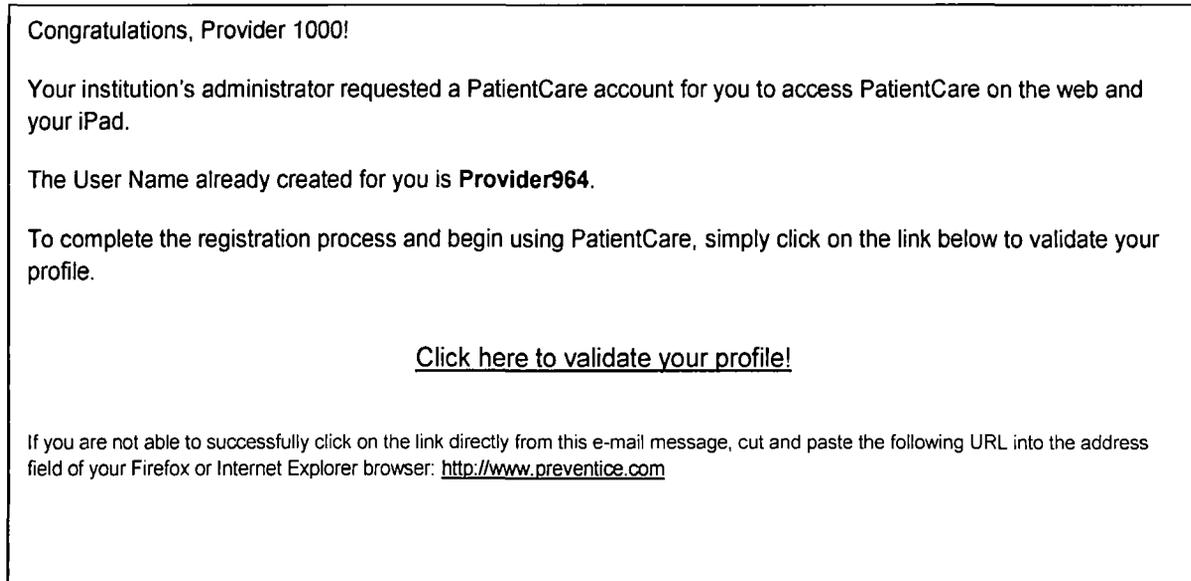


Figure 3 Example Validation email

Click on **Click here to validate your profile** and you go to a series of screens at the PatientCare Web Portal where you validate your profile and create your password. Figure 4 shows the sequence of screens you go through.



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First, you need to accept the End User License Agreement to use the site. Read the agreement and click **Agree To These Terms** to continue. You cannot proceed or use the PatientCare Web Portal or PatientCare for iPad tools if you do not accept these terms.

Once you agree to the terms, create your password for your profile. You use this and your User Name (Provider964 in this example) to log on to PatientCare. Passwords should follow conventions for your Institution.

Validate and update any information in your profile. Those items marked with an asterisk (*) are required.

Review your profile. If all fields are correct, click Finish.

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Preventive End User License Agreement

[Preventive End User License Agreement](#)

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I Agree To These Terms

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 1 - Choose Your Password

Choose Password:

Retype Password:

Next

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 2 - Validate Your Profile Information

* indicates required field

* First Name: * Last Name:

* Email Address: Gender:

Address: City:

Country: Postal Code:

State: Call Phone:

Office Phone:

Back **Next**

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 3 - Review Your Profile

Provider Profile

First Name: Provider Last Name: 1000

Email Address: Provider964@gmail.com Gender:

Address: City:

Country: United States Postal Code:

State: Call Phone:

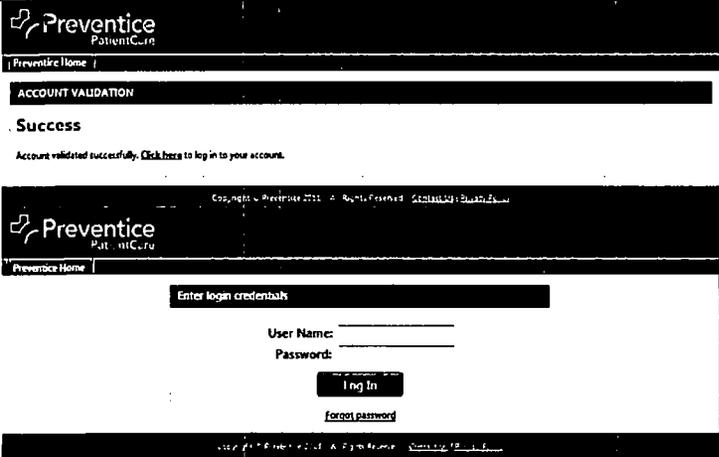
Office Phone:

Back **Finish**



Your profile is complete. Click on the [Click Here](#) link to log on to PatientCare.

This is the log on screen for the PatientCare Web Portal. Use your User Name and Password to log on.



The screenshot shows two sequential pages from the Preventive PatientCare web portal. The top page is titled 'ACCOUNT VALIDATION' and displays a 'Success' message: 'Account validated successfully. Click here to log in to your account.' The bottom page is the login screen, featuring the 'Preventive PatientCare' logo, a 'Preventive Home' link, and a form with the heading 'Enter login credentials'. The form includes fields for 'User Name:' and 'Password:', a 'Log In' button, and a 'forgot password' link. A copyright notice 'Copyright © Preventive 2012. All Rights Reserved. SiteMap | Log Out | Help' is visible at the bottom of the login page.

Figure 4 Validating Your Provider Profile

The Institution administrator can now sign on to the PatientCare web portal and create profiles for the health care providers. A health care provider must have a profile before they can sign on to PatientCare.

Provider List Display

The Provider List is only available to the institution administrator and is shown when the institution administrator logs on to the PatientCare platform. The list shows all healthcare providers at the institution who are licensed and have profiles.



Preventice PatientCare

Welcome back, New

Profile & Settings Help & Support Logout

PROVIDER LIST MY INSTITUTION

Provider List Add Provider

SORT BY: Provider Name FIND PROVIDER:

Provider Name	Total Patients	Provider Status
Bun, Test	0	Resend validation email
Burd, test	0	Resend validation email
Burrichter, Scott	1	Completed
Davidson, PA	1	Completed
Hamm, Greg	1	Completed
Harold, Maude	0	Resend validation email
House, Gregory	1	Resend validation email
Jacobson, Jon	0	Completed
Johnson, Riley	0	Resend validation email
Jones, Howard	1	Resend validation email

Viewing Providers 21 - 30 of 49 Page 3 of 5 Go to page:

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Figure 5 Provider List

The display shows the provider name, the number of patients authorized and the current PatientCare status:

Complete: The provider verified their profile.

Resend Verification email: The provider created a profile but did not verify. Clicking on **Resend Verification Email** sends a note from Preventice to the provider using the email address in the provider profile. The email is a duplicate of the original validation email. The provider must click the link in the email, agree to the end user license agreement, set a password and validate profile information.



Institution Profile

Selecting the **My Institution** tab displays the profile for the institution.

The screenshot shows the Preventice Patient Care interface. At the top, there is a navigation bar with the Preventice logo on the left and a user greeting "Welcome back, New" on the right, with links for "Profile & Settings", "Help & Support", and "Logout". Below the navigation bar, there are two tabs: "PROVIDER LIST" and "MY INSTITUTION", with "MY INSTITUTION" being the active tab. The main content area is titled "Institution Profile" and displays the following information:

A Davidson Clinic		Institution ID: 3830	
#131			

Below this, there is a section titled "Institution Profile" containing the following details:

Name: A Davidson Clinic	Address: 56575 111th St
Institution ID: 3830	State: Distrito Federal
City: Menahga	Country: Argentina
Postal Code: 56464	Fax:
Office Phone: +52 - 701-307-3675	

At the bottom of this section, there is a button labeled "Edit Institution Profile".

Figure 6 Institution Profile

Preventice created the profile for your institution. Select **Edit Institution Profile** to change any of the data in the profile except the institution ID.



Create New Provider Wizard

Use the **Add Provider** profile wizard to create a profile for the healthcare provider in the institution. When you create the profile, you also assign the license seat used by the provider. You must provide the following information to create a provider profile:

- Provider's information:
 - First and last name
 - E-mail address
 - Desired user name
- License assigned to the provider

Start the wizard by clicking on the **Add Provider** button on the Provider List display.

Identify provider information: First name, last name and email are required.

Specify user name for the provider for using PatientCare. Each user name must be unique within your organization.

Select the provider license.

Select provider as physician assistant, ECG technician, managing physician or prescribing physician.

If physician assistant or managing physician, select the associated patient license used when the physician assistant or managing physician creates patient profiles.



Verify all data and press
Finish or go back and correct
information.

ADD NEW PROVIDER PROFILE X

Review Provider Information

Provider Information

First Name: Provider	Last Name: 1100
Email Address: Provider964@gmail.com	Gender:
Address:	City:
Country:	Postal Code:
State:	Cell Phone:
Office Phone:	

Provider User Name

User Name: Provider1100

Provider Role

Provider Role: Managing Physician

Provider License Information

License: 987654 - Provider Seats: 50

Patient License Information

License: 876543 - Patient Seats: 50

ADD NEW PROVIDER PROFILE X

Provider added successfully

The provider profile has been added successfully. Would you like to add another provider?

Figure 7 Add Provider Wizard



Changing a Provider Profile

Change a provider profile by selecting the provider name from the Provider List display. See Figure 5 on p.9.

When you click **Edit Profile**, you will be able to edit the fields in the provider profile.

The figure consists of two screenshots of the Preventice PatientCare web application. Both screenshots show the 'Provider 1100' profile page, with 'ID #337' and 'User Name: Provider1100' displayed at the top. The page is divided into several sections: 'Provider Profile', 'Licenses', 'Seats to Consume', 'Licenses to Administer', and 'Administration'.
 The top screenshot shows the 'Edit Profile' button. The 'Provider Profile' section contains the following fields:
 - First Name: Provider
 - Last Name: 1100
 - Email Address: Provider904@gmail.com
 - Gender: (dropdown menu)
 - Address: (text field)
 - City: (text field)
 - Country: (dropdown menu)
 - Postal Code: (text field)
 - States: (dropdown menu)
 - Cell Phone: (text field)
 - Office Phone: (text field)
 The bottom screenshot shows the 'Save' and 'Cancel' buttons. The 'Provider Profile' section contains the following fields:
 - * indicates required field
 - * First Name: Provider
 - * Last Name: 1100
 - * Email Address: Provider904@gmail.com
 - Gender: Select gender (dropdown menu)
 - Address: (text field)
 - City: (text field)
 - Country: Select country (dropdown menu)
 - Postal Code: (text field)
 - State: Select state (dropdown menu)
 - Cell Phone: (text field)
 - Office Phone: (text field)
 The 'Licenses' section contains two tables:
 1. 'Seats to Consume':

License Code	Seats	License Type	Status
937654	50	Provider	Active

 2. 'Licenses to Administer':

License Code	Seats	License Type
876543	50	Patient

 The 'Administration' section contains a 'Resend validation email' button and a 'Send Email' button.

Figure 8 Change Provider Profile



Changing the Institution Administrator Profile

To change your profile, click on **Profile and Settings** at the top of any display. Use the profile display to make changes.

Change the profile information by clicking the **Edit** button.

You can also change or reset your password from this display.

Make any changes and save your updated profile.

The screenshots show the 'Profile & Settings' page for an Institution Administrator. The page includes a header with the Preventive PatientCare logo and navigation links for 'PROVIDER LIST' and 'MY INSTITUTION'. The main content area is titled 'Institution Administrator Profile' and contains a form with the following fields:

- * Indicates required field
- * First Name:
- * Last Name:
- * Email Address:
- * Phone Number:

At the bottom of the form are 'Save' and 'Cancel' buttons. The footer of the page includes copyright information for Preventive 2012 and links for 'Contact Us' and 'Privacy Policy'.

Figure 9 Changing the Institution Administrator Profile

Resources

The following documents are available on the PatientCare Help and Support page. You can access this page from any PatientCare screen.

- *BodyGuardian General Information*
- *PatientCare Managing Patients*
- *PatientCare Viewing Patient Data*
- *BodyGuardian Instructions for Use*



Appendix 6: Draft Labeling - PatientCare: Managing Patients



PatientCare Managing Patients



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Overview

Figure 1 provides an overview of the flow for using Preventice BodyGuardian®. This document covers the use of the PatientCare Web Portal to create and manage patient profiles.

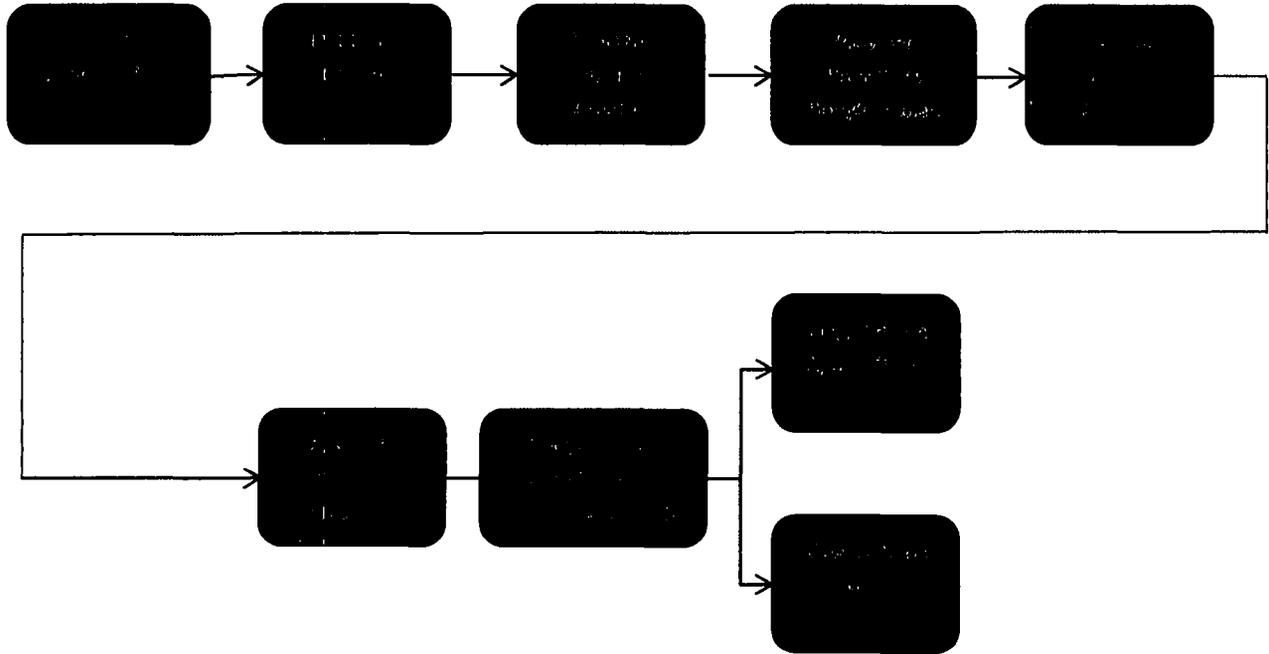


Figure 1 Overview of BodyGuardian

Managing Patient Profiles and Device Assignments

At least one individual in each institution fills the role of **physician assistant** or **managing physician**. The institution administrator creates a profile for the physician assistant or managing physician and Preventice sends a validation email. Follow the secure link in the email to accept the end user license for the platform, set your password and verify contents of your physician assistant or managing physician profile.

The institution administrator creates your profile, and Preventice sends you a validation email. Figure 2 is what you see in your inbox; Figure 3 is an example of the email contents. Your User Name for PatientCare is in the email (Provider964 in this example).



account
Your PatientCare registration is nearly complete

Figure 2 Inbox View of Validation email

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Congratulations, Provider 1000!

Your institution's administrator requested a PatientCare account for you to access PatientCare on the web and your iPad.

The User Name already created for you is **Provider964**.

To complete the registration process and begin using PatientCare, simply click on the link below to validate your profile.

[Click here to validate your profile!](#)

If you are not able to successfully click on the link directly from this e-mail message, cut and paste the following URL into the address field of your Firefox or Internet Explorer browser: <http://www.preventice.com>

Figure 3 Example Validation email

Click on **Click here to validate your profile** and you go to a series of screens at the PatientCare Web Portal where you validate your profile and create your password. Figure 4 shows the sequence of screens you go through.



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First, you need to accept the End User License Agreement to use the site. Read the agreement and click **Agree To These Terms** to continue. You cannot proceed or use the PatientCare Web Portal or PatientCare for iPad tools if you do not accept these terms.

Once you agree to the terms, create your password for your profile. You use this and your User Name (Provider964 in this example) to log on to PatientCare. Passwords should follow conventions for your Institution.

Validate and update any information in your profile. Those items marked with an asterisk (*) are required.

Review your profile. If all fields are correct, click Finish.

Preventive PatientCare
ACCOUNT VALIDATION

Preventive End User License Agreement

Preventive End User License Agreement

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I Agree To These Terms

Preventive PatientCare
ACCOUNT VALIDATION

Step 1 - Choose Your Password

Choose Password:

Retype Password:

Next

Preventive PatientCare
ACCOUNT VALIDATION

Step 2 - Validate Your Profile Information

* Indicates required field

* First Name: * Last Name:

* Email Address: Gender:

Address: City:

Country: Postal Code:

State: Cell Phone:

Office Phone:

Back **Next**

Preventive PatientCare
ACCOUNT VALIDATION

Step 3 - Review Your Profile

Provider Profile

First Name: Provider	Last Name: 1000
Email Address: Provider964@gmail.com	Gender:
Address:	City:
Country: United States	Postal Code:
State:	Cell Phone:
Office Phone:	

Back **Finish**



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Your profile is complete. Click on the [Click Here](#) link to log on to PatientCare.

This is the log on screen for the PatientCare Web Portal. Use your User Name and Password to log on.

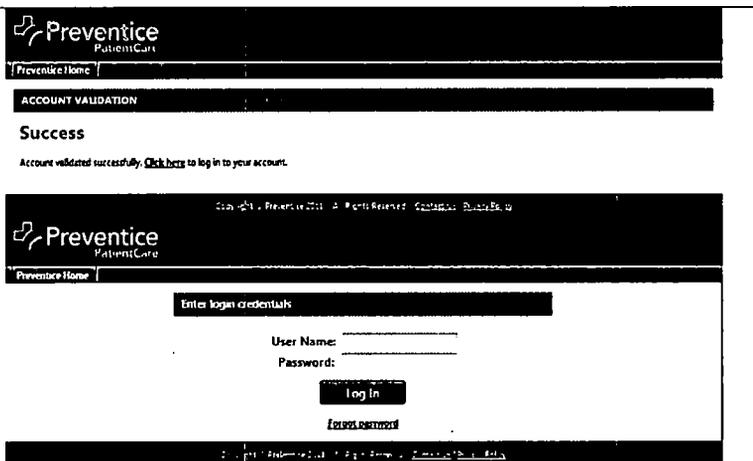


Figure 4 Validating Your Provider Profile

Log in to the PatientCare portal to create and manage profiles for patients who use the BodyGuardian system.



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Patient List Display

The first display you see when you sign in to PatientCare is the Patient List display, as shown in Figure 5.

The screenshot shows the Patient List interface. Callout A points to the 'Preventice PatientCare' logo. Callout B points to the 'PATIENT LIST' tab. Callout C points to the 'Total Events' column header. Callout D points to the 'Medical Events' column header. Callout E points to the 'Add Patient' button. The interface includes a navigation bar with 'Welcome back, Mary', 'Profile & Settings', 'Help & Support', and 'Logout'. Below the navigation bar is the 'Patient List' title and a note: 'The "Total Events" and "Medical Events" columns are displaying events for the last 14 days'. There is a 'SORT BY: Total Events' dropdown and a 'FIND PATIENT:' search field. The main table lists patient records with columns for Patient Name, Last Event Date, Total Devices, Total Events, and Medical Events. The footer shows 'Viewing Patients 1 - 15 of 56', 'Page 1 of 4', and 'Go to page: 1'.

Patient Name	Last Event Date	Total Devices	Total Events	Medical Events
1002_Patient	3/2/2012 @ 11:27 AM CST	4	336	Total = 16f
3001_Patient	3/6/2012 @ 4:00 PM KST	17	187	Total = 11f
1001_Patient	3/7/2012 @ 12:06 PM CST	4	173	Total = 4f
Patient_1	10/3/2011 @ 4:56 PM CST	4	0	Total = 0
Patient_2	10/4/2011 @ 8:24 AM CST	3	0	Total = 0
3_Patient	10/6/2011 @ 5:46 AM CST	2	0	Total = 0
4_Patient	10/4/2011 @ 10:04 PM CST	2	0	Total = 0
105_Patient	11/21/2011 @ 5:17 PM CST	3	0	Total = 0
100s_Patient	10/8/2011 @ 9:01 PM CST	4	0	Total = 0
102_Patient	11/23/2011 @ 12:51 PM CST	2	0	Total = 0
103_Patient	---	2	0	Total = 0
150_Patient	---	0	0	Total = 0
104_Patient	11/21/2011 @ 4:05 PM MST	3	0	Total = 0
105_Patient	---	2	0	Total = 0
106_Patient	---	3	0	Total = 0

Figure 5 Patient List Display

Patients with full listings (last event date, total devices, total events and medical events) shown are those whose profiles you created or are authorized to. You create a patient profile by selecting the **Add Patient (E)** button.



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Fields on the Patient List show the following categories:

- A. **Last Event Data** is the last upload of data from the BodyGuardian control unit to the PatientCare portal. This helps you keep track of who is currently using BodyGuardian control units.
- B. **Number of Devices** is the number of BodyGuardian devices (control units) defined for this patient. Devices are defined when the Patient Profile is created; each patient is assigned at least two devices.
- C. **Total Events** is the total of all medical events as defined by thresholds, random events or patient action events over the last 14 days.
- D. **Medical Events** is a summary of the medical events recorded by the BodyGuardian over the last 14 days.
 - a. **Patient initiated** (represented by a blue person icon) specifies the number of times a patient pressed the Send Data button on the BodyGuardian. A patient presses the button when he/she experiences symptoms.
 - b. **Medical protocol** (represented by a red heart with a cross) indicates the number of times BodyGuardian has flagged data as being outside an acceptable medical protocol defined for a patient (E.g., heart rate too slow, heart rate too fast given patient activity level at that time, or occurrence of heart rate variability event.)
- E. **Add Patient** starts a series of displays (set-up wizard) that creates a profile for a new patient.

Add Patient Profile

You create a profile for each patient using BodyGuardian. In that profile, you define the BodyGuardian control units provided to the patient and the healthcare providers who can view patient data. Start the set-up wizard by clicking the **Add Patient** button on the Patient List display.

Before starting the set-up wizard, collect necessary information. This includes information about the patient, devices assigned to the patient and the prescribed medical events thresholds for the patient. See Figure 6 on p. 12 for the set-up wizard screen flow.

Patient Information

Collect the following information for each patient:

- First and last name
- Time zone
- Gender
- Date of birth
- Address (optional)
- Email address (optional)
- Healthcare providers (physicians, physician assistants, ECG technicians) who can view patient data



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Authorized Healthcare Providers

Only authorized healthcare providers can view a patient's medical data. You authorize providers when you create a patient profile, or you can add them later by editing a patient profile. Authorized providers must have profiles defined in the system. You can view patient data for those profiles you create.

BodyGuardian Control Unit Information

You need the following information for each BG Control Unit assigned to a patient:

Display name a descriptive name from the BG Control Unit assigned to the patient

Internal device ID in the format "00:80:E1:FC:nn:nn" when "nn" is a unique identifying number for that device (Found on a label on the inside of the lid of the box that contains BodyGuardian control unit)

Note: Enable a specific device (internal device ID) for only one patient.

Prescription Configuration Information

The BodyGuardian control unit uses threshold values to determine when a medical event occurs. If necessary, under the direction of a physician, you can change the measurement thresholds.

Heart Rate Thresholds

Bradycardia defines the minimum heart rate for the patient in beats per minute. Default value is 40 bpm. When the heart rate drops below this threshold, a medical protocol event is marked.

Tachycardia (while at rest)¹ is the point at which the heart rate is too high while the level of activity is below the defined activity level threshold. Default value is 120 bpm.

Heart Rate Variability specifies the maximum acceptable variance in heart rate. Set as a beats per minute variability and defaults to 30-bpm. If the calculated heart rates changes by more than this amount over two preset time intervals (10-seconds), an event is set..

Activity Level Thresholds

A 3-axis accelerometer (horizontal, vertical, side-to-side) in the BodyGuardian control unit calculates activity levels.

The threshold specified indicates when the patient is at rest. The value specified is from one to 100, with 100 being high activity. Patient activity level below the specified threshold indicates the patient is at rest. The At Rest default is 10.

Respiration Rate Thresholds

Bradypnea specifies the minimum acceptable respiration rate in breaths per minute. The default value is six.

¹ If you want to monitor the patient for Tachycardia (abnormally rapid heart rate) only, set the **Activity Level Threshold** to its maximum and the **Tachycardia While at Rest** threshold to the desired Tachycardia threshold



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Tachypnea (while at rest)² is the point at which the respiration rate is too high when the level of activity is below the activity level threshold. The default value is 24.

Device Thresholds

Reliability is the level below which the signals received by the BodyGuardian control unit are unreliable. Specify a percentage value with zero being no signal and 100 being the best signal. The default value is 85.

Communication Interval specifies how often the BodyGuardian control unit sends random event cardiac data. One 120-second ECG strip is sent when this interval expires in addition to any medical protocol or patient initiated events that occurred during that time. The value is set in minutes. Default value is 60.

Sensitivity defines how sensitive BG Control unit is to noise and artifacts on the cardiac signals. Specified as a relative value from zero to 100 (default of 50). For patients with little muscle or flesh mass, a lower sensitivity level may be needed; for those with higher levels of muscle or flesh mass, a higher sensitivity level may be needed.

Add Patient Wizard

Enter identifying information about the patient.

ADD NEW PATIENT PROFILE [X]

Step 1 - Patient Information

Please enter the profile information for the patient

* indicates required field

* First Name: _____ * Last Name: _____

* Gender: * Date of Birth: ____/____/____ MM/DD/YYYY

* Timezone:

Address: _____ City: _____

State: Postal Code: _____

Country: Email Address: _____

Select the license used for the patient.

ADD NEW PATIENT PROFILE [X]

Step 2 - Patient License

Please select the license for the patient

Select license:

Define your health care provider role relationship to the patient.

ADD NEW PATIENT PROFILE [X]

Step 3 - Relationship to Patient

Please select your relationship to the patient

Select role:

² If you want to monitor the patient for Tachypnea (abnormally rapid breathing) only, set the **Activity Level Threshold** to its maximum and the **Tachypnea While at Rest** threshold to the desired tachypnea threshold



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Select those healthcare providers who can view patient data.

ADD NEW PATIENT PROFILE [X]

Step 4 - Patient Authorizations

Authorize providers to patient data according to their current role

ECG Tech (ECG Technician)

Physician Wizard/Modal (Consulting Physician)

12 12 (ECG Technician)

12 12 (Consulting Physician)

Back Next

Configure BodyGuardian control units now or add them later by editing the patient profile.

ADD NEW PATIENT PROFILE [X]

Proceed to device configuration?

You have entered enough information to create the patient profile. Would you like to configure BodyGuardian devices for the patient at this time?

Yes, I would like to configure the BodyGuardian devices for the patient. [v]

Back Next

Create identifiers for the control units prescribed to the patient. **Note:** Enabled Device ID numbers must be unique.

ADD NEW PATIENT PROFILE [X]

Step 5 - Device Information

** indicates required field*

Device #1

Device Type: BodyGuardian Control Unit

* Device Name: _____

* Device ID: 00:80:E1:FC:____

Enabled:

Device #2

Device Type: BodyGuardian Control Unit

* Device Name: _____

* Device ID: 00:80:E1:FC:____

Enabled:

Hint: Device ID refers to the specific MAC address that is unique to the patient's control unit. It can be found on the outside label of the BodyGuardian lot used for shipping the control unit. The first part of the ID has been filled in for you.

Back Next

If necessary, under the direction of a physician, you can change the measurement thresholds.

ADD NEW PATIENT PROFILE [X]

Step 6 - Device Thresholds

Heart Rate Thresholds (beats/min)

40 Bradycardia

120 Tachycardia While At Rest

30 Heart Rate Variability

Activity Level Thresholds

10 At Rest

Respiration Thresholds (breaths/min)

6 Bradypnea

24 Tachypnea While At Rest

Device Thresholds

85 Reliability

50 Sensitivity

60 Communication Interval

Back Next



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ADD NEW PATIENT PROFILE

Review Patient Information

Patient Information

First Name: Patient	Last Name: 9999
Gender: Male	Date of Birth: 3/8/1954
Timezone: (GMT-07:00) Arizona	
Address:	City:
Country:	Postal Code:
State:	Email Address:

Patient License

Patient License: 876543 - Patient Seats: 50

Authorized to View Patient

Individual	Role
1000, Provider	Managing Physician
1100, Provider	Managing Physician

Device Information

Device 1	Device 2
Pat99901	Pat99902
00:80:E1:FC:22:23	00:80:E1:FC:22:24
Enabled	Enabled

Device Thresholds

Heart Rate Thresholds (beats/min)	Respiration Thresholds (breaths/min)
Bradycardia: 40	Bradypnea: 6
Tachycardia While At Rest: 120	Tachypnea While At Rest: 24
Heart Rate Variability: 35	Device Thresholds
Activity Level Thresholds	Reliability: 85
At Rest: 10	Sensitivity: 50
	Communication Interval: 60

ADD NEW PATIENT PROFILE

Patient added successfully

The patient profile has been added successfully. Would you like to add another patient?

Review the data; go back to make changes or finish.

Click Yes to start the wizard for another patient.

Figure 6 Add Patient Wizard Flow

Patient Profile: View and Edit

You can view and edit a patient profile by selecting a patient from the Patient List display. You will see the Patient Profile displayed below:



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PATIENT LIST		
Patient 1001 ID #2159		View ECG Data
Patient Profile		
First Name: Patient	Last Name: 1001	
Gender: Male	Date of Birth: 3/1/1933	
Timezone: (GMT-06:00) Central Time (US & Canada)		
Address:	City:	
Country:	Postal Code:	
State:	Email Address:	
Edit Profile		
Devices		
BodyGuardian Devices - 2		Add New Device Edit Thresholds
Dev 2 00:80 11:FC:41:CC	Enabled	Edit Device Remove Device
Dev 1 00:20:11:FC:41:CD	Enabled	Edit Device Remove Device
Patient License		
License: #192838 - 500 Seats		
Authorized to View Patient		
Individual	Role	Add Provider
Doc Doctor20	Prescribing Physician	Remove
M Physician Assistant	Physician Assistant	Remove

Figure 7 Patient Profile Display

From this display, you can do the following:

Edit Profile allows you to change any information shown in the Patient Profile sections.

Edit Thresholds allows you to edit threshold values originally defined for the patient. See *Prescription Configuration Information* on p. 9 for threshold definitions.

Add New Device allows you to add (define) a new BodyGuardian device used by the patient. See *BodyGuardian Control Unit Information* on p. 9 for configuration information.

Edit Device allows you to edit configuration values for a BodyGuardian control unit. See *BodyGuardian Control Unit Information* on p. 9 for configuration information.

Remove Device removes a BodyGuardian control unit. The control unit is no longer associated with that patient.

Add Provider allows you to authorize a provider to view a patient's data.



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Remove Provider allows you to remove a provider previously authorized to view a patient's data.

Use the View ECG Data button in the upper right to navigate to displays of a patient's cardiac data. See the document Viewing Patient Data on the Help and Support site for information on viewing patient data.

Resources

The following documents are available on the PatientCare Help and Support page. You can access this page from any PatientCare screen.

- *BodyGuardian General Information*
- *PatientCare Administrator's Guide*
- *PatientCare Viewing Patient Data*
- *BodyGuardian Instructions for Use*



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Appendix 7: Draft Labeling - PatientCare: Viewing Patient Data



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PatientCare Viewing Patient Data

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March 2012



Preventice

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Overview

Figure 1 provides an overview of the flow for using Preventive BodyGuardian. This document covers the use of the PatientCare Web Portal and the Preventive PatientCare for Apple® iPad® App (the iPad is not provided with the BodyGuardian system) to view patient data collected by BodyGuardian.

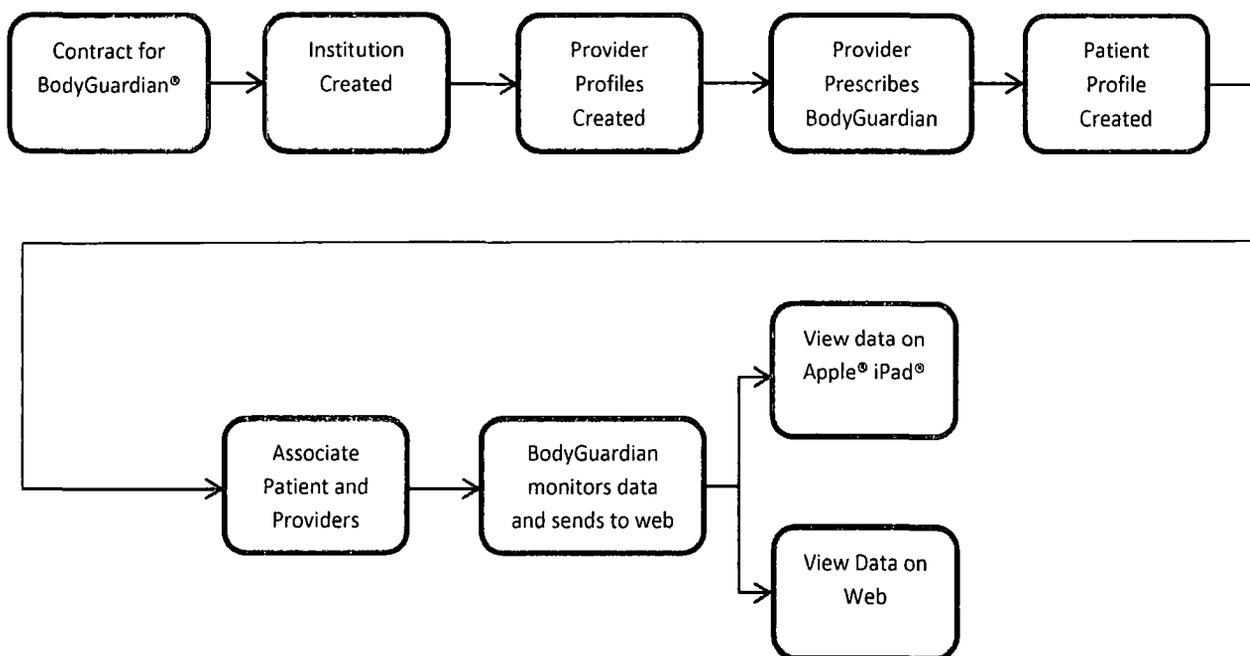


Figure 1 Overview of BodyGuardian

You can view patient data by using a web browser (Microsoft® Internet Explorer 7 or 8 or Firefox Version 10) and connecting to the PatientCare Web Portal or you can use your Apple® iPad® to download data from the PatientCare server and view it on an iPad.

This document is for the providers who view patient data for BodyGuardian® patients. Physicians and physician assistants can view patient data and edit medical event thresholds; ECG technicians can only view patient data.

BodyGuardian® is a registered trademark of Preventive
 Apple® and iPad® are registered trademarks of the Apple Corporation.
 Microsoft® is a registered trademark of the Microsoft Corporation



Data Collected by BodyGuardian

BodyGuardian collects data and sends it to the PatientCare Web Portal. The data sent includes ECG and physiological data associated with a Medical Protocol event, a Patient Initiated (by pressing the button on the BG Control Unit) or random data. Using the tools provided by PatientCare, you view visualizations of the collected data.

Medical Protocol Event

When a Physician Assistant or Managing Physician creates a Patient Profile (see the *PatientCare Managing Patients* document), they specify thresholds that define when a Medical Protocol event occurs. When a Medical Protocol Event occurs, the BG Control Unit immediately collects and sends ECG and physiological data from 60-seconds before to 60-seconds after the event occurs.

A complete profile of the patient's heart rate, respiration rate and activity level information is also collected along with the medical protocol event (30-minute summary graphs of these physiological data are shown).

Heart Rate Thresholds

The BG Control Unit gathers a single-channel ECG using electrocardiogram front-end support (signal acquisition, amplification, signal conditioning). The BG Control Unit calculates heart rate by sampling the number of R wave peaks in a preset time interval (10-seconds) and extrapolating that to beats per minute.

Bradycardia threshold defines the minimum acceptable heart rate for the patient. If the heart rate drops below this threshold, the BG Control Unit marks it as a medical protocol event (of type Bradycardia).

Tachycardia While at Rest threshold defines the point at which the heart rate is too high for the level of activity. When the patient's heart rate exceeds the Tachycardia While at Rest threshold (while the patient activity level is at or below the At Rest Activity Level threshold), the BG Control Unit marks a Tachycardia While at Rest medical protocol event.

Note: You can set the thresholds to monitor for tachycardia. Set the **Activity Level Threshold** to its maximum and the **Tachycardia While at Rest** threshold to the desired Tachycardia threshold.

Heart Rate Variability (HRV) threshold defines the maximum acceptable variance in patient heart rate. When the calculated heart rate varies by more than this, a Heart Rate Variability medical protocol event is marked. The BG Control unit marks R-R variability events using the Heart Rate Variability threshold defined in the patient profile. The threshold is in beats per minute, but the BG Control Unit marks a variability event based on a preset time interval of 10-seconds. The BG App on the Smartphone uses the R-R variability to derive the HRV over a full minute.

For example, when the threshold is 30-bpm (the default) a variance of more than five bpm over a 10-second interval triggers an HRV medical protocol event. The change measured here selects ECG



tracings that are more likely to indicate arrhythmia (based on dropped beats or increased heart rate) for physician review.

Respiration Rate Thresholds

The BG Control Unit determines the patient's respiration rate using bio-impedance. The BG Control Unit injects a low voltage charge to the patient's skin from one electrode and measures the change in voltage over a fixed distance to the receiving electrode, which reads the voltage. The BG Control Unit uses those changes to determine when a breath occurs. The voltage drops slightly when the patient inhales because of the increased distance between electrodes (caused by chest expansion). Using averages of these collected data, the BG Control Unit determines when a breath occurs by comparing the current voltage reading against the average.

Bradypnea threshold defines the minimum acceptable respiration rate for the patient. If the respiration rate drops below this threshold, the BG Control Unit marks it as a medical protocol event (of type Bradypnea).

Tachypnea While at Rest threshold defines the point at which the respiration rate is too high for the level of activity. The BG Control Unit triggers a medical protocol event when the patient's respiration rate exceeds the Tachypnea While at Rest threshold (while the patient activity level is at or below the At Rest Activity Level threshold).

Note: You can set the thresholds to monitor for Tachypnea (abnormally rapid breathing). Set the **Activity Level Threshold** to its maximum and the **Tachypnea While at Rest** threshold to the desired tachypnea threshold.

Activity Level Threshold

The BodyGuardian Control Unit contains a three-axis (vertical, horizontal, and side-to-side) accelerometer to detect movement in three directions. The BG Control Unit uses the data from the accelerometer to measure patient activity. The threshold specified in the patient profile defines when the patient is 'at rest'. Activity level can range from zero to 100, with 100 being high activity. The default threshold is 10.

Patient Initiated event Data

When a physician prescribes BodyGuardian, they tell the patient what symptoms to watch for, such as dizziness. When these symptoms occur, the patient presses the button on the BG Control Unit. The BG Control Unit collects and sends ECG and physiological data from 60-seconds before to 60-seconds after the button is pushed. The BG Control Unit marks the data as being from a patient-initiated event.

Random Event Data

When the Physician Assistant or Managing Physician creates a Patient Profile, (see the *PatientCare Managing Patients* document), they specify a **Communications Interval** (normally 60-minutes). When this time interval expires, the BG Control Unit marks and sends one random 120-second ECG strip. This random strip is in addition to any Medical Protocol or Patient Initiated events. The random event data



provides a view of the patient's normal ECG data.

Data Reliability

The BodyGuardian Control Unit assesses the reliability of ECG signals and respiration rate signals.

ECG and Heart Rate Reliability

The BG Control Unit assesses the reliability of the ECG signal by measuring the signal to noise ratio of the signal used to calculate the Heart Rate. Noise can come from movement artifact, muscle contractions, ambient electrical signals and poor electrode contact. As BodyGuardian users are ambulatory and active, signal noise will vary significantly. If the signal used to calculate the Heart Rate includes too much noise, the data is less reliable. When the Heart Rate reliability falls below a threshold the ECG and Heart Rate data is rejected and not used as data for Medical Thresholds. This implementation increases the specificity of Medical Thresholds in the ambulatory setting for BodyGuardian as a remote cardiac event monitor.

Respiratory Rate Reliability

The BodyGuardian determines respiratory rate by measuring the bio-impedance and measuring the change in charge as the chest wall moves with respiration. Body movement, body position, muscle contractions and most importantly electrode contact can influence noise in the signal. The BodyGuardian measures both the charge change and the noise. If the noise exceeds a level the data for respiratory rate is rejected and respiratory rate is reported as not a valid value. If the respiratory rate is not valid it is not used in medical threshold calculations. This method is designed to report respiratory rate that has high reliability.



PatientCare Provider Profiles

Before you can log on to the PatientCare Web Portal or use the PatientCare for iPad app, you must have an active profile for PatientCare. Your institution administrator creates your profile, and Preventice sends you a validation email. Figure 2 is what you see in your inbox; Figure 3 is an example of the email contents. Your User Name for PatientCare is in the email (**Provider964** in this example).

account Your PatientCare registration is nearly complete

Figure 2 Validation email - Inbox View

Congratulations, Provider 1000!

Your institution's administrator requested a PatientCare account for you to access PatientCare on the web and your iPad.

The User Name already created for you is **Provider964**.

To complete the registration process and begin using PatientCare, simply click on the link below to validate your profile.

[Click here to validate your profile!](#)

If you are not able to successfully click on the link directly from this e-mail message, cut and paste the following URL into the address field of your Firefox or Internet Explorer browser: <http://www.preventice.com>

Figure 3 Validation email

Click on **Click here to validate your profile** and you go to a series of screens at the PatientCare Web Portal where you validate your profile and create your password. Figure 4 shows the sequence of screens you go through.

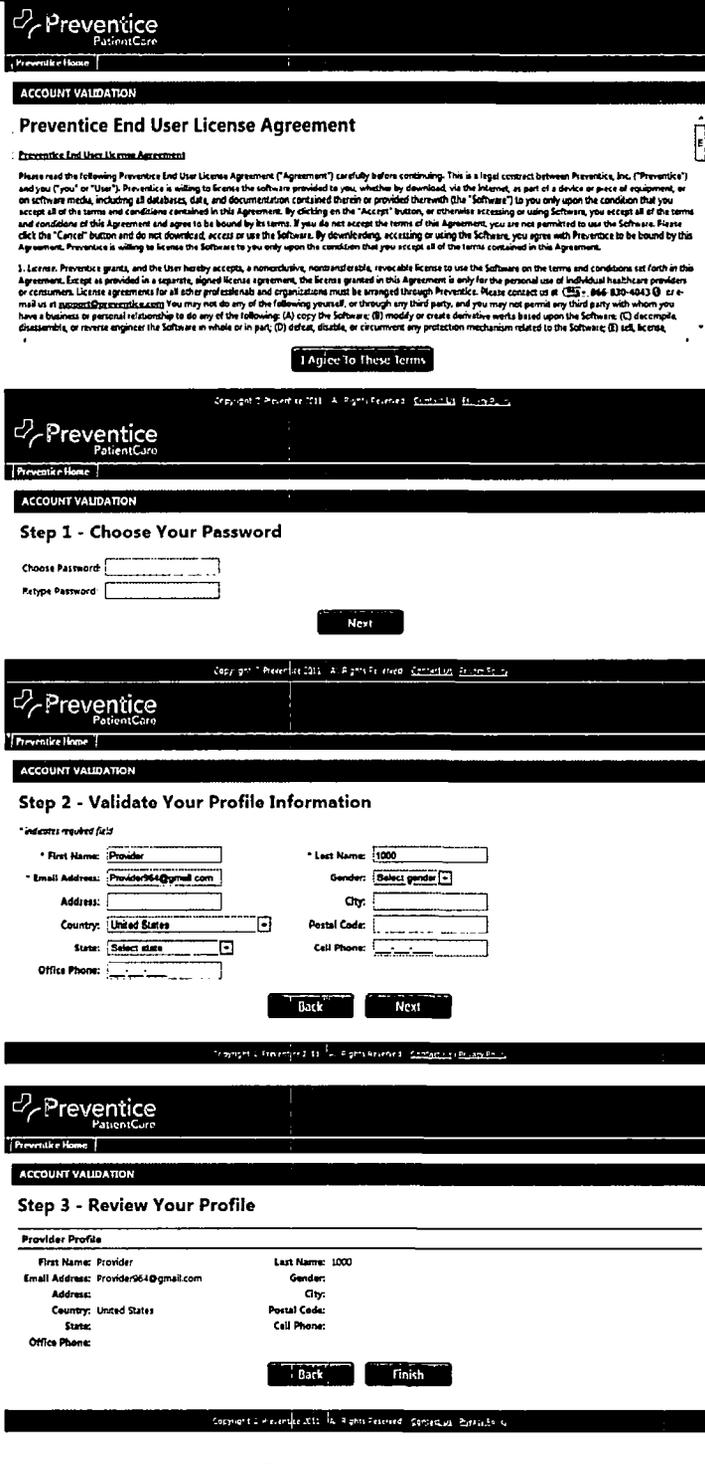


First, you need to accept the End User License Agreement to use the site. Read the agreement and click I Agree To These Terms to continue. You cannot proceed or use the PatientCare Web Portal or PatientCare for iPad tools if you do not accept these terms.

Once you agree to the terms, create your password for your profile. You use this and your User Name (Provider964 in this example) to log on to PatientCare. Passwords should follow conventions for your Institution.

Validate and update any information in your profile. Those items marked with an asterisk (*) are required.

Review your profile. If all fields are correct, click Finish.



Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Preventive End User License Agreement

Preventive End User License Agreement

Please read the following Preventive End User License Agreement ("Agreement") carefully before continuing. This is a legal contract between Preventive, Inc. ("Preventive") and you ("you" or "User"). Preventive is willing to license the software provided to you, whether by download, via the Internet, as part of a device or piece of equipment, or on software media, including all databases, data, and documentation contained therein or provided hereunder ("Software") to you only upon the condition that you accept all of the terms and conditions contained in this Agreement. By clicking on the "Accept" button, or otherwise accessing or using Software, you accept all of the terms and conditions of this Agreement and agree to be bound by its terms. If you do not accept the terms of this Agreement, you are not permitted to use the Software. Please click the "Cancel" button and do not download, access or use the Software. By downloading, accessing or using the Software, you agree with Preventive to be bound by this Agreement. Preventive is willing to license the Software to you only upon the condition that you accept all of the terms contained in this Agreement.

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I Agree to these Terms

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 1 - Choose Your Password

Choose Password:

Retype Password:

Next

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 2 - Validate Your Profile Information

* indicates required field

* First Name: * Last Name:

* Email Address: Gender:

Address:

City:

Country: Postal Code:

State: Cell Phone:

Office Phone:

Back **Next**

Preventive PatientCare
Preventive Home

ACCOUNT VALIDATION

Step 3 - Review Your Profile

Provider Profile

First Name: Provider Last Name: 1000

Email Address: Provider964@gmail.com Gender:

Address: City:

Country: United States Postal Code:

State: Cell Phone:

Office Phone:

Back **Finish**

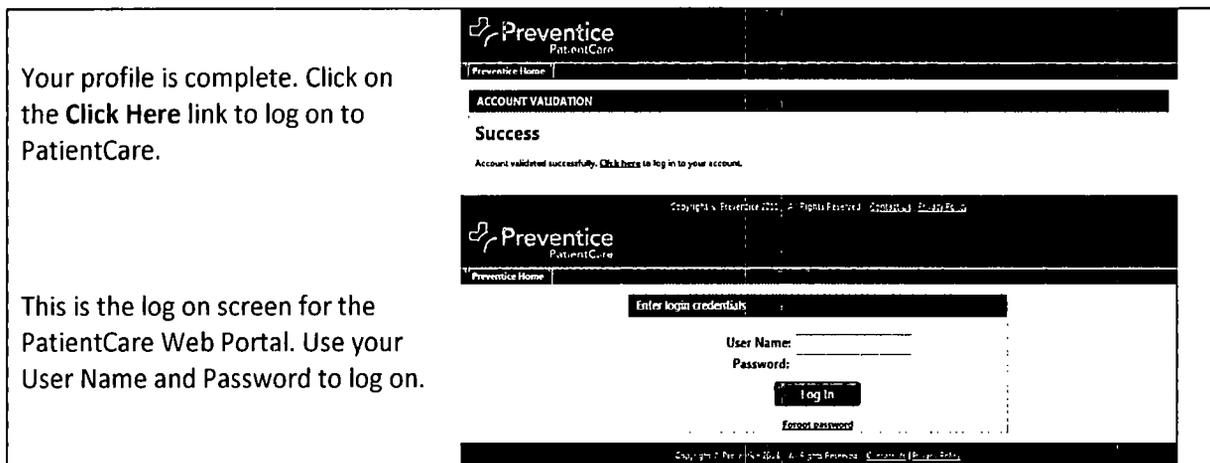


Figure 4 Validating a Provider Profile

Using the PatientCare Web Portal

You can now sign on to the PatientCare web portal and view data for your patients. See *Preventice PatientCare for iPad* on p. 30 to use the iPad app.

Patient List

When you sign on to the PatientCare portal, you see a list of all patients assigned to you (if your role is a Managing Physician or Physician, you see all patients. However, for those patients for whose data you are not authorized, you see the Patient Name only). You can view medical data for these patients. If one of your patients is missing from the list, contact your physician assistant to ensure that the patient has a profile and that you are an authorized provider.

The data you see is the latest received from the patient's BodyGuardian control unit in the last 14 days. You can view older data once you select a patient. Generally, BodyGuardian transmits data when an event occurs or at scheduled time intervals. However, if the BodyGuardian is out of range of the BodyGuardian Connect or the phone is turned off or not connected to the internet, transmission can be delayed until the phone is online and within range. If the phone cannot connect to the server, it will continue to attempt connecting until successful.





Welcome back, Mary

[Profile & Settings](#)
[Help & Support](#)
[Logout](#)

Patient List

[Add Patient](#)

The "Total Events" and "Medical Events" columns are displaying events for the last 14 days.

SORT BY: Total Events

FIND PATIENT:

Patient Name	Last Event Date	Total Devices	Total Events	Medical Events
1002_Patient	3/2/2012 @ 11:27 AM CST	4	336	Total = 365
3001_Patient	3/6/2012 @ 4:00 PM KST	17	187	Total = 118
1001_Patient	3/7/2012 @ 12:06 PM CST	4	173	Total = 45
Patient_1	10/3/2011 @ 4:56 PM CST	4	0	Total = 0
Patient_2	10/4/2011 @ 6:24 AM CST	1	0	Total = 0
3_Patient	10/6/2011 @ 8:46 AM CST	2	0	Total = 0
4_Patient	10/4/2011 @ 10:04 PM CST	2	0	Total = 0
105_Patient	11/21/2011 @ 9:17 PM CST	3	0	Total = 0
100a_Patient	10/8/2011 @ 9:01 PM CST	4	0	Total = 0
102_Patient	11/23/2011 @ 12:51 PM CST	2	0	Total = 0
103_Patient	---	2	0	Total = 0
150_Patient	---	0	0	Total = 0
104_Patient	11/21/2011 @ 4:05 PM MST	3	0	Total = 0
105_Patient	---	2	0	Total = 0
106_Patient	---	1	0	Total = 0

Viewing Patients 1 - 15 of 56

Page 1 of 4

Go to page:

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Figure 5 Patient List

The Patient List displays the following information:

Last Event Data is the date of the most recent event.

Total Devices is the total number of BodyGuardian control units assigned to a patient.

Total Events is the number of all types of events that have occurred in the last 14 days. This is the total of medical protocol events, patient initiated events and random events.

Event Summary is the medical protocol (represented by red heart with a cross) and patient initiated (represented by blue person icon) events that have occurred in the last 14 days. The column shows the number of each event type and the total of the two event types.



You can sort the list by **Last Event Date**, **Patient Name**, **Total Devices**, **Medical Protocol Events** or **Total Events**. Select a patient from the list by clicking on the name. Physicians and ECG Technicians then see the ECG Event Calendar (Figure 7); Physician Assistants and **Managing Physicians** see the Patient Profile screen (Figure 6) and click **View ECG Data** in the upper right corner.

PATIENT LIST

Patient 1001
ID #2159
View ECG Data

Patient Profile

First Name: Patient	Last Name: 1001
Gender: Male	Date of Birth: 3/1/1933
Timezones: (GMT-06:00) Central Time (US & Canada)	
Address:	City:
Country:	Postal Code:
State:	Email Address:

Edit Profile

Devices

BodyGuardian Devices - 2

Add New Device
Edit Thresholds

Device	Status	Action	Action
Dev 2 <small>00:80:01:FC:41:CD</small>	Enabled	Edit Device	Remove Device
Dev 1 <small>00:80:01:FC:41:CD</small>	Enabled	Edit Device	Remove Device

Patient License

License: #192838 - 500 Seats

Authorized to View Patient

Individual	Role	
Doc Doctor20	Prescribing Physician	Remove
M Physician Assistant	Physician Assistant	Remove

Add Provider

Figure 6 Patient Profile



data as being outside medical protocol thresholds defined for that patient. The medical events include the following:

- Bradycardia
- Tachycardia while at rest¹
- Heart rate variability
- Bradypnea
- Tachypnea while at rest²

Random event (represented by green cross) is a two-minute ECG recording randomly selected for review each hour. BodyGuardian collects this data to provide normal reference periods for the patient. No medical protocol or patient initiated event is associated with a random event.

¹ See *Heart Rate Thresholds: Beats per Minute* on p. 21 for a description of monitoring for Tachycardia.

² See *Heart Rate Thresholds: Beats per Minute* on p. 21 for a description of monitoring for Tachypnea.



ECG Strip

The first graph on the page shows 60 seconds before the event and 60 seconds after the event. A vertical line at the center of the strip represents the time the event occurred.

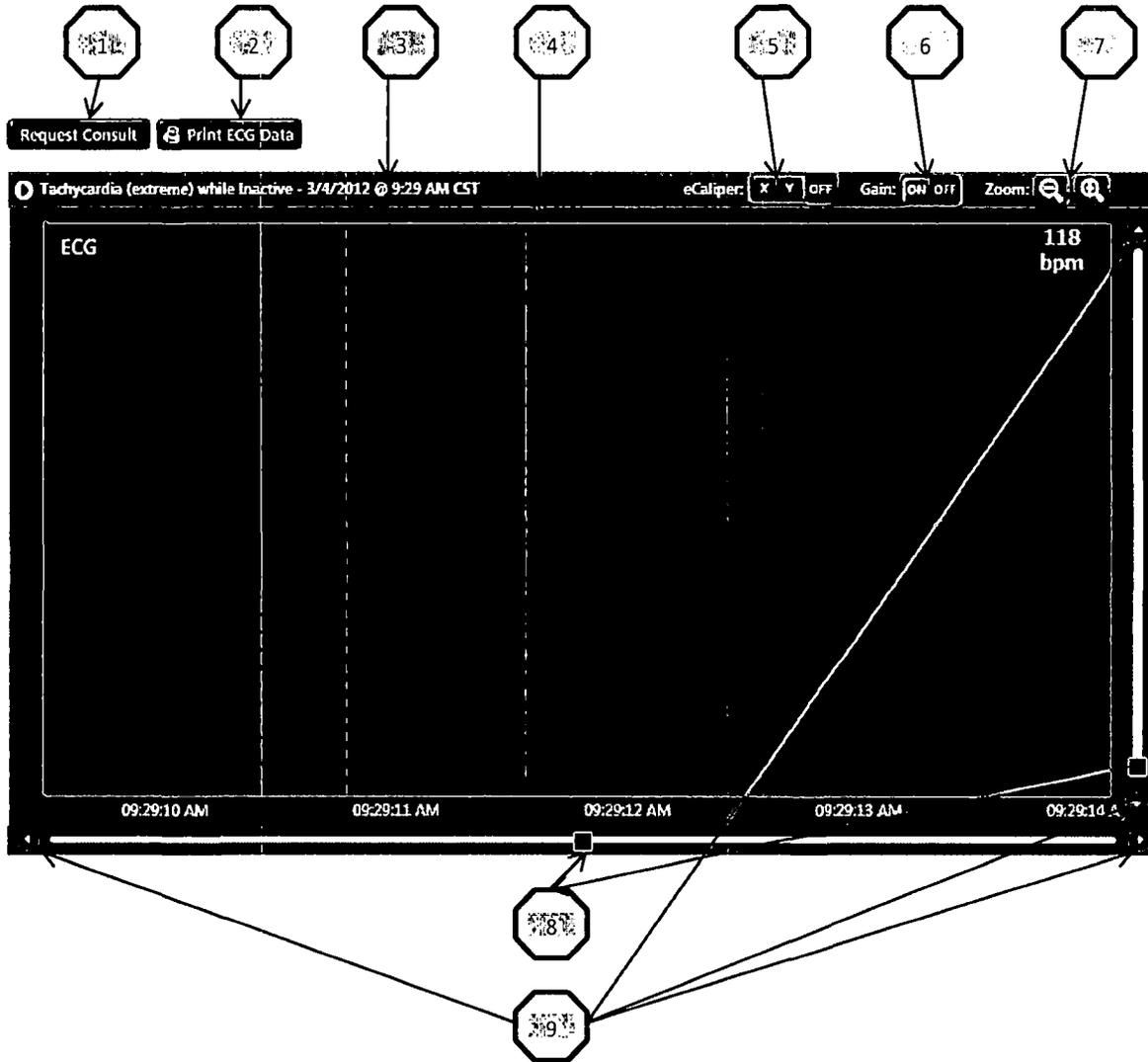


Figure 8 ECG Strip



See Heart Rate Thresholds on p 6 for the description of how BodyGuardian marks and collects cardiac data. See Heart Rate Thresholds on p. 8 for a description of the reliability of the Heart Rate data.

The X-axis shows the time with 25mm representing one second. The grid has markers for each .2-second interval (5-mm segments). The Y-axis shows cardiac voltage in millivolts.

A green ECG line indicates that signal strength was good during data acquisition. If the signal reliability drops below a defined threshold, the line is orange.

In Figure 8, callouts include the following selectable buttons and controls:

1. **Request Consult** (not shown for ECG Technicians) allows you to send a note to another health care provider in your institution or another institution requesting a patient consult.
2. **Print ECG Data** initiates a print out of data.
3. **Event Reference** specifies type of event and the time at which it occurred.
4. **Event Centerline** centers the ECG graph on the event; the full ECG strip is 120 seconds (60 seconds before and 60 seconds after the event). Approximately six seconds appears in the display at one time. Use the slider control to move the strip left or right.
5. **eCaliper X Y OFF** turns eCaliper on and specifies the axis to use or turns eCaliper off. eCaliper is a tool for measuring distances between waves and highlighting selected sections of the graph. See *ECG eCaliper* below.
6. **Gain On/Off** can specify that only the y-axis is zoomed when zoom controls is used. When Gain is off, both x and y-axes are zoomed.
7. **Zoom** magnifies in or telescopes out on the ECG display.
8. **Slider Bar Controls** move the display left or right, up or down.
9. Use **Scroll Button Controls** for slow movement and fine control of the graph position. (Left, right, up, down)

Use the left and right arrows (at the top left of the screen) to navigate to the next or previous event.



ECG eCaliper

The eCaliper is a tool you can use to work with data in the ECG display. When eCaliper is on, it measures the distance between two points on the graph and correlates that distance to time (seconds) or current (millivolts). Start eCaliper by selecting the axis to use.

ECG eCaliper: X-Axis

When you select eCaliper for the x-axis, you then select two points on the graph and measure time between those two points. You can use eCaliper on zoomed images.

Use the cursor to select one point. A small circle appears and shows the time at that point. Hold down the left-mouse button and drag the cursor to the second point (another small circle appears showing the time at that point). Release the cursor and eCaliper highlights the time interval between the points. The time (in seconds) of the highlighted segment appears in the top left of the display.

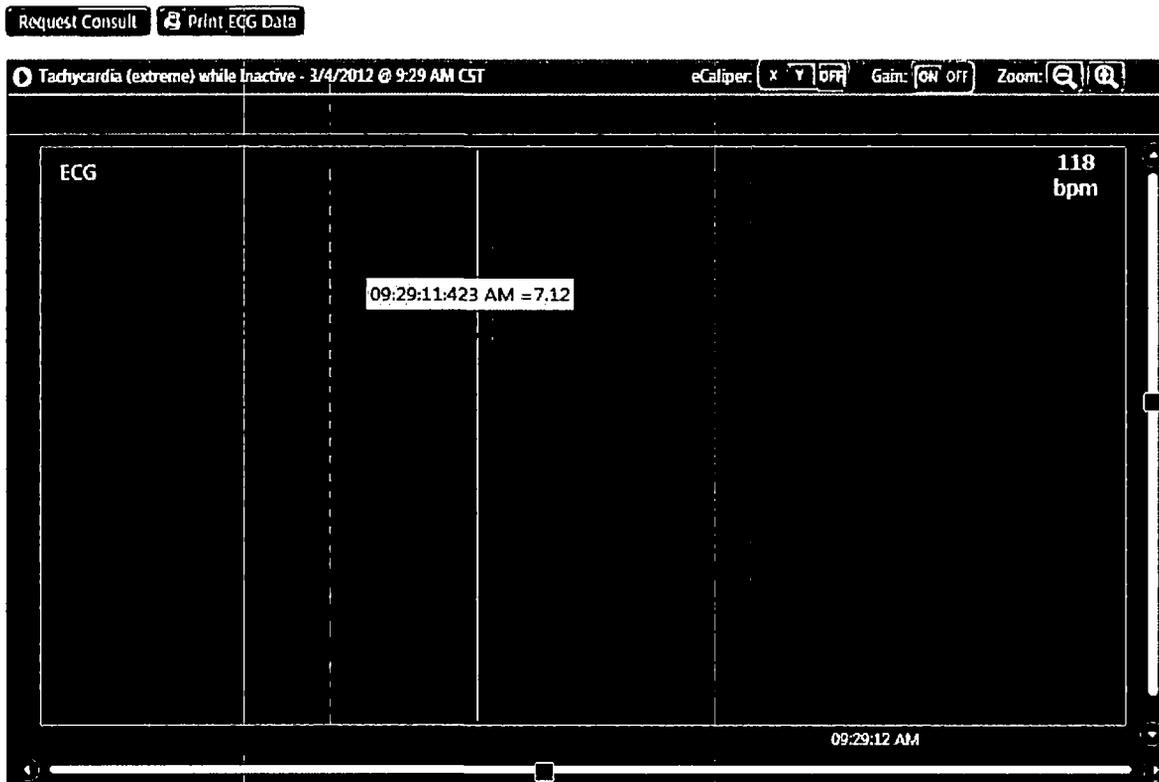


Figure 9 x-axis eCaliper with First Point Selected





Figure 10 x-axis eCaliper with Segment Defined

Note the highlighted segment of the strip. The upper left corner shows the time of the interval selected: E.g., 'You have selected 0.5346 secs'.

You can move the display left or right using slider controls at the bottom right of the display. The highlighted area is fixed. The ECG strip behind it moves up or down, left or right.



ECG eCaliper: y-Axis

When you select eCaliper for the y-axis, you select two points on the graph and measure the difference in voltage (millivolts) between those two points.



Figure 11 y-axis eCaliper with First Point Selected

Use the cursor to select one point. A small circle appears and shows the current (in millivolts) at that point. Hold down the left-mouse button and drag the cursor to the second point. Another small circle appears and millivolts (mV) at that point show. Release the cursor and eCaliper highlights the distance between the points. The millivolts (difference between the two points) of the highlighted segment is shown in the top left of the display.



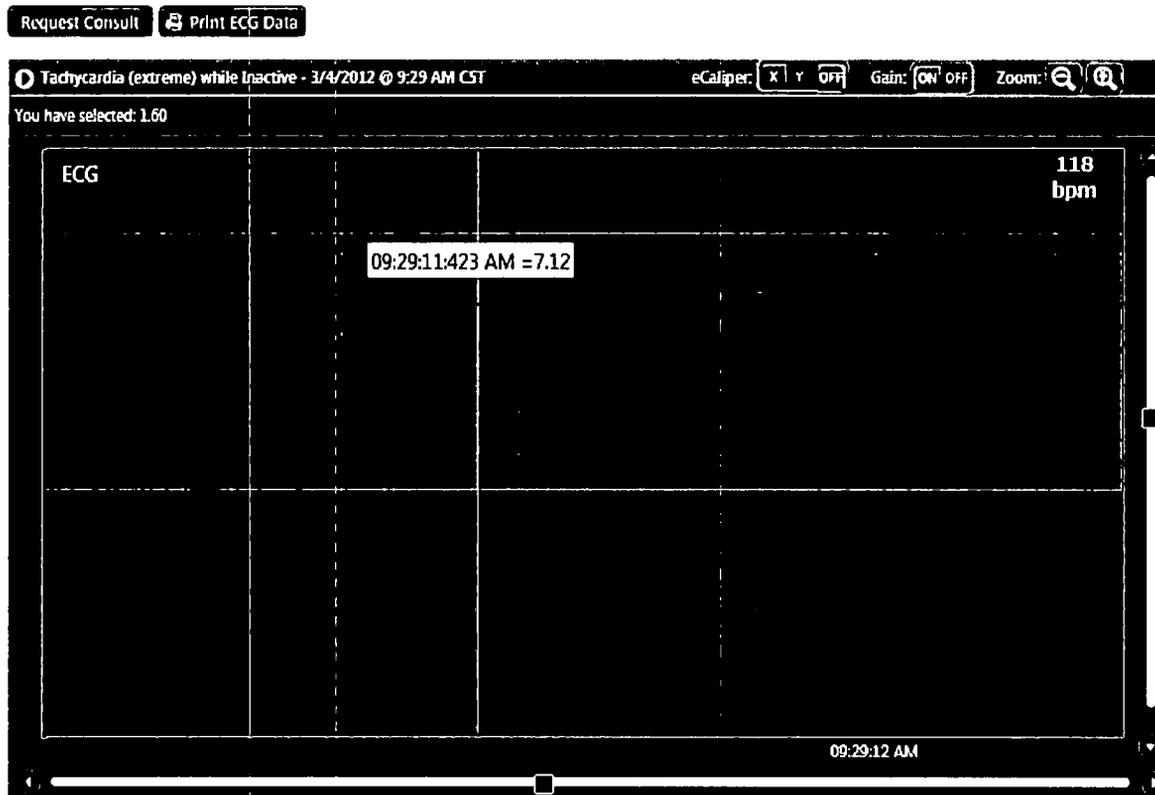


Figure 12 y-axis eCaliper With Segment Selected

Note the highlighted segment of the strip. The upper left corner shows the difference in voltage, e.g., 'You have selected 1.60.'

You can move the display up or down using the slider control at the right side of the display. The highlighted area is fixed. The ECG strip behind it moves up or down.



Heart Rate

This display shows the heart rate in beats per minute at the time of the event. See Heart Rate Thresholds on p. 6 for a description of how BodyGuardian marks, collects and derives heart rate. See ECG and Heart Rate Reliability on p. 8 for a description of the reliability of the Heart Rate data.

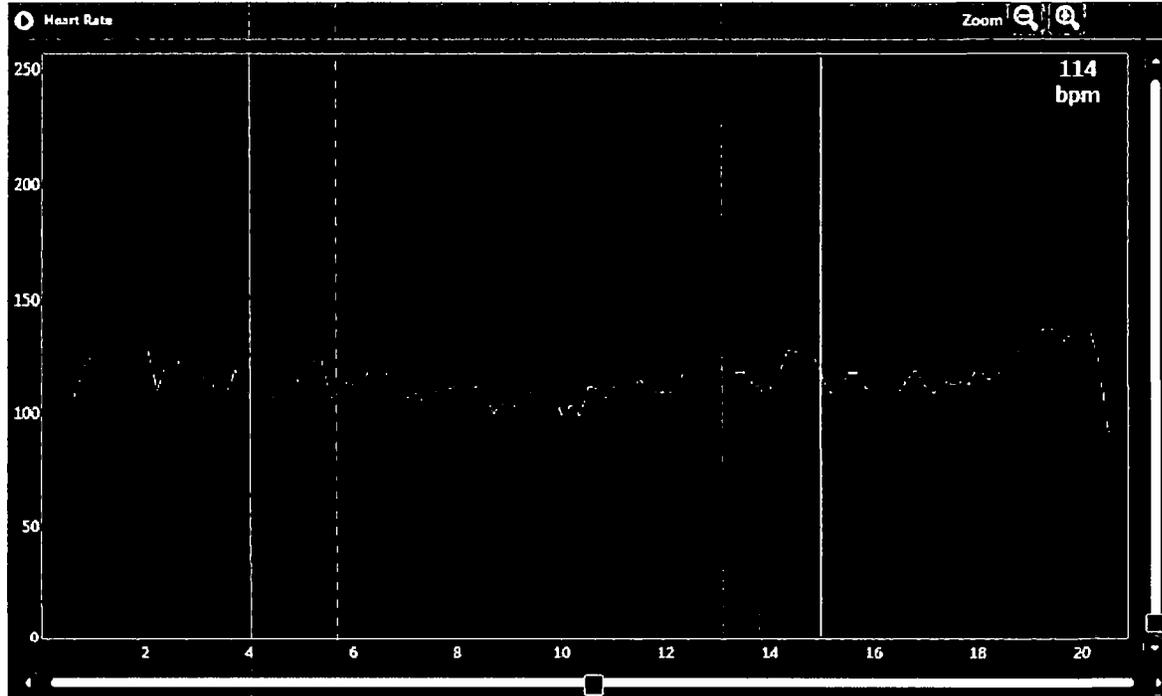


Figure 13 Heart Rate Graph

The graph shows the average heart rate over a 30-minute period. The center of the graph (represented by the bold vertical line) is the time of the selected event. You can zoom in or out on the display using the zoom buttons or move the graph left or right, up or down using the slider controls.

The heart rate shown in the upper right corner may differ from that shown on the ECG strip display because the heart rate on the display is an average over a 30-minute period. The display on the ECG strip is an average over a 2-minute period.

If the signal is unreliable, the graph line will show in orange.



Respiration Rate

This display shows the rate of respiration in breaths per minute at the time of the event. See Respiration Rate Thresholds on p. 7 for the description of how BodyGuardian derives respiration rate. See Respiratory Rate Reliability on p. 8 for a description of how BodyGuardian ensures signal integrity.

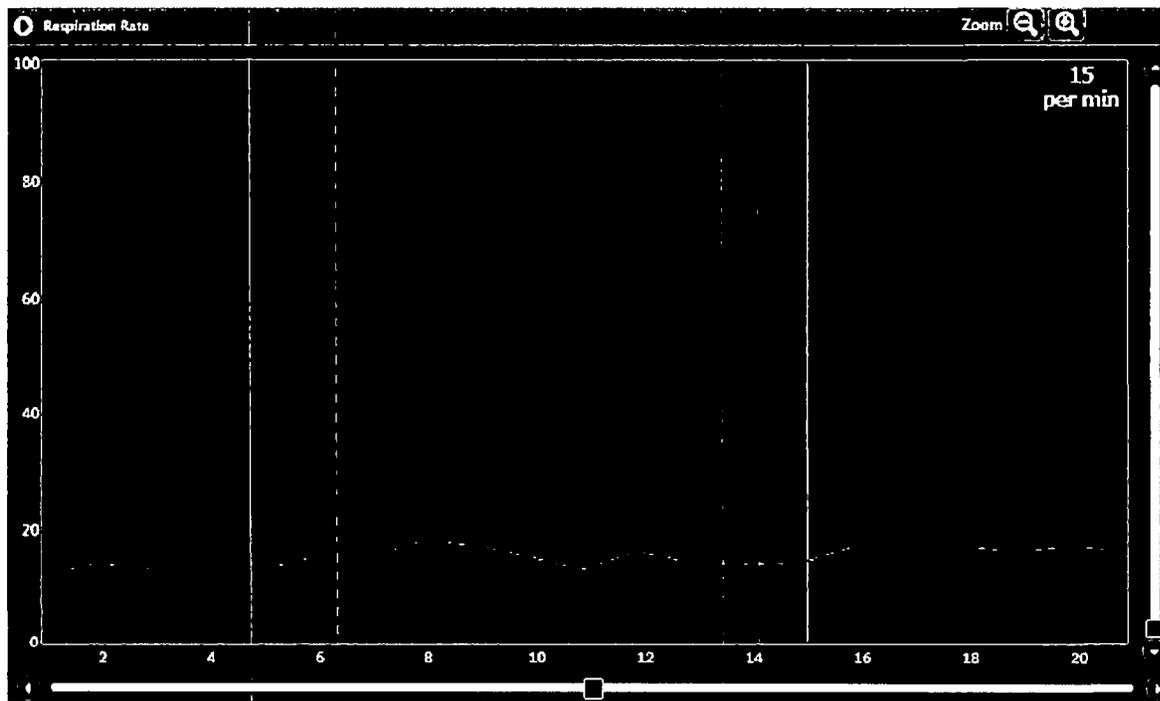


Figure 14 Breathing Rate Graph

The graph shows the average breathing rate in breaths per minute for the full 30 minutes with the graph centered on the time of the event. You can zoom in or out on the display using the zoom buttons or use the slider controls to move the display left or right, up or down.



Activity Level

This display shows the level of activity at the time of the event. The y-axis scale is from zero (no activity) to 100 (very high level of activity). The BodyGuardian control unit calculates the level using the values measured by the 3-axis accelerometer in the BodyGuardian control unit. See Activity Level Threshold on p. 7 for a description of how Activity Level is collected.

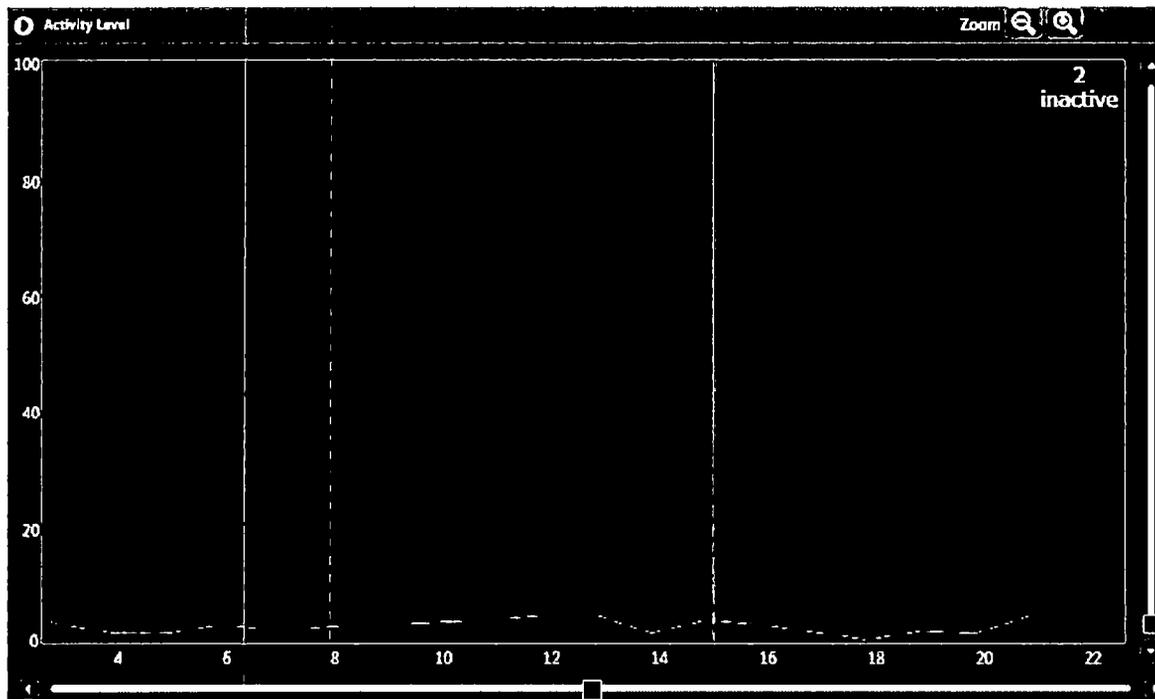


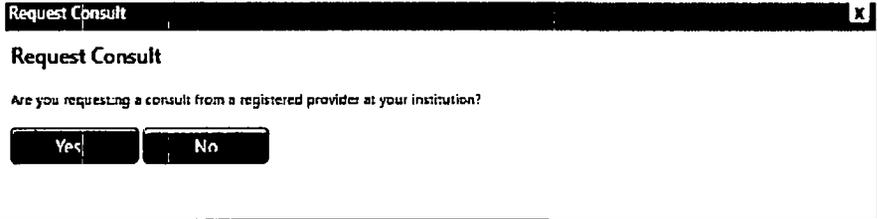
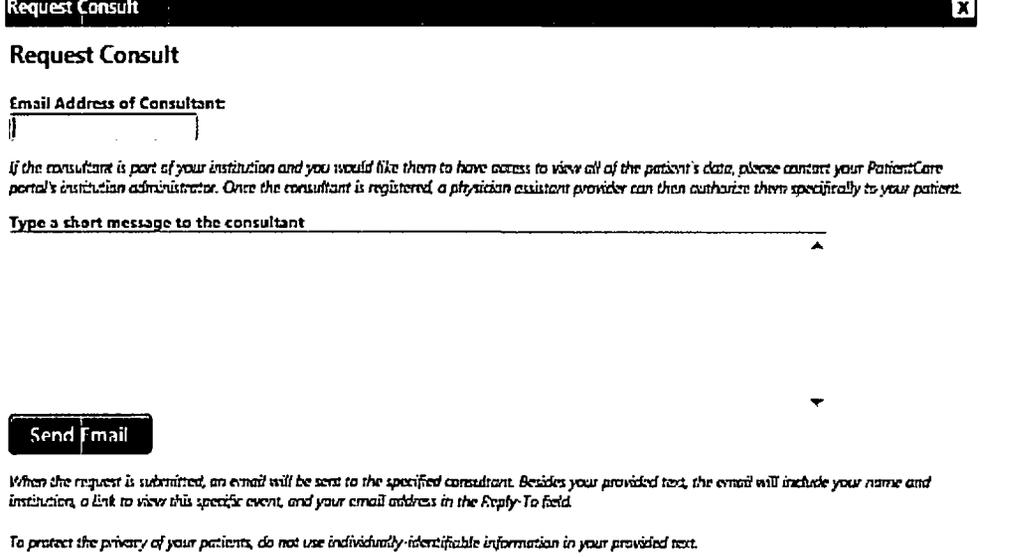
Figure 15 Activity Level Graph

The display shows a 30-minute graph with the graph centered on the time of the event and the average activity level (2 in this sample) for 30 minutes. The bold vertical line represents the event. If the average activity level is over the patient activity-level threshold, the value is **active**. Otherwise, the **inactive** label shows. You can zoom in or out on the display using the zoom buttons or move the display left or right, up or down using the slider controls.



Request Consult

Request Consult is not available to ECG Technicians. When you request a consult, a window appears asking whether the physician you want to consult is within your institution. If the consultant has a provider license for your institution, you can select the name from a provider list. If not, enter the consulting physician's email address. Use the text box to add a description of the patient and the event. Preventice sends your request as an email to the consultant. The email contains the notes you entered and a link to the cardiac data screen for the patient. Your email is the Reply-To address for the consultant's reply. The link is available for 30 days.

<p>Select whether the consulting physician is in your institution.</p>	
<p>Specify an email address and add a description of the reason for a consult.</p>	



<p>The consulting physician receives an email.</p>	<p>Preventice +</p> <p>M Physician Assistant from Manges Med would like you to consult on a cardiac event and has attached these notes:</p> <hr/> <p>Please take a look at this ECG strip for a 29-year old male in good condition.</p> <p>To view the cardiac event data, click on the provided link.</p> <p>Click here to view the cardiac event data for the patient</p> <p>If you are not able to successfully click on the link directly from this e-mail message, cut and paste the following URL into your browser's address field:</p> <p>Tips:</p> <ul style="list-style-type: none">• The link will remain active for 30 days• You can respond directly to the requestor by using the Reply button on this email• Use Internet Explorer or Firefox browsers when viewing the cardiac event data
--	--

Figure 16 Request Consult Flow

Patient Profile

Select **View Patient Profile** from the ECG Event Calendar (see Figure 7 on p.14).



PATIENT LIST

Patient 1001
ID #2159
View ECG Data

Patient Profile

First Name: Patient	Last Name: 1001
Gender: Male	Date of Birth: 3/1/1933
Timezones: (GMT-06:00) Central Time (US & Canada)	
Address:	City:
Country:	Postal Code:
State:	Email Address:

Edit Profile

Devices

BodyGuardian Devices - 2

Add New Device
Edit Thresholds

Device	Status	Action	Action
Dev 2 00:80:E1:FC:41:CC	Enabled	Edit Device	Remove Device
Dev 1 00:80:E1:FC:41:CD	Enabled	Edit Device	Remove Device

Patient License

License: #192838 - 500 Seats

Authorized to View Patient:

Individual	Role	
Doc Doctor20	Prescribing Physician	Remove
M Physician Assistant	Physician Assistant	Remove

Add Provider

Figure 17 Patient Profile

You can edit medical thresholds by clicking on **Edit Thresholds**. You do not see this button if your role is ECG technician.

Changing Medical Protocol Thresholds

You may need to adjust the original medical threshold values defined for a patient. The following display allows you to make necessary changes:



Edit thresholds
X

Heart Rate Thresholds (beats/min)

Bradycardia

Tachycardia While At Rest

Heart Rate Variability

Activity Level Thresholds

At Rest

Respiration Thresholds (breaths/min)

Bradypnea

Tachypnea While At Rest

Device Thresholds

Reliability

Sensitivity

Communication Interval

Figure 18 Changing Thresholds

Change thresholds by moving slider controls with your mouse or by entering the value in the box.

Heart Rate Thresholds: Beats per Minute

Bradycardia defines the minimum heart rate for a patient in beats per minute. Default value is 40 bpm.

Tachycardia While at Rest specifies the point at which the heart rate is too high while activity level of activity is below defined activity level threshold. Default value is 120 bpm.

Note: You can set the thresholds to monitor for tachycardia. Set the **Activity Level Threshold** to its maximum and the **Tachycardia While at Rest** threshold to the desired Tachycardia threshold.

Heart Rate Variability specifies the maximum acceptable variance in heart rate. Set as a beats per minute variability and defaults to 36-bpm. If the calculated heart rates changes by more than this amount over two preset time intervals (10-seconds), an event is set.

Activity Level Threshold

A 3-axis accelerometer (horizontal, vertical and side-to-side) in the BodyGuardian control unit determines activity level. The threshold specified indicates when the patient is at rest. Values specified are from one to 100, with 100 being high activity. The value here indicates when the patient is at rest. The default threshold is 10.

Respiration Rate Thresholds

Bradypnea specifies the minimum acceptable respiration rate in breaths per minute.

Tachypnea (while at rest) specifies the point at which the respiration rate is too high while the level of activity is low below the low activity level threshold.

Note: You can set the thresholds to monitor for Tachypnea (abnormally rapid breathing). Set the **Activity Level Threshold** to its maximum and the **Tachypnea While at Rest** threshold to the



desired tachypnea threshold.

Device Thresholds

Reliability Threshold specifies the level below which signals received by the BodyGuardian control unit are considered unreliable. Expressed as a percentage value of good ECG samples with zero being no signal and 100 being the best signal

Sensitivity defines how sensitive BG Control unit is to noise and artifacts on the cardiac signals. Specified as a relative from zero to 100 (default of 50). For patients with little muscle or flesh mass, a lower sensitivity level may be needed; for those with higher levels of muscle or flesh mass, a higher sensitivity level may be needed.

Communication Interval specifies how often the BodyGuardian control unit sends cardiac data when no medical protocol or patient initiated events have occurred. Default value is 60 minutes.



Preventice PatientCare for iPad

Figure 19 provides an overview of the flow for using the Preventice BodyGuardian. This document covers the physician's use of an app, the Preventice PatientCare for iPad, on an Apple iPad tablet computer to view patient cardiac data collected by BodyGuardian.

Note: The iPad is not provided with the BodyGuardian system.

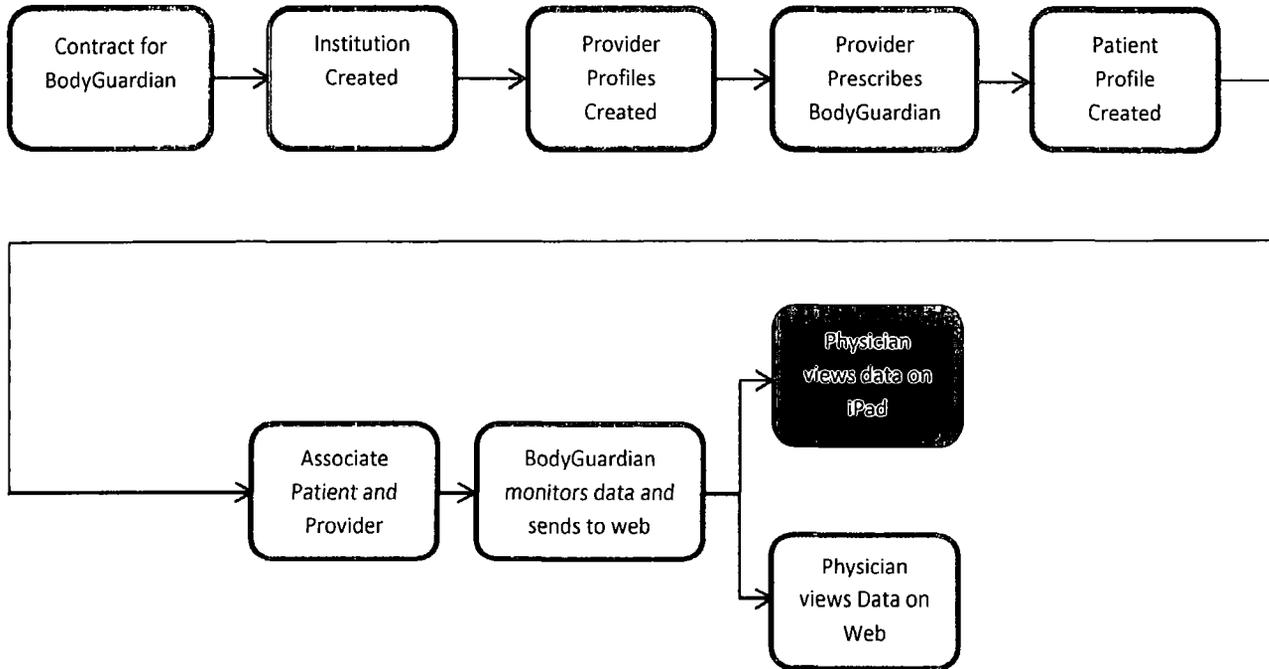


Figure 19 Overall Flow of BodyGuardian

Contact your Institution Administrator to get the PatientCare for iPad App.

Using the PatientCare for iPad App

Before you can use the PatientCare for iPad app, you must have an active profile for the PatientCare site. Your institution administrator creates your profile and Preventice sends you a validation email (see PatientCare Provider Profiles on p. 6). Figure 4 on p. 11 shows the steps required to validate your profile.

Figure 20 provides an overview of the displays shown when using the PatientCare for iPad app.



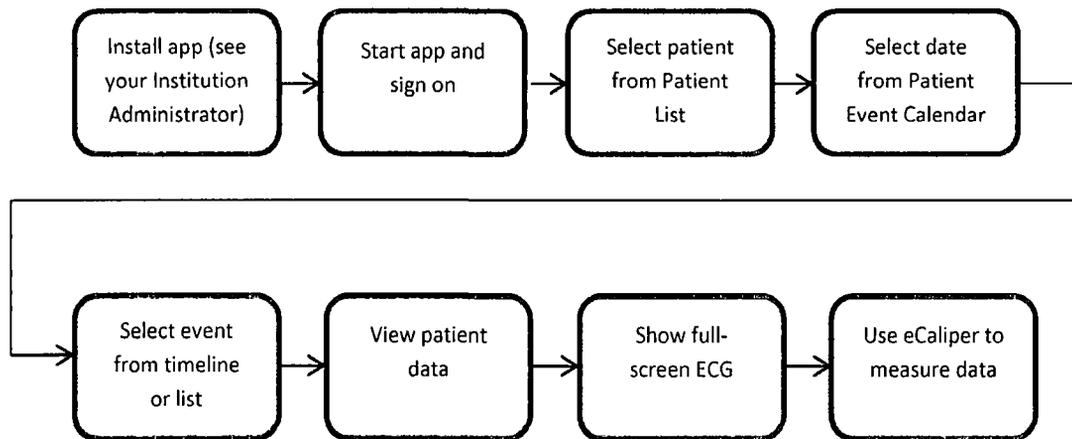


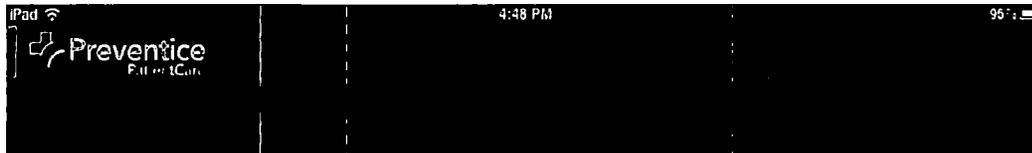
Figure 20 PatientCare for iPad App Flow

Starting the PatientCare app



Start the application by tapping its icon on the iPad. When the app opens, log in with your credentials (user-name and password).





Log In

User name:

Password:

Log In



Figure 21 iPad Log in Screen

Home (Patient Activity View)

The patients shown on the list are those whose medical data you can view. If one of your patients is missing from the list, ask your physician assistant to ensure that the patient has a profile and that you are an authorized provider.



Patient Patient ID	Last Download Date Synchronization details	Recent Patient Data Detail to be synchronized	Sync data
100, Patient 1834	Never 0 0 Total:0	Never 0 0 Total: 0	
1001, Patient 2159	Never 0 0 Total:0	27 minutes ago 2 9 Total: 54	
100a, Patient 1743	Never 0 0 Total:0	4 months ago 0 0 Total: 0	
102, Patient 1744	Never 0 0 Total:0	3 months ago 0 0 Total: 0	
103, Patient 1747	Never 0 0 Total:0	4 months ago 0 0 Total: 0	
104, Patient 1755	Never 0 0 Total:0	3 months ago 0 0 Total: 0	
105, Patient 1758	Never 0 0 Total:0	Never 0 0 Total: 0	

Figure 22 Patient Activity on iPad

Last Download Date is the date data was last downloaded from PatientCare for this patient. The number of medical protocol (represented by red heart with a cross) and patient initiated (represented by blue person icon) events that have occurred in the last 14 days are shown below the date. The total entry includes medical protocol, patient initiated, and random events.

Recent Patient Data is the date and time information was last sent from the patient's BodyGuardian control unit to PatientCare. If this date is later than the last download to iPad date, current data is available at PatientCare. The number of medical protocol (represented by red heart with a cross) and patient initiated (represented by blue person icon) events that have occurred in the last 14 days are shown below the date. The total entry includes medical protocol, patient initiated, and random events.

Sync Data When there is newer patient data at PatientCare than on the iPad (as noted when the



times are different in columns two and three), tapping that arrow initiates a data transfer from the server to the iPad.

Tap on a patient and, when the Patient Calendar screen appears, tap on the date of the event you want to view. The events calendar screen (see Figure 23) displays.

Tap the **Refresh List** button to update the patient entries with new information.

Cardiac

Tapping the **Cardiac** button takes you back to the last Patient Calendar List of Events display you were viewing.

Patient Calendar of Events Display

The calendar part of the display shows the month with event indicators on the days an event occurred. If no patient data is on the iPad, the current month displays. If there is patient data on the iPad, the month in which the last event occurred displays (with the day of that event highlighted). Tap any day and the data for that date displays.



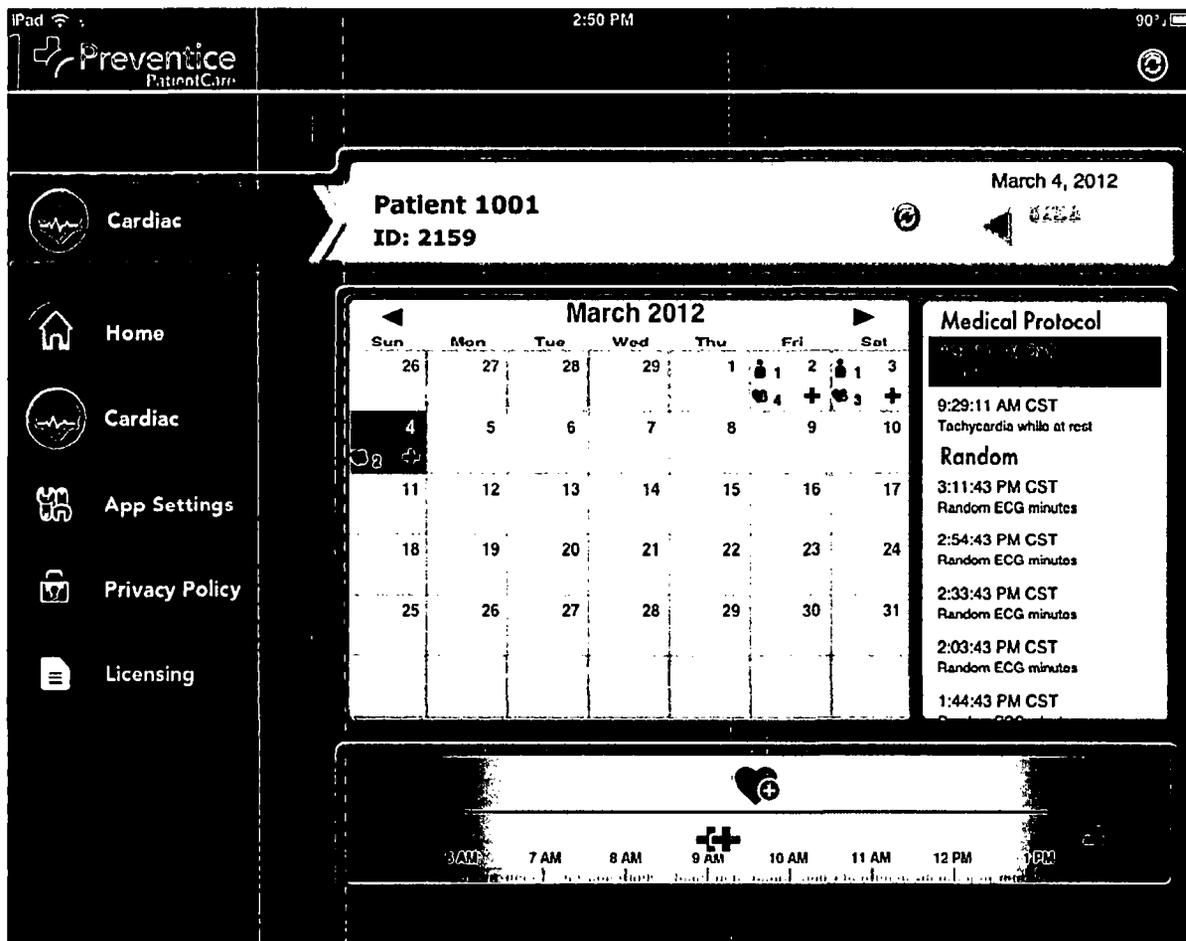


Figure 23 Event Calendar on iPad

The right side of the calendar display lists the events by type and time of occurrence. Tap any event to see the cardiac data associated with that event.

An event timeline is under the calendar. The lower part represents the 24-hour day and the upper part shows when events have occurred on that timeline. If an event indicator is gray, the data for that event has not been loaded to the iPad from the server. Tap the indicator and the app requests the data from PatientCare. A filled in indicator indicates that the data is available on the iPad. A red heart with a plus sign indicates a medical protocol event, a blue person picture is a patient initiated event and a green plus sign is a random ECG strip.

Tap any event from the event list or the event timeline, and the data for that event displays on the Patient Event Display (see Figure 24.)

Event Data Display

The patient event data display (Figure 24) shows the recorded data for the selected event.



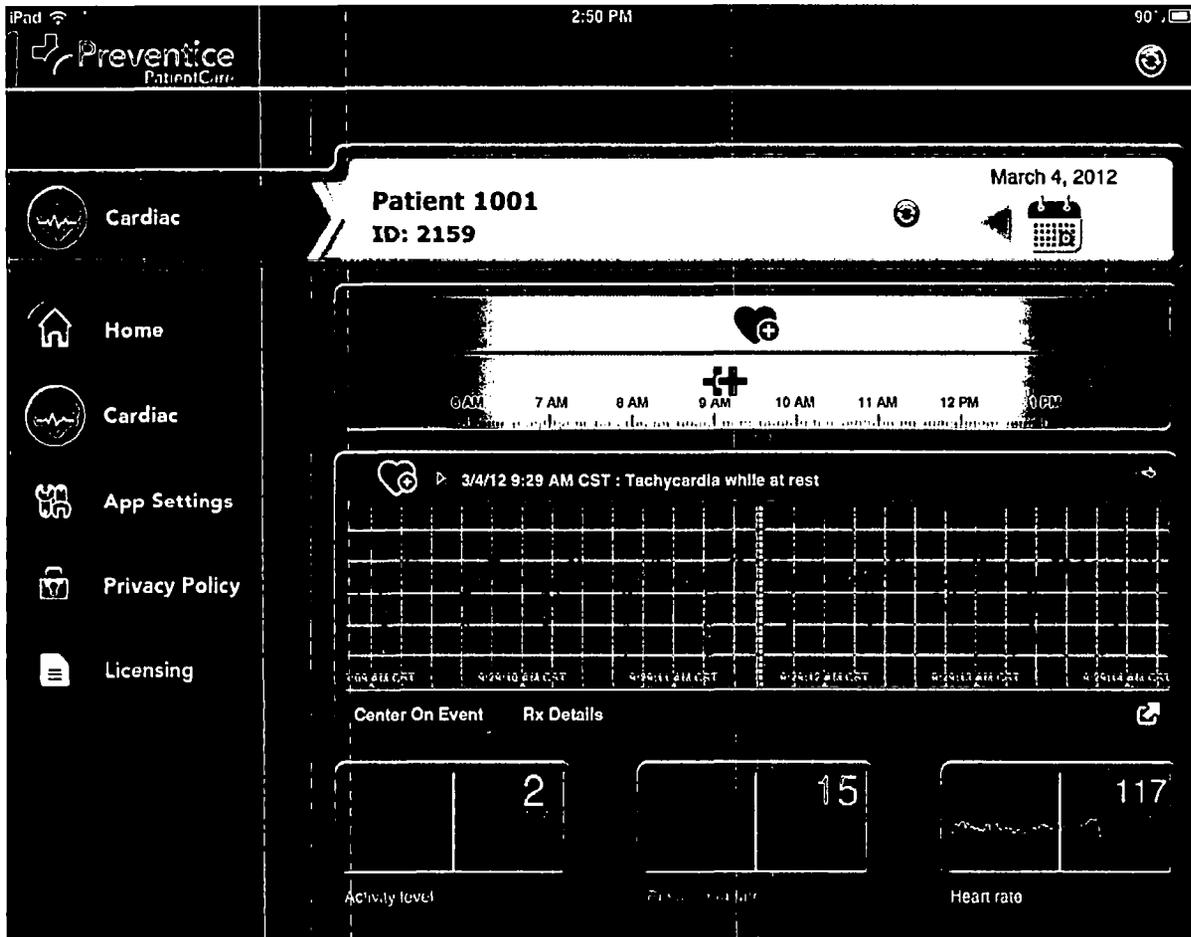


Figure 24 Event Display on iPad

The Patient Event Display has five parts.

Event timeline with the selected event highlighted (the event icon is enlarged).

ECG strip shows cardiac data from up to one minute before and one minute after the selected event. See Heart Rate Thresholds on p. 6 for the description of how BodyGuardian marks and collects cardiac data. See on p. 8 for a description of the reliability of the ECG data.

Activity level shows activity level at the time of the event. A thirty-minute graph displays with the graph centered on the time of the event. The number shown is the average activity level over the 1-minute before and 1-minute after the event. See Activity Level Threshold on p. 7 for a description of how Activity Level is collected.

Respiration rate is the rate of breathing in breaths per minute at the time of the event. A thirty-minute graph displays with the graph centered on the time of the event. The number shown is the average respiration rate over the 1-minute before and 1-minute after the event. See



Respiration Rate Thresholds on p. 7 and Respiratory Rate Reliability on p. 8.

Heart rate is average heart rate over the 1-minute before and 1-minute after the event. The center of the graph (represented by the bold vertical line) is the time of the selected event.

If the signal is unreliable, the graph line will show in orange. See Heart Rate Thresholds on p. 6 for the description of how BodyGuardian marks and collects cardiac data. See ECG and Heart Rate Reliability on p. 8 for a description of the reliability of the Heart Rate data.

On this display, you can:

- **Tap Center on Event** positions the ECG strip at the exact time of the event at the middle of the screen and shows a bold pale pink vertical line at that point.
- Tap **View Rx Details** to see details on the thresholds that generated the event. See *Displaying Rx Details* on p. 44 .
- Tap the arrow  in the lower right of the ECG strip to see a full screen view of the ECG strip.
- Navigate from day to day with the forward and back arrows on either side of the calendar icon.
- Select an event from the event timeline. If an event indicator is hollow, the data is not on the iPad.
- Navigate from event to event using the forward and back arrows on the event timeline.
- Tap the purple and orange arrows at the top to synchronize all data for the patient.
- Tap the purple and orange arrows on the ECG strip to synchronize data for that event.



ECG Data Display

Figure 25 shows the full screen ECG strip display. See Heart Rate Thresholds on p. 6 for the description of how BodyGuardian marks and collects cardiac data. See on p. 8 for a description of the reliability of the data.

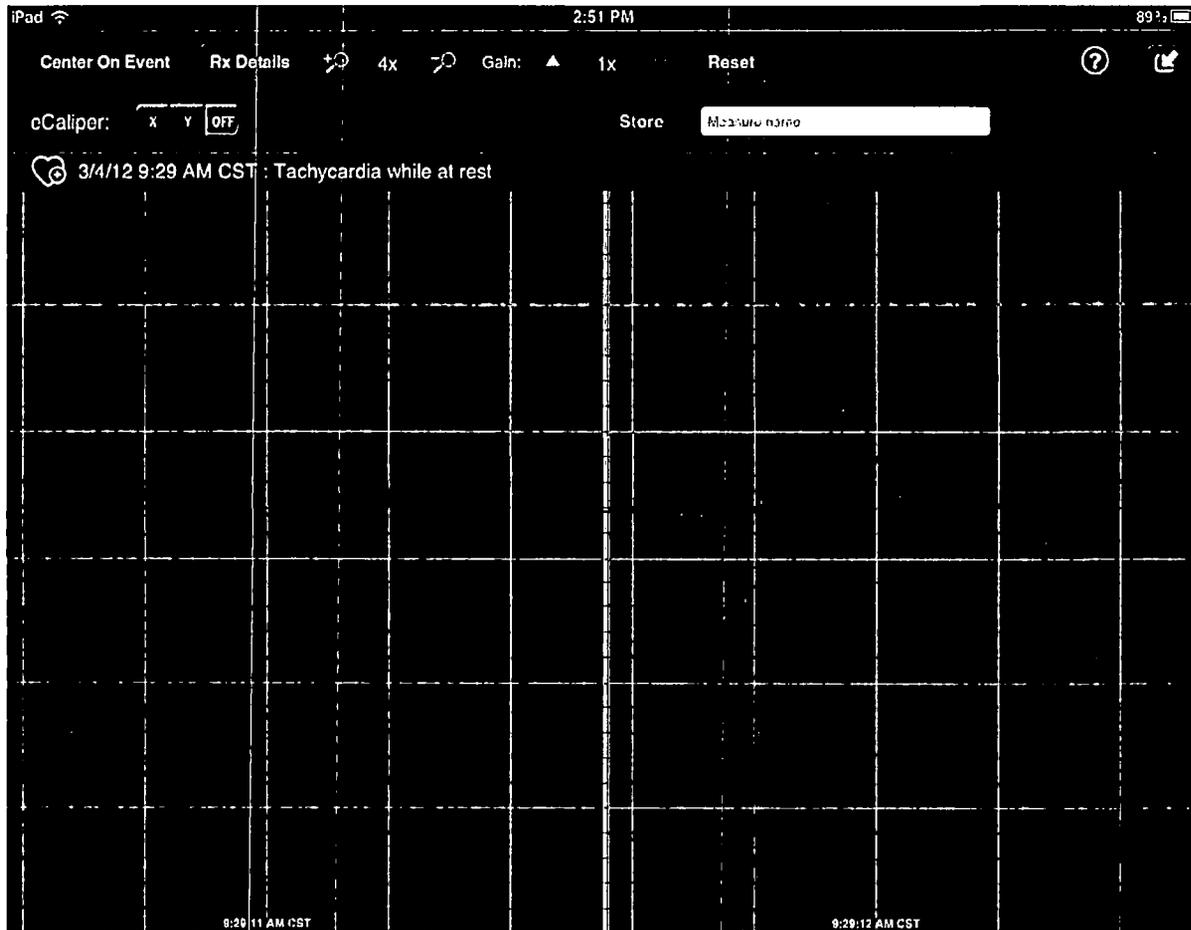


Figure 25 Full Screen ECG on the iPad

The upper left of the screen shows the selected event.

eCaliper selects the axis, x or y, to apply eCaliper against (or, turns off eCaliper). When eCaliper is on, you use the slider controls to manipulate the portion of the strip shown. The caliper is off when you first see this display for a patient. See *ECG eCaliper* on p. 40.

Center on event positions the ECG strip at the exact time of the event at the middle of the screen and shows a bold white vertical line at that point.

Rx Details tapping this shows the thresholds that caused this medical event to be set (see *Displaying*



Rx Details on p. 44.)

Gain works against the y-axis only and is similar to zoom control (magnify or shrink the view). Touch the up-arrow to increase gain or the down arrow to decrease.

Zoom in (magnifying glass with a +) or out (magnifying glass with a -) on the entire display.

Resets the zoom and gain back to their original state. The eCaliper and eCaliper history do not change.

Toggle Full screen mode , tap to go back to the Patient Event Display (Figure 24 on p.36.).



Shows hints on using eCaliper.



ECG eCaliper

The eCaliper is a tool you can use to work with data in the ECG display. When the eCaliper is on, it measures the distance between two points on the graph and correlates that distance to time (seconds) or current (millivolts (mV)). Tap **eCaliper X** (or, double tap on the screen) to turn on for the x-axis or **eCaliper Y** for the y-axis.

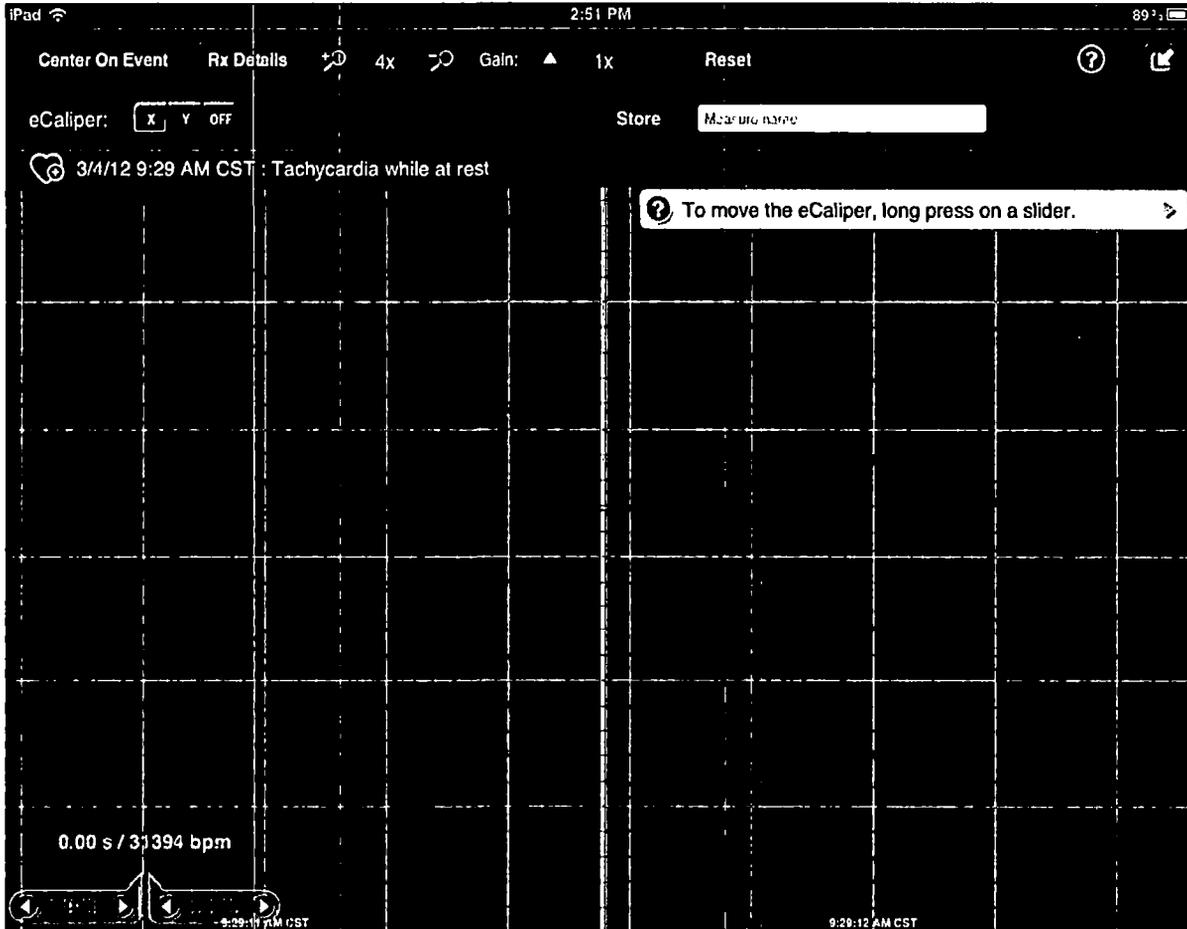
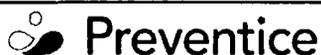


Figure 26 eCaliper Initial Screen

ECG eCaliper: X-Axis

When you select eCaliper for the x-axis, you can select two points on the graph and measure time between those two points. You can use eCaliper on zoomed charts.

Use a slider control (touch and drag the slider bar) to select one point. As you move the slider, text appears showing the time between points and the calculated heart rate. You fine-tune the positions using the left and right arrows on the slider controls. The time (in seconds) of the highlighted segment appears in the top left of the display.



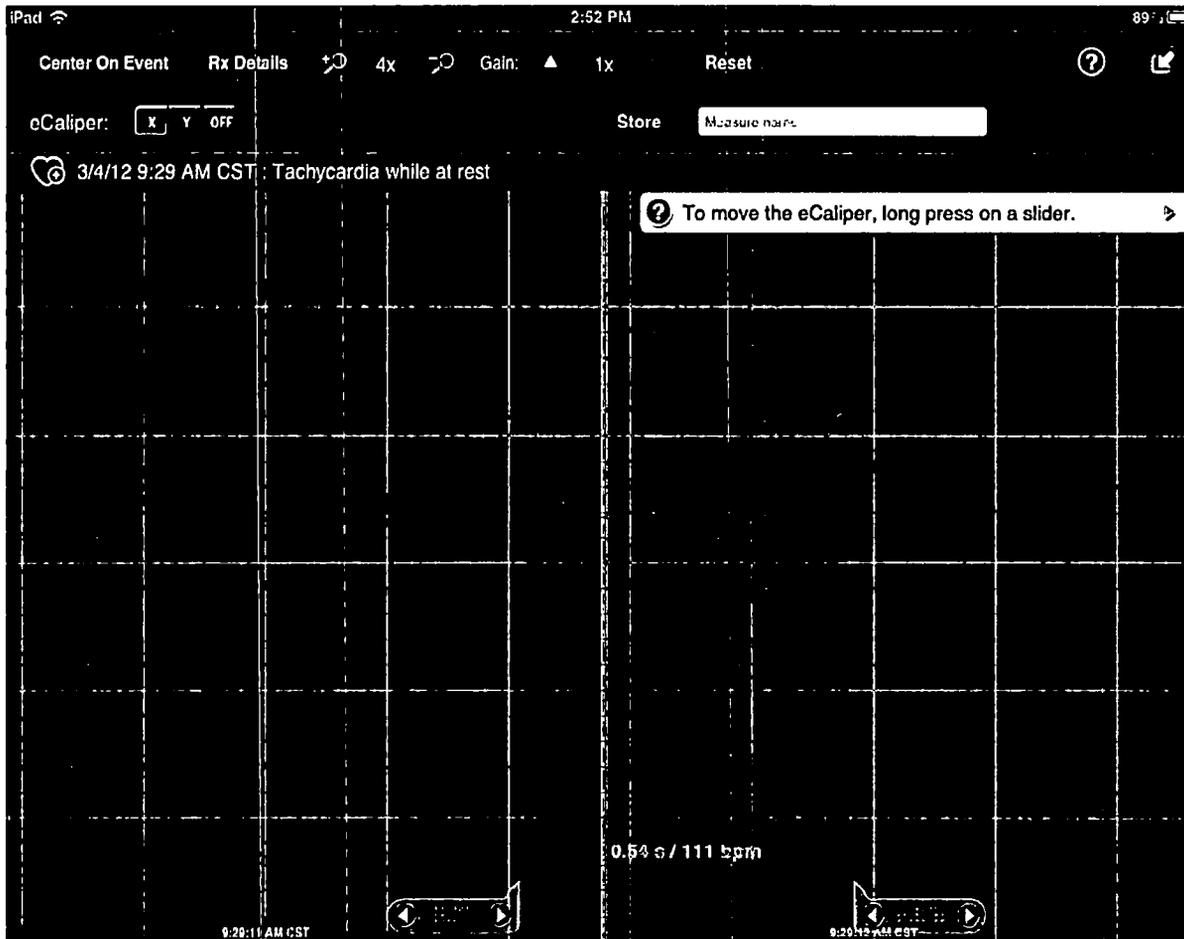


Figure 27 eCaliper on x-axis for iPad

Note the highlighted segment of the strip. The text in the highlighted area (1.05 s / 57 bpm) is the time, in seconds between the two points and the calculated heart rate in that interval.

You move the screen left or right by dragging the screen. You move the highlighted area by long pressing (touching and holding) a slider control; a directional icon appears and you can move the highlighted area left or right.



ECG eCaliper: y-Axis

When you select eCaliper for the y-axis, you can select two points on the graph and measure the difference (in millivolts) between those two points.

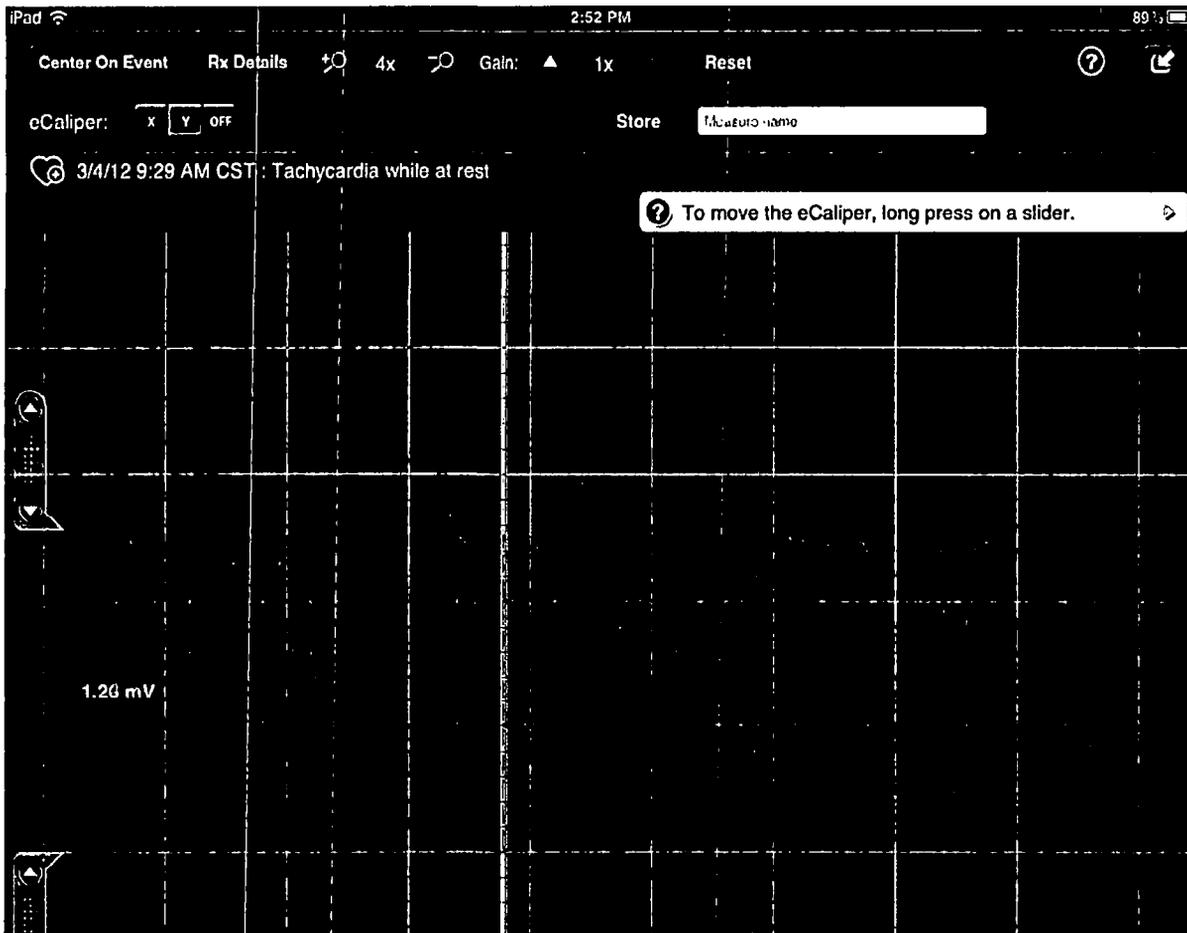


Figure 28 eCaliper for y-axis on the iPad

Note the highlighted segment of the strip. The millivolts (0.17 mV in this example) are the difference between the two selected points.

You can move the display up or down by touching and dragging the screen. You move the highlighted area by long pressing (touching and holding) a slider control; a directional icon appears and you can move the highlighted area up or down.

Saving and Retrieving ECG Measurements

You can save (store) any measurements you select in eCaliper and retrieve those for later viewing. To store a measurement, select the desired interval and then tap the box to the right of Store. The iPad keyboard appears (see Figure 29 on p. 43.)



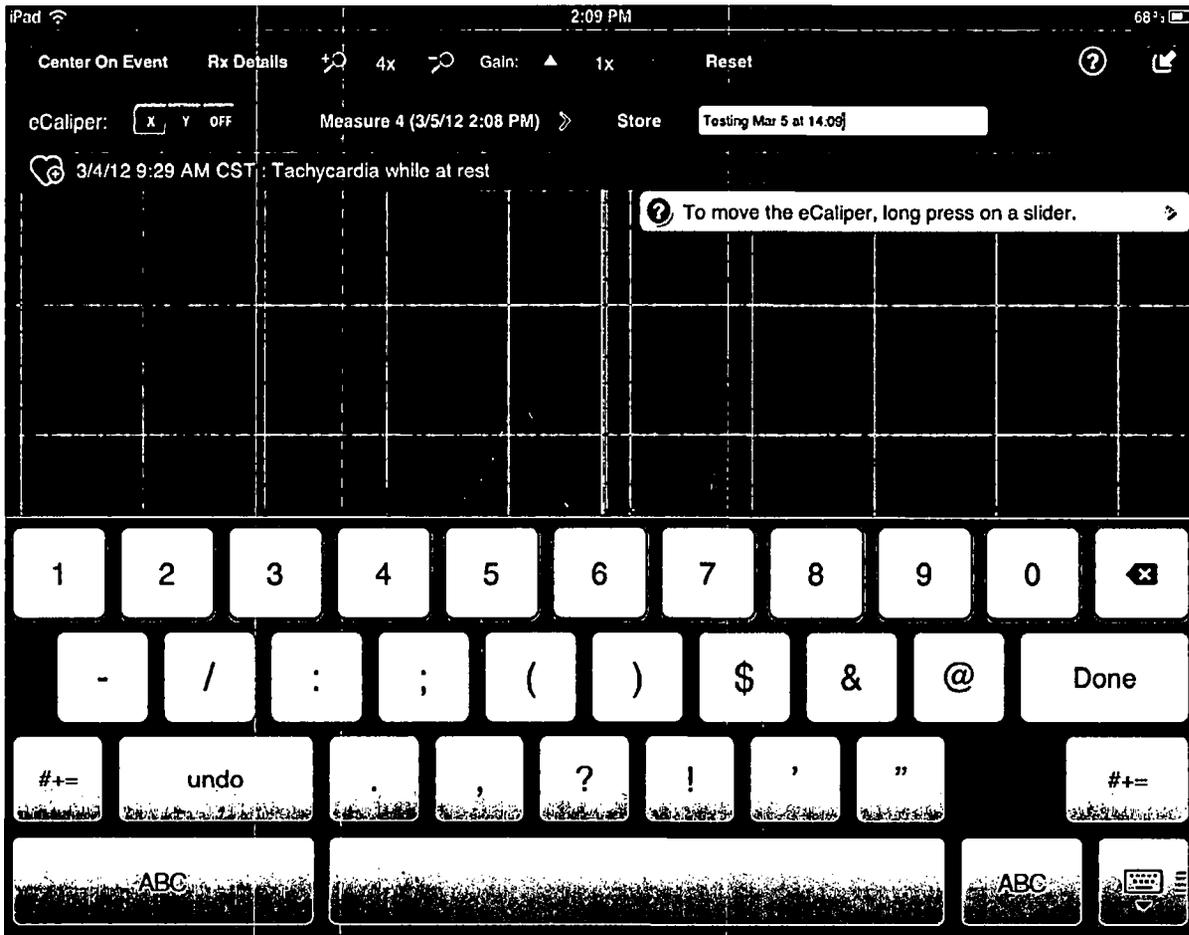


Figure 29 Storing eCaliper Measurements

Enter the name you want for the measurement and tap **Store**; the app automatically adds the current date and time to the name.

To recall a stored measurement, tap on the arrow (>) to the left of **Store**; the available stored measurements appear (Figure 30). Tap the desired measurement and the display updates using that measurement.



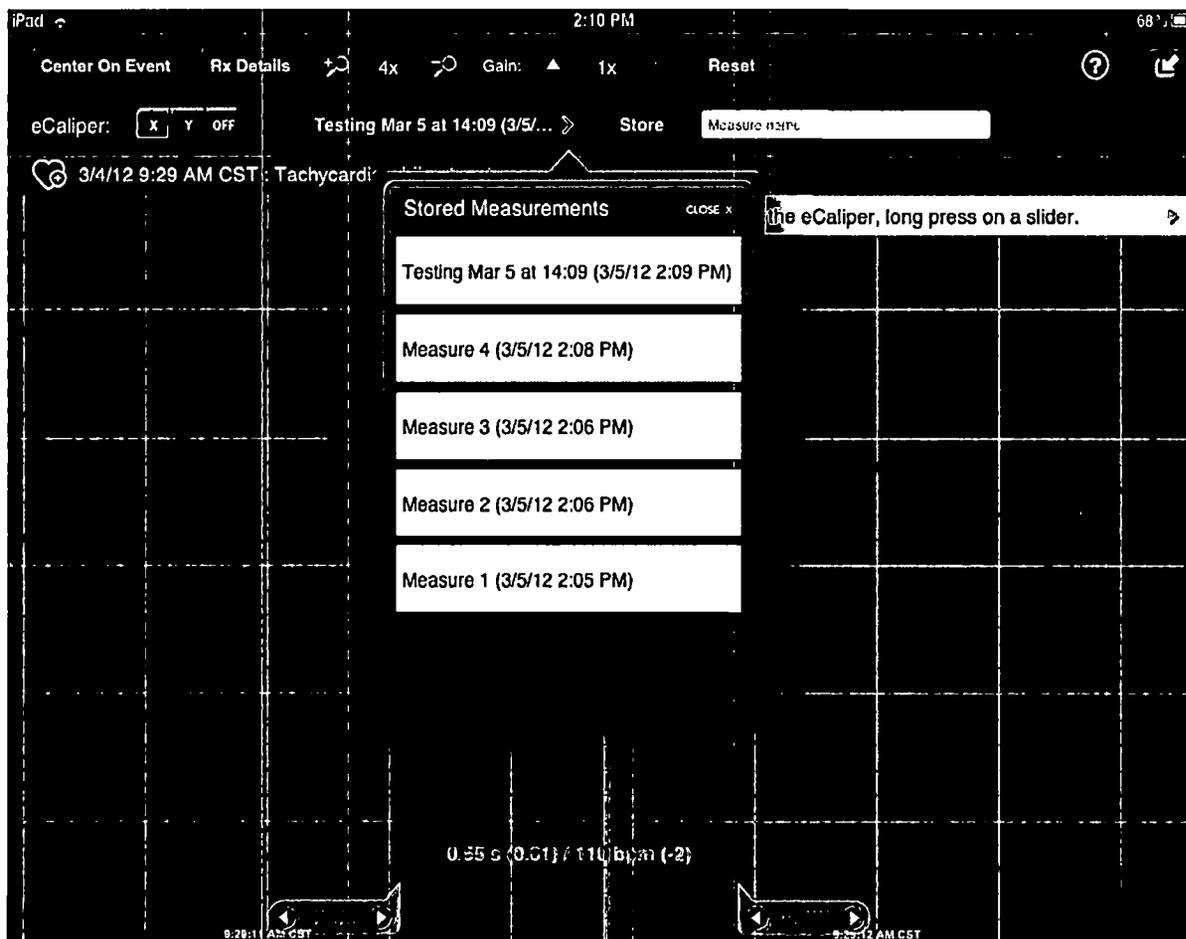


Figure 30 Recalling Stored eCaliper Measurements

Stored measurements for the x and y-axis are independent of each other.

Displaying Rx Details

Tapping Rx Details shows the threshold values that generated the medical protocol event.



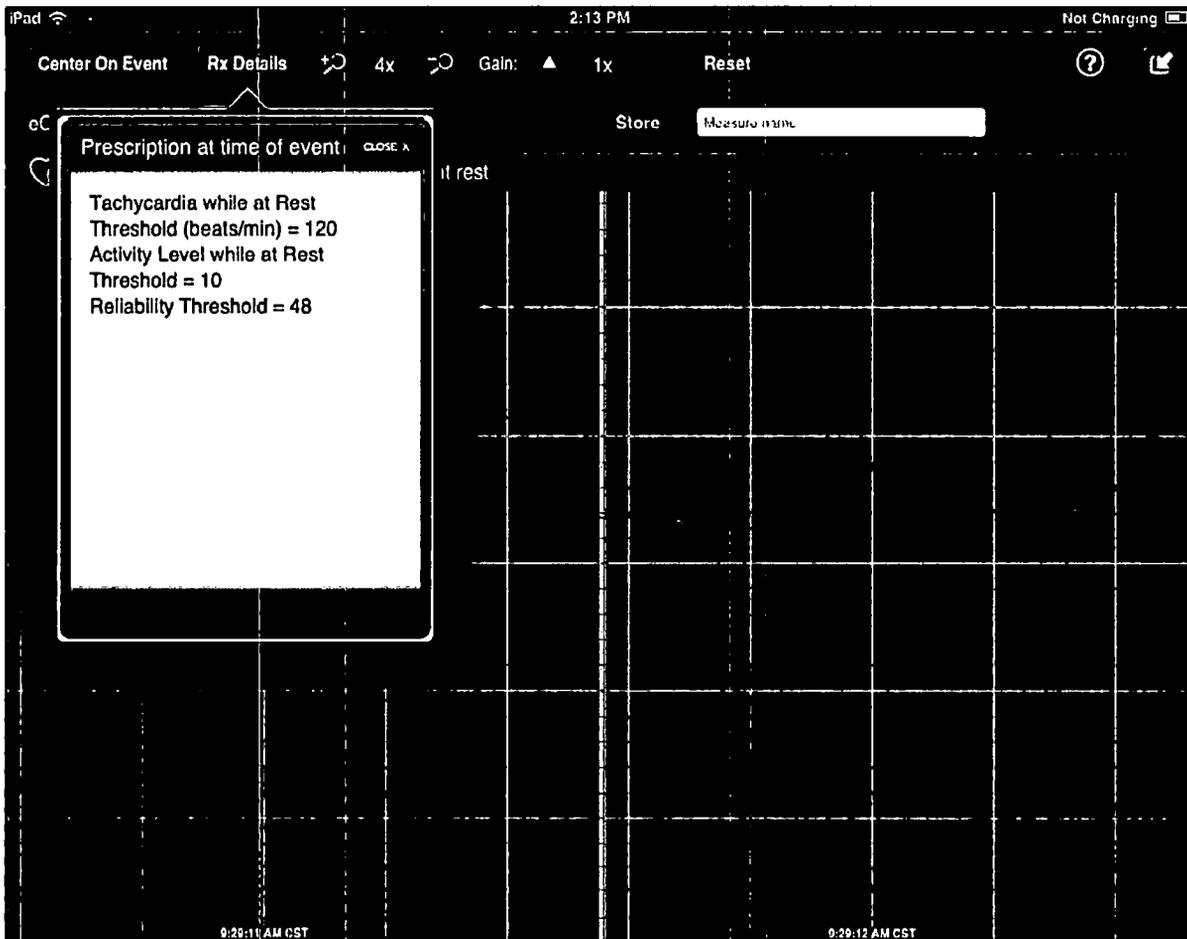


Figure 31 Displaying Rx Details

The thresholds shown are those set in the patient's profile.

App Settings

Tapping the App Settings button on the Home (Patient Activity view) screen allows you to change certain application settings. The settings you can change are:

Data retention threshold: Patient information downloaded to the iPad is, by default, retained for 90-days. You can change the data retention time by tapping App Settings. Tap the **Change** button to the right of 'Data retention threshold' and select the desired threshold. Data older than the threshold is removed from the iPad.

Network credentials: Allows you log on with a different User. Tapping the **Change** button takes you to the sign on screen where you can change the user name.

Cloud communications log: Displays any error messages or download problems. Tap **Refresh** to update the list or **Clear** to remove all messages.



Privacy Policy

Tapping the **Privacy Policy** button displays the Preventice Privacy policy applicable to this application.

Licensing

Tapping this button displays the complete Preventice End User License Agreement (EULA). When you verified your provider credentials with Preventice, you accepted this license.

Resources

The following documents are available on the PatientCare Help and Support page. You can access this page from any PatientCare screen.

- *BodyGuardian General Information*
- *PatientCare Managing Patients*
- *PatientCare Administrator's Guide*
- *BodyGuardian Instructions for Use*



Appendix 8: Predicate Labeling



P00873-001 Rev. B

AVIVO™ Mobile Patient Management System

INSTRUCTIONS FOR USE

Rx only

Indications for Use

The AVIVO Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:

- ECG
- Heart Rate (including HR variability)
- Activity
- Posture
- Body Temperature
- Respiration rate (including RR variability)
- Body fluid status

Description of the Device

The AVIVO Mobile Patient Management System includes:

- a) PiiX™ - an adherent patient-worn device containing multiple sensors used to track a suite of physiological parameters. PiiX can collect up to 72 ECG episodes. However, PiiX must be replaced after 7 days of use or when the end of life indicator appears. An end of life indicator as shown below, will light up when the PiiX needs to be replaced.
- b) zLink™ - a device that receives data from the PiiX and transmits to the Server.
- c) zLink Base – a charging station for the zLink.
- d) zLink Holster – a wearable holder for the zLink.
- e) Prep wipes – wipes used for cleaning the skin prior to applying the PiiX.

The AVIVO System enables remote monitoring of physiological parameters in ambulatory patients to:

- a) facilitate patient and medical management, and
- b) assist physicians/health practitioners in the diagnosis and identification of various clinical conditions/events/trends.

Contraindications

1. PiiX should not be used on patients with known allergies or hypersensitivities to adhesives or hydrogel.

Precautions

1. PiiX should not be used on patients with implantable devices with active minute ventilation sensors.
2. PiiX may cause mild discomfort, skin irritation, redness, itching, rash, contact dermatitis in some individuals. The device should be removed if any pain or discomfort occurs. If skin irritation or redness persists after the device has been removed, a topical anti-inflammatory cream may be applied to the area (in consultation with your health care provider).
3. PiiX is intended for single patient use.
4. PiiX should be removed prior to external defibrillation or an MRI scan.
5. PiiX should not be applied to broken, damaged or irritated skin.
6. PiiX is water resistant but not waterproof. It should not be submerged in water (showering is acceptable, but swimming and submersion bathing are prohibited).
7. PiiX should not be disassembled.
8. Replace the PiiX if it peels off; do not reapply the PiiX.
9. Replace the PiiX if it appears damaged.
10. No creams or lotions should be applied immediately prior to use of PiiX.
11. This product is recommended for adult use.

The AVIVO Patient Management System is not intended to replace direct communication with your healthcare provider. The system data should not be used alone, but should be used along with all other clinical data and exams to come to a diagnosis. Additionally, it will not summon emergency response personnel in the event you need help. Talk to your healthcare provider immediately if you have any concerns, or if your condition changes. The AVIVO System is not an emergency response service. Seek medical advice if you experience any symptoms that concern you.

Step-by-step Operating Instructions – AVIVO Mobile Patient Management System

No specific training is needed for the use of this system.
zLink should be set-up first prior to PiiX application.

zLink Set-up

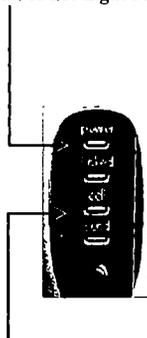
1. Plug the zLink into a standard electrical outlet.



zLink
Data

2. Dock zLink into the Base. The lights will automatically come on, confirming zLink is ON.

Power Light:
BLUE Light ON: Full charge confirmed
AMBER Light ON: Low charge warning
AMBER Light Flashing: Battery capacity less than 10%. Full charge may take up to 4 hours



Cell Light:
BLUE: Adequate cell coverage
AMBER: No cell coverage. Move zLink to another location

Other lights on the zLink are utilized only if troubleshooting is necessary. Refer to these lights only if asked by a Corventis Customer Service representative.

zLink may also be turned ON and OFF manually. To turn zLink ON when zLink is not docked in the Base, press the round Power button located below the lights. All lights will come on, confirming zLink is ON. To turn zLink OFF, press the round Power button for several seconds until all the lights turn off.

3. To initiate use, charge the zLink for a minimum of 4 hours before removing it from the zLink Base

Keep your zLink in the Base overnight, every night. With a full charge, the zLink will remain charged for up to 12 hours. Preferably, the zLink should be kept within 30 feet (9 meters) of the patient as much as possible to ensure data transmission.

PiiX Application



PiiX

First device:

1. Trim (rather than shave) hair in intended location. Avoid moles and pimples.
2. Use alcohol wipe provided with PiiX to clean the skin where the device is intended to be applied. Allow the skin to dry.
3. Remove the PiiX from the foil pouch by tearing at the notch and apply immediately.
4. Remove the covers from the underside of the PiiX.
5. Handle the PiiX on the edges until the PiiX is placed on the skin.

- Place the PiiX in a diagonal position only, oriented with Corventis at the top. Noting the picture below, place the device in the chest region, to the left of the sternum and starting at the clavicle (or collarbone) referred to as the 'left quadrant'.



- The PiiX must be in direct contact with the skin. Once applied, press the edges firmly against the skin.

Look for these indicators to appear on the PiiX display:



FILLED CIRCLE SYMBOL: Indicates the PiiX™ is successfully activated. This symbol will appear when skin contact is made and may blink during duration of use.



CIRCLE MARK WITH LINE: Indicates it is necessary to remove your PiiX™ and replace it with a new PiiX™ (unless your prescription has ended.)

PiiX Removal:

- Peel back the edge of the PiiX. Slowly and gently push the skin away from the PiiX as it is removed. Rapid removal can cause skin irritation.
- If the PiiX does not peel easily, soak the device with water to assist in softening the adhesive.
- If skin irritation persists, leave the area exposed or under light clothing. Consult your healthcare provider for any topical treatment options.

Physician Web Services

Go to www.corventis.com to login

First time login:

- Enter User Name and the Password provided and click **Submit**.
- Answer the Secret Question. Next, enter new password. Confirm new Password and click **Submit**. "Password has been changed" notification will appear.
- Click on **Login** to proceed to the Home page.

Subsequent logins:

- Enter your User Name and Password and click on **Submit** to proceed to the home page.

Transport and Storage Instructions

Storage temperature: 0°C to 40°C

Instructions on how to safely dispose of the PiiX and zLink

Both PiiX and zLink have Lithium-ion batteries and must not be disposed of in a fire. If unable to properly dispose of the product or components in accordance with local and federal regulations contact Corventis at: +1-877-247-PiiX (7449), or (408) 790-9393.

User Assistance Information

If the AVIVO Mobile Patient Management System is not operating properly, please contact Corventis Customer Service at: +1-877-247-PiiX (7449), or (408) 790-9393.

Maintenance Instruction for zLink

For cleaning, gently wipe with a soft dry cloth. Please attempt to keep zLink dust free. zLink is not waterproof and should be kept dry. This device does not have serviceable components. Please call Corventis Customer Service number if the device does not appear to be working properly.

Do not disassemble, crush, puncture, short external contacts or circuits, dispose of in fire or water, or expose a battery pack to temperatures higher than 60°C. Please refer to Patient Guide for zLink return instructions.

Label Symbol Definition

Symbol and Definition	Symbol and Definition
 Consult Instructions for Use	 Do Not Reuse
 Consult Instructions for Use (Mandatory)	 Use-by (Year-month) or (year-month-date)
 Caution: consult accompanying documents	 Latex Free
 Batch Number	 Serial Number
 Date of Manufacturer	 Catalogue Number
 Non-Sterile	 Manufacturer's Name and Address
 Temperature Limitations	 Collection of electrical and electronic equipment
 Type BF applied part; Denotes device is not in direct contact with cardiac muscle	 Wireless Transmission Symbol
IP34 - Ingress protection 3 means protection against objects >=2.5mm in diameter (tools) 4 means protection against water splashing (shower)	Rx only - Federal (USA) law restricts this product to sale by or on the order of a physician.
 Class II Equipment	

Specifications

	Adherent Device	zLink
Shelf life	4 month	N/A
Battery Capacity	2300mAh	1800mAh @ C/5 Rate @ 23°C
Battery Charger Power Requirement	N/A	100-240VAC, 50/60Hz, 15W
Battery Life	7 days nonrechargeable	Provides 12 hrs of function before recharging
Battery Voltage	3.0 Volts	3.7 Volts
Operating Temperature	0°C to 41°C	0°C to 45°C
Maximum Temperature of the Applied Part	44°C	N/A
Storage Temperature (power off)	0°C to 40°C	0°C to 40°C
Operating Humidity	10% to 95%	10% to 95%
Storage Humidity	5% to 95%	5% to 95%
ECG <ul style="list-style-type: none"> • Sampling Rate • Digital Resolution • Input Dynamic Range • Input Offset Dynamic Range • Timing Accuracy 	200Hz 10bits +/- 5 mV +/- 300mV +/- 5 ms	N/A N/A N/A N/A N/A
Sampling Rate <ul style="list-style-type: none"> • ECG • Impedance • Accelerometer 	200 Hz (+/- 5%) 4 Hz 0.25 Hz (+/- 2%)	N/A N/A N/A
Measurement Ranges <ul style="list-style-type: none"> • Heart Rate • Impedance • Respiration • Posture 	25 to 250 BPM 10 to 150 Ohms 4 to 60 BrPM +/- 2g range in x,y,z direction	N/A N/A N/A N/A
Data Storage <ul style="list-style-type: none"> • Capacity • Type 	7 days Digital flash non-removable	7 days Digital flash non-removable
Weight	50g / 1.8oz max	150g / 5.3oz max
Communication Means	RF Wireless between PiiX and zLink	Cellular Phone between zLink and Server

The heart rate algorithm of the AVIVO™ Mobile Patient Management System detects the peak of each R-wave and calculates the interval between successive R-waves. The RR intervals are then used to calculate beat-to-beat heart rate values, which are then aggregated into 5-minute and 24-hour averages for display. The pause algorithm monitors the time between successive R-wave peaks. A timer is reset upon each R-wave peak detection, and a pause trigger is activated if the timer advances to 4 seconds without an R-wave detection.

The arrhythmia detection algorithm of the AVIVO™ Mobile Patient Management System was tested according to ANSI/AAMI EC57 (Testing and reporting performance results of cardiac rhythm and ST segment measurement algorithms) for ventricular tachycardia and ventricular fibrillation and determined to have an average sensitivity of 96.9% and an average positive predictive value (PPV) of 85.3%.

This equipment complies with International Standard IEC 60601-1-2 for electromagnetic compatibility for medical electrical equipments. Medical electrical equipment needs special precautions regarding EMC, and all equipment must be installed and put into service according to the EMC information provided upon request by calling Corventis Customer Service at 1-877-247-PiiX (7449) / 1 (408) 790-9393, or at www.corventis.com. Portable and mobile RF communication equipments can affect nearby medical electrical equipment. The zLink uses RF energy for its internal operations. The RF emission is very low and within IEC 60601-1-2 acceptable limits. It will not likely cause any interference with nearby equipment.

User Assistance Number:

If the AVIVO System is not operating properly, please contact Corventis Customer Service:
1-877-247-PiiX (7449)
1 (408) 790-9393

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