K143513

December 10, 2014

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type:	Traditional 510(k)
Holder Name:	iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 San Francisco, CA. 94103
Registration No.	3007208829

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this **Traditional 510(k)** to request market clearance of the ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service. This is the initial submission; there were no prior 510(k) submissions for this device.

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous ECG information for long-term monitoring (up to 14 days). It consists of three components: (1) ZIO SR Patch Recorder with Bluetooth technology, (2) ZIO SR Wireless Gateway, and (3) ZIO ECG Utilization Service (ZEUS) System.

The ZIO® SR ECG Monitoring Service is an incremental change that adds wireless transmission capabilities to iRhythm Technologies' FDA cleared devices ZIO Patch (K121319) and ZEUS System (K142681) to incorporate a single ZIO ECG Monitoring Service.

Enclosed are two copies of a Traditional 510(k) premarket notification for the ZIO SR ECG Monitoring Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This Traditional 510(k) has been formatted in compliance with FDA's October 22, 1998 guidance document titled, Guidance for Industry and Staff: Frequently Asked Questions on the New 510(K) Paradigm. Additional considerations have been given to the FDA's July 28, 2014 Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

Thank you in advance for your consideration of this application. If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

Rich Laguna
Director of Quality & Regulatory Affairs

PREMARKET NOTIFICATION

TRADITIONAL 510(K)

ZIO® SKYRUNNER (SR)
ELECTROCARDIOGRAM (ECG) MONITORING SERVICE

SUBMISSION DATE
December 10, 2014

IRHYTHM TECHNOLOGIES, INC.
650 TOWNSEND STREET, SUITE 380
SAN FRANCISCO, CA 94103

SECTION 1
MEDICAL DEVICE USER FEE COVER SHEET (FORM FDA 3601)

Form Approved OMB No. 0910-0511 Expiration Date April 30, 2016. 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/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
IRHYTHM TECHNOLOGIES INC 650 Townsend Street Suite 380 San Francisco CA 94103 US	Rich Laguna 2.1 E-MAIL ADDRESS rlaguna@irhythmtech.com 2.2 TELEPHONE NUMBER (include Area code) 415-632-5749 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****9544	

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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

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

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

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

[X] NO, I am not a small business

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

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

[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

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

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

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

[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

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

[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT

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

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4) 03-Dec-2014

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

SECTION 2
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)/
CDRH 510(k) Screening Checklist

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

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

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/10/2014	(b)(4)	

SECTION A TYPE OF SUBMISSION

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

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

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

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
iRhythm Technologies, Inc.	300720829		
Division Name *(if applicable)*	Phone Number *(including area code)*		
	(415)632-5700		
Street Address	FAX Number *(including area code)*		
650 Townsend Street, Ste 380	(415)632-5701		
City	State / Province	ZIP/Postal Code	Country
San Francisco	CA	94103	USA
Contact Name			
Rich Laguna			
Contact Title	Contact E-mail Address		
Director QA/RA	rlaguna@irhythmtech.com		

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

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

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

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

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

☐ Response to FDA correspondence:

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

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

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

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

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

☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

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

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

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

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

☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

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

☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	DSH	2	DXH	3	DQK	4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

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

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

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K121319	1	ZIO PATCH	1	iRhythm Technologies, Inc.
2	K142681	2	ZEUS (ZIO ECG Utilization Service) SYSTEM	2	iRhythm Technologies, Inc.
3	K121628	3	EPI MINI ECG PORTABLE HEALTH MONITORING SYSTEM (EPI MINI)	3	EPI Mobile Health Solutions (S) PTE LTD
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Medical magnetic tape recorder

	Trade or Proprietary or Model Name for This Device		Model Number
1	ZIO SR ECG Monitoring Service	1	K100
2		2	
3		3	
4		4	
5		5	

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

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

Data Included in Submission

☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
DSH	870.2800	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

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

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

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler		
Company / Institution Name		Establishment Registration Number		
Division Name *(if applicable)*		Phone Number *(including area code)*		
Street Address		FAX Number *(including area code)*		
City		State / Province	ZIP Code	Country
Contact Name	Contact Title		Contact E-mail Address	

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	5-70	AAMI ANSI ISO	ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices. (General I (QS/RM))	2010	03/16/2012
2	19-4	AAMI ANSI IEC	ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC))	2012	07/09/2014
3	19-1	AAMI ANSI IEC	IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.	2007	10/17/2014
4	19-6	IEC	IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [including: technical corrigendum 1 (2011)]. (General II	2010	07/09/2014
5	3-27	AAMI ANSI ISO	ISO 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)	2012	07/09/2014
6	3-52	AAMI ANSI	EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)	2010	01/30/2014
7	2-156	AAMI ANSI ISO	ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)	2013	07/09/2014

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

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

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

SECTION 2
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)/
CDRH 510(k) Screening Checklist

SCREENING CHECKLIST FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

___ Special 510(k) - Do Sections 1 and 2

___ Abbreviated 510(k) - Do Sections 1, 3 and 4

_X__ Traditional 510(k) or no identification provided - Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present	Inadequate or Missing
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.		
Table of Contents.		
Truthful and Accurate Statement.		
Device's Trade Name, Device's Classification Name and Establishment Registration Number.		
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).		
Proposed Labeling including the material listed on page 3-4 of the Premarket Notification [510)] Manual.		
Statement of Indications for Use that is on a separate page in the premarket submission.		
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.		
510(k) Summary or 510(k) Statement.		
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.		
Identification of legally marketed predicate device. *		
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]		
Class III Certification and Summary. **	N/A	
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]	N/A	
510(k) Kit Certification ***	N/A	

* - May not be applicable for Special 510(k)s.
** - Required for Class III devices, only.
*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

SECTION 2
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)/
CDRH 510(k) Screening Checklist

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the sponsor's own, unmodified predicate device.		
A description of the modified device and a comparison to the sponsor's predicate device.		
A statement that the intended use(s) and indications of the modified device, as described in its labeling, are the same as the intended uses and indications for the sponsor's unmodified predicate device.		
A statement that the modification has not altered the fundamental technology of the sponsor's predicate device.		
A Design Control Activities Summary that includes the following elements (a-e):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.		
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.		
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.		
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.		

SECTION 2
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)/
CDRH 510(k) Screening Checklist

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity **[**For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.]**		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

* - When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

SECTION 2
CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)/
CDRH 510(k) Screening Checklist

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
c) Software Documentation:		

Items with checks in the "Present but Deficient" column require additional information from the sponsor. Items with checks in the " Missing" column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No
Reviewer:_____ Concurrence by Review Branch:____

Date:_____

The deficiencies identified above 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/cdrh/modact/leastburdensome.html

SECTION 3
CDRH SPECIAL 510(k) COVER LETTER
TABLE OF CONTENTS
GENERAL INFORMATION

December 10, 2014

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type: Traditional 510(k)
Holder Name: iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA. 94103

Registration No. 3007208829

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this **Traditional 510(k)** to request market clearance of the ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service. This is the initial submission; there were no prior 510(k) submissions for this device.

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous ECG information for long-term monitoring (up to 14 days). It consists of three components: (1) ZIO SR Patch Recorder with Bluetooth technology, (2) ZIO SR Wireless Gateway, and (3) ZIO ECG Utilization Service (ZEUS) System.

The ZIO® SR ECG Monitoring Service is an incremental change that adds wireless transmission capabilities to iRhythm Technologies' FDA cleared devices ZIO Patch (K121319) and ZEUS System (K142681) to incorporate a single ZIO ECG Monitoring Service.

Enclosed are two copies of a Traditional 510(k) premarket notification for the ZIO SR ECG Monitoring Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This Traditional 510(k) has been formatted in compliance with FDA's October 22, 1998 guidance document titled, Guidance for Industry and Staff: Frequently Asked Questions on the New 510(K) Paradigm. Additional considerations have been given to the FDA's July 28, 2014 Guidance for Industry and Food and Drug Administration Staff - The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)].

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

Thank you in advance for your consideration of this application. If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

Rich Laguna
Director of Quality & Regulatory Affairs

TABLE OF CONTENTS

APPENDICES

SECTION 3
CDRH SPECIAL 510(k) COVER LETTER
TABLE OF CONTENTS
GENERAL INFORMATION

GENERAL INFORMATION

Applicant:
iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
U.S.A
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:
Rich Laguna
Director of Quality & Regulatory Affairs
415-632-5749

DEVICE INFORMATION

Trade/Proprietary Name:
ZIO® SR ECG Monitoring Service

Classification:
Recorder, Magnetic Tape, Medical, 21 CFR§870.2800
Computer, diagnostic, programmable, 21CFR§870.1425
Transmitters and receivers, electrocardiograph, telephone, 21CFR§870.2920

Product Codes:
DSH, DQK, DXH

Device Class:
II

Establishment Registration:
3007208829

Manufacturing Facility:
iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
U.S.A
Phone: 415-632-5700
Fax: 415-632-5701

SECTION 4
INDICATIONS FOR USE STATEMENT

510(k) Number (if known):_____

Device Name: ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service

Indications for Use:

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

Prescription Use __**X**__ And/Or Over the Counter Use _____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

SECTION 5
510(k) SUMMARY

This summary of the 510(k) premarket notification for the ZEUS System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

SECTION 5
510(k) SUMMARY

510(k) Notification K _____

GENERAL INFORMATION

Applicant:

iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
U.S.A
Phone: 415-632-5700
Fax: 415-632-5701

Contact Person:

Rich Laguna
Director Quality & Regulatory Affairs
eMail: rlaguna@irhythmtech.com
Phone: 415-632-5749
Fax: 415-632-5701

Date Prepared: December 10, 2014

DEVICE INFORMATION

Classification:

Recorder, Magnetic Tape, Medical, 21 CFR§870.2800
Computer, diagnostic, programmable, 21CFR§870.1425
Transmitters and receivers, electrocardiograph, telephone, 21CFR§870.2920

Product Codes:

DSH, DQK, DXH

Trade Name:

ZIO® SR ECG Monitoring Service

Generic/Common Name:

Medical magnetic tape recorder

PREDICATE DEVICE(S)

ZEUS (ZIO ECG Utilization Services) System [K142681]
ZIO PATCH [K121319]
EPI MINI [K121628]

SECTION 5
510(k) SUMMARY

INDICATIONS FOR USE

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

PRODUCT DESCRIPTION

The ZIO® SR ECG Monitoring Service consists of three components: (1) ZIO SR Patch Recorder with Bluetooth technology, (2) ZIO SR Wireless Gateway, and (3) ZIO ECG Utilization Service System.

The ZIO® SR Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic data transmission for up to 14 days. The ZIO® SR Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of an ECG strip of 90-second duration. The wireless transfer of data is enabled by the ZIO® SR Gateway, which requires proximity and reception but no patient interaction. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom-rhythm correlation in the ZIO SR Report. Alternatively, the patient can enter symptom logs and view received transmissions via an online patient portal.

At the conclusion of the wear period (up to 14 days), the patient removes the ZIO® SR Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of symptomatic or continuous ECG data at iRhythm's Clinical Center (iCC) the ECG data is downloaded, the data is processed through the algorithm and delivered to the QA Tool module where the results are reviewed and/or adjusted by iRhythm Certified Cardiographic Technicians (CCT's) for accuracy. iRhythm employed and trained Patch in-take and CCT personnel follow internal procedures for processing and are made aware of algorithm performance anomalies. Any software anomalies are visible to and manually corrected by iRhythm Technologies CCT's during the QA review and/or Patch Report edits. The CCT generates a final report of the ECG findings contained within the data; thereby enabling the provision of a complete ECG processing and analysis service.

Upon explicit request from a clinician responsible for the patient's healthcare, longer segments of ECG data from the continuous recording on the Patch can also be wirelessly retrieved during the wear period.

Automated ECG analysis performance was quantified for any claimed analysis metrics. The resulting statistics demonstrate sensitivity and positive predictivity levels which satisfy requirements and minimize safety or efficacy concerns.

SECTION 5
510(k) SUMMARY

SUBSTANTIAL EQUIVALENCE

The indications for use for the ZIO® SR ECG Monitoring Service are substantially equivalent to the indications for use for the predicate devices. The performance testing results demonstrate that any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Therefore, the ZIO® SR ECG Monitoring Service is substantially equivalent to the predicate device.

NONCLINICAL TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

There are no required FDA performance standards for the ZIO® SR ECG Monitoring Service. All necessary performance testing was conducted on the ZIO® SR ECG Monitoring Service to support determination of substantial equivalence to the predicate devices. The results confirm by examination and provision of objective evidence that the design output met the design input requirements in conformance with the following list of recognized consensus standards:

- ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices
- IEC 60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests
- IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-2-47:2012, Medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)
- EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)
- ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

CONCLUSION

The ZIO® SR ECG Monitoring Service is substantially equivalent to the predicate devices.

SECTION 6
TRUTHFUL AND ACCURATE STATEMENT
CONFIDIENTIALITY STATEMENT

IRHYTHM TECHNOLOGIES, INC.

ZIO® SR ECG Monitoring Service

TRUTHFUL AND ACCURATE STATEMENT
As required by 21 CFR §807.87(j)

I certify that, in my capacity as Executive Vice President, Research & Development of iRhythm Technologies, Inc., I believe to the best of my knowledge that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been knowingly or willfully omitted.

(b)(6) [redacted]

December 9, 2014
Date

Executive Vice President, Research & Development
iRhythm Technologies, Inc.

SECTION 6
TRUTHFUL AND ACCURATE STATEMENT
CONFIDENTIALITY STATEMENT

IRHYTHM TECHNOLOGIES, INC.

ZIO® SR ECG Monitoring Service

CONFIDENTIALITY STATEMENT

iRhythm Technologies, Inc. considers the information in this submission to be confidential commercial information and has taken precautions to protect the confidentiality of this information under 21 CFR§807.95, Confidentiality of Information. iRhythm Technologies, Inc. request that this premarket notification and proprietary information herein be treated as confidential in accordance with the Freedom of Information Act.

SECTION 7
CLASS III PRODUCT SUMMARY AND CERTIFICATION

This is not a Class III device and is not substantially equivalent to a Class III device; therefore the Literature Search and Certification requirements of the Safe Medical Devices Amendments (SMDA) of 1990 are not applicable.

SECTION 8
STANDARDS DATA REPORT FOR 510(k)s (FORM FDA 3654)

8.1. Recognized Consensus Standards

In this section, please find a complete list of standards used in the preparation of this Traditional 510(k). The Standards Data Reports (Form FDA 3654) for each standard are provided in the following order:

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.					
1	Standards No. 5-70	Standards Organization AAMI ANSI ISO	Standards Title ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices. (General I (QS/RM))	Version 2010	Date 03/16/2012
2	Standards No. 19-4	Standards Organization AAMI ANSI IEC	Standards Title ES60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005. mod). (General II (ES/EMC))	Version 2012	Date 07/09/2014
3	Standards No. 19-1	Standards Organization AAMI ANSI IEC	Standards Title IEC 60601-1-2 Edition 3: 2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests.	Version 2007	Date 10/17/2014
4	Standards No. 19-6	Standards Organization IEC	Standards Title IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [including: technical corrigendum 1 (2011)]. (General II	Version 2010	Date 07/09/2014
5	Standards No. 3-27	Standards Organization AAMI ANSI ISO	Standards Title ISO 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)	Version 2012	Date 07/09/2014
6	Standards No. 3-52	Standards Organization AAMI ANSI	Standards Title EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)	Version 2010	Date 01/30/2014
7	Standards No. 2-156	Standards Organization AAMI ANSI ISO	Standards Title ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)	Version 2013	Date 07/09/2014

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices. (General I (QS/RM))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-70	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☐	☒
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ISO 14971:2007/(R)2010 (Corrected 4 October 2007), medical devices - applications of risk management to medical devices. (General I (QS/RM))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-4	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1:2005/(R)2012 and A1:2012,, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (iec 60601-1:2005, mod). (General II (ES/EMC))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
SEE ATTACHED		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EC 60601-1-2:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3). (General II (ES/EMC))

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-1	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☒	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EC 60601-1-2:2007-03, medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests (edition 3). (General II (ES/EMC))

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home he

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#19-6	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐
Title of guidance:		

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

IEC 60601-1-11 Edition 1.0 2010-04, medical electrical equipment - part 1-11: general requirements for basic safety and essential performance - collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home he

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#3-27	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☐	☒
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☒	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☒	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☒	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☒	☐
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: ____________________

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ISO 60601-2-47:2012, medical electrical equipment -- part 2-47: particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. (Cardiovascular)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
SEE ATTACHED		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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

Form Approved: OMB No. 0910-0120; Expiration Date: 1/31/2017

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)

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

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

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

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EC12:2000/(R)2010, disposable ecg electrodes. (Cardiovascular)

CONFORMANCE WITH STANDARD SECTIONS*

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

TYPE OF DEVIATION OR OPTION SELECTED ❖

DESCRIPTION

JUSTIFICATION

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

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

Title of guidance: _____

[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

ISO 10993-1:2009/(R) 2013, biological evaluation of medical devices -- part 1: evaluation and testing within a risk management process. (Biocompatibility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ❖		
DESCRIPTION		
JUSTIFICATION		

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

❖ Types of deviations can include an exclusion of a section in the standard, a deviation brought on by the SIS supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Page 2 of 2

Add page

EXTENT OF STANDARD CONFORMANCE: SUMMARY REPORT TABLE		
STANDARD TITLE:	IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, Edition 3.1 2012-08	FDA Recognition # 19-4
CONFORMANCE WITH STANDARD SECTIONS		

(b)(4) Extent of Standard Conformance: Summary Report Table

[redacted]

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

(b)(4) Extent of Standard Conformance: Summary Report Table

SECTION 9
DEVICE DESCRIPTION

Trade/Proprietary Name:
ZIO® SR ECG Monitoring Service

Classification:
Recorder, Magnetic Tape, Medical, 21 CFR§870.2800
Computer, diagnostic, programmable, 21 CFR§870.1425
Transmitter and Receivers, Electrocardiograph, Telephone, 21 CFR§870.2920

Review Panel:
Cardiovascular

Product Code:
DSH, DQK, DXH

Device Class:
II

9.1 Device Overview

The ZIO® SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service with Wireless Transmission is a service incorporating a single-patient-use ECG monitor worn for up to 14 days that provides a continuous, single-channel recording as well as symptomatic ECG information transmission. The ECG information is managed by a software system used to process and report on the ECG data. The Service does not provide "real-time" monitoring. The ZIO SR ECG Monitoring Service has the same intended use as iRhythm Technologies' currently FDA-cleared ZIO XT Patch (K121319) and ZEUS System (K142681), with (b)(4) (b)(4)

The continuous ECG recording, data analysis, and reporting aspects of the ZIO SR service are identical to the predicate ZIO XT and ZEUS System functionalities. Continuous recording for up to 14 days is supported by the equivalent (b)(4) (b)(4)

SECTION 9
DEVICE DESCRIPTION

(b)(4)

SECTION 9
DEVICE DESCRIPTION

(b)(4)

Figure 3. ZIO SR Gateway

SECTION 9
DEVICE DESCRIPTION

(b)(4)

9.2 Wireless Connectivity

(b)(4)

9.2.1 Button Press

The button on the ZIO SR patch remains identical to the button on the ZIO XT patch, with the same mechanical features that enable a patient to quickly locate the button, easily press the button, and receive a clear tactile sensation that provides feedback of success.

SECTION 9
DEVICE DESCRIPTION

9.2.2 Short-Range RF Communication

(b)(4)

[redacted]

9.2.3 Long-Range RF Communication

(b)(4)

[redacted]

SECTION 9
DEVICE DESCRIPTION

(b)(4)

[redacted]

SECTION 9
DEVICE DESCRIPTION

(b)(4)

[redacted]

SECTION 9
DEVICE DESCRIPTION

(b)(4)

[redacted]

SECTION 9
DEVICE DESCRIPTION

(b)(4) Device Description

[redacted]

SECTION 9
DEVICE DESCRIPTION

9.5 Device Specifications

PERFORMANCE CHARACTERISTICS	
ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	Use upon opening
ELECTRICAL CHARACTERISTICS	
Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Short-range RF	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Cellular RF	800 / 1900 MHz CDMA Effective Radiated Power ≤ 300mW
POWER CHARACTERISTICS	
Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	14 days
PHYSICAL CHARACTERISTICS	
Patch Dimensions	5.2 x 2.0 x 0.5 inches
Patch Weight	24.7 g
Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g
ENVIRONMENTAL CHARACTERISTICS	
Operational Temperature	36 to 104 degrees
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IPx4
Gateway IP Classification	IPx2

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

10.1 Substantial Equivalence

This section establishes substantial equivalence through a comparative analysis of the ZIO® SR ECG Monitoring Service and the identified predicate device(s). The comparative analysis includes consideration of indications for use, product labeling, system performance, and technological characteristics.

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

10.2 Comparison to Predicate Device(s)

Table 1. Comparison of FDA Product Codes & Device Classification

Specification	ZIO® SR ECG Monitoring Service [K_TBD]	ZIO Patch [K121319]	ZEUS (ZIO ECG Utilization Service) System [K142681]	EPI Mini ECG Portable Health Monitoring System ("EPI Mini") [K121628]
Classification Code	DSH / DXH / DQK	DSH	DQK	DSH / DXH / DPS
Regulation Number	870.2800 / 870.2920 / 870.1425	870.2800	870.1425	870.2800 / 870.2920 /870.2340
Common Classification Name	Medical magnetic tape recorder	Medical magnetic tape recorder	Programmable diagnostic computer	Medical magnetic tape recorder
	Telephone electrocardiograph transmitter and receiver			Telephone electrocardiograph transmitter and receiver
	Programmable diagnostic computer			Electrocardiograph
Device Classification Name	Recorder, Magnetic Tape, Medical	Recorder, Magnetic Tape, Medical	Computer, Diagnostic, Programmable	Transmitter And Receivers, Electrocardiograph, Telephone

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

Table 2. Comparison of Indications For Use

Device	Indications For Use
ZIO SR **[K_TBD]**	The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.
ZIO Patch **[K121319]**	The ZIO Patch is a prescription-only, single-patient-use, continuously recording ECG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.
ZEUS System **[K142681]**	The ZEUS System is intended for use by qualified medical professionals for assessment of a patient's recorded ambulatory ECG data from patients 18 years or older. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.
EPI Mini **[K121628]**	The EPI Mini Portable ECG Recorder ("EPI Mini") is intended for use with a patient's smartphone to record, store and wirelessly transmit physiological data to a remote server. It is indicated for individuals who are at risk for cardiac disease, experience transient symptoms suggesting possible cardiac arrhythmia or have existing heart conditions. The device can function as an Rx product when prescribed by and used under the supervision of a physician for the purpose of monitoring a patient's ECG data. It is not a diagnostic device. The EPI Mini is intended for use by adults who suffer from cardio-vascular disease, are considered high risk for possible cardiovascular events or are concerned about their heart function and rhythm.

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

Table 3. Comparison of ECG Recording and Telemetry Devices

Specification	ZIO SR [K_TBD]	ZIO Patch [K121319]	EPI Mini [K121628]
PERFORMANCE CHARACTERISTICS			
ECG Channels	1	1	1
Memory Capacity	14 days	14 days	30 sec events
Storage Medium	Linear Flash Memory	Linear Flash Memory	Linear Flash Memory
Recording Format	Continuous	Continuous	Patient-initiated event
Service Life	Up to 14 days	Up to 14 days	Unknown
Storage Shelf Life	6 months	6 months	Unknown
Ambulatory Use	Yes	Yes	Yes
Form Factor	Adhesive Patch with integrated electrodes Wireless Gateway for telemetry	Adhesive Patch with integrated electrodes	Hand-held device with integrated electrodes Patient's smartphone for telemetry
Reuse	Single patient	Single patient	Up to 5 registered users
ECG RECORDING CHARACTERISTICS			
Frequency Response	0.5 Hz to 30 Hz	0.5 Hz to 30 Hz	-
Input Impedance	≥ 10 Mohm	≥ 10 Mohm	-
Differential Range	± 1.65 mV	± 1.65 mV	-
Sampling Rate	200 Hz	200 Hz	-
Resolution	10 bits	10 bits	-
DATA TRANSMISSION CHARACTERISTICS			
Data Telemetry	Yes	No	Yes
Telemetry Technology	2.4GHz Bluetooth Low Energy RF and Cellular 800/1900MHz CDMA RF	-	2.4GHz Bluetooth RF and Cellular 800/1900MHz RF (Smartphone)
Telemetry Data Type	Patient-Triggered Event, 90 sec Clinician-Requested Data	-	Patient-Triggered Event, 30-45 sec
Transmission Time	<4 minutes	-	<10 minutes

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

Specification	ZIO SR [K_TBD]	ZIO Patch [K121319]	EPI Mini [K121628]
Telemetry User Requirement	No user intervention required as long as wireless is in-range	-	Install smartphone application, pairing the EPI Mini and smartphone, record and send ECG signal
PHYSICAL CHARACTERISTICS			
Recording Device Dimensions	5.2 x 2.0 x 0.5 in 132 x 51 x 14 mm	5.2 x 2.0 x 0.5 in 132 x 51 x 14 mm	3.0 x 1.8 x 0.6 in 75.4 x 46.4 x 15.0 mm
Recording Device Weight	24.7 g	24.7 g	58 g
Telemetry Device Dimensions	6.2 x 3.4 x 0.8 in 157 x 86 x 20 mm	-	Commercial Android/Blackberry Smartphones
Telemetry Device Weight	158 g	-	Varies
ENVIRONMENTAL SPECIFICATIONS			
Operational Temperature	36 - 104° F 2 - 40° C	36 - 104° F 2 - 40° C	41 - 100° F 5 - 38° C
Operational Altitude	-1,000 - 10,000 ft -305 - 3,048 m	-1,000 - 10,000 ft -305 - 3,048 m	-
Allowable Transit Temperature	-4 - 104° F -20 - 40° C	-4 - 104° F -20 - 40° C	32 - 104° F 0 - 40° C
Recommended Storage Temperature	64 - 80° F 18 - 27° C	64 - 80° F 18 - 27° C	32 - 104° F 0 - 40° C
Storage Humidity	10% - 95% (non-condensing)	10% - 95% (non-condensing)	35% - 85% (non-condensing)
Storage Altitude	-1,000 - 14,000 ft -305 - 4,267 m	-1,000 - 14,000 ft -305 - 4,267 m	-

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

10.2.1 Device Codes & Classification

The ZIO® SR ECG Monitoring Service (also called ZIO SR) is classified based on the features it shares with the predicate devices described in Table 1. The ZIO SR is classified as a DSH (Medical magnetic tape recorder) because it retains the same continuous electrocardiograph recording functionality as the ZIO Patch. (b)(4)

(b)(4)

10.2.2 Intended / Indications for Use

A comparison of the Indications for Use (IFU) for each of the devices is provided in Table 2. In an analogous manner to the Device codes, the elements of recording and analysis in the ZIO SR IFU are clearly evident in the indications of the ZIO Patch and ZEUS System (upon which it is based), while the third element of symptomatic ECG event transmission can be found in the indications of the EPI Mini device. Therefore, the intended use of the device, as described in its labeling, is substantially equivalent to the predicate device(s).

10.2.3 Product Labeling

The proposed product labeling for the ZIO® SR ECG Monitoring Service is substantially equivalent to the predicate device labeling. Please refer to **Section 11 – Proposed Labeling**.

10.2.4 Performance Characteristics

The next four subsections align with those of Table 3, beginning with the comparative analysis of performance characteristics of the submission and three predicates. This section is largely identical for the ZIO SR and ZIO Patch devices, given the former was built on the platform of the latter device. The one area of difference (b)(4)

10.2.5 ECG Recording Characteristics

The ZIO SR device is identical to the ZIO Patch in all of its ECG recording characteristics.

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

10.2.6 Data Transmission Characteristics

The ZIO SR device is substantially equivalent to the EPI Mini in its telemetry characteristics. In both devices, ECG events are captured when the patient initiates a transmission by pressing a button. The ZIO SR Patch captures a 90-second strip of data and transmits the strip automatically via a Bluetooth connection to a Gateway device, which then transmits via a Cellular CDMA connection to iRhythm servers. This mechanism is substantially equivalent to that of the EPI Mini, which captures a 30-second strip of ECG data and transmits via Bluetooth to the patient's smartphone, which then transmits to the EPI Health Concierge via Cellular connection. Event transmission times are comparable.

Where the two devices differ is (b)(4) [redacted]

(b)(4) [redacted]

Further discussion of the ZIO SR wireless features can be found in **Section 9 – Device Description**.

10.2.7 Physical Characteristics

The physical characteristics of the ZIO SR Patch are identical to the physical characteristics of the ZIO Patch. The same patient-contact components are used in both devices, including the adhesives, plastic housings, and electrodes.

The physical characteristics of the ZIO SR Gateway (Telemetry Device) differ (b)(4) [redacted] However, the ZIO SR Gateway is similar in size to larger smartphones such as the Samsung Galaxy Note or iPhone 6 Plus. While the patient is asked to carry the Gateway as an additional device, in the case of the EPI Mini, the recording device is, similarly, a specific-use portable device that must be carried to enable recordings. As such, the physical characteristics of the telemetry devices are considered substantially equivalent.

10.2.8 Environmental Specifications

The environmental specifications of the ZIO SR are identical to those for the ZIO Patch.

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

(b)(4) Software Information

[redacted]

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

(b)(4) Software Information

[redacted]

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

(b)(4)

[redacted]

(b)(4)

SECTION 10
SUBSTANTIAL EQUIVALENCE DISCUSSION
COMPARISON TO THE CLEARED DEVICE

(b)(4)

SECTION 11
PROPOSED LABELING

Proposed Labeling
In accordance with 21 CFR 807.87e

See Appendix B – Labeling

11.1. ZIO SR ECG MONITORING PROPOSED LABELING

This section provides a list of the proposed ZIO SR labeling that can be found in Appendix B - Labeling:

Part Number	Description
K100A201C.A	ZIO SR Product Box (Central)
N100A3021.02	ZIO SR Patch Bottom Label (common ZIO XT Patch)
N100A3022.01	ZIO SR Patch Barcode Sticker (common ZIO XT Patch)
K102A3006.A	ZIO SR Gateway Back Label
K100A4010.A	ZIO SR Clinical Reference Manual
K100A4030.A	ZIO SR Patient Instructions and Button Log
K100A2007.A	ZIO SR Skin Prep & Placement Card

11.2. PREDICATE DEVICE LABELING – ZIO PATCH

For comparison purposes, product labeling describing the predicate device can be found in Appendix B - Labeling:

Part Number	Description
N100A202C.01	ZIO XT Patch Product Box (Central)
N100A3021.02	ZIO XT Patch Bottom Label (common ZIO SR Patch)
N100A3022.01	ZIO XT Patch Barcode Sticker (common ZIO SR Patch)
N100A4010.01	ZIO XT Patch Clinical Reference Manual
N100A4032.01	ZIO XT Patch Instructions and Button Log
N100A2007.03	ZIO XT Patch Skin Prep & Placement Card

11.3. PREDICATE DEVICE LABELING - ZEUS SYSTEM

For comparison purposes, product labeling describing the predicate device can be found in Appendix B - Labeling:

Part Number	Description
D100A4080	ZIO Reports XT Operator Manual
S100A4001	ZEUS Data Sheet

11.4. PREDICATE DEVICE LABELING - EPI MINI

For comparison purposes, product labeling describing the predicate device can be found in Appendix B - Labeling:

Part Number	Description
LPI-0007-01	EPI Mobile Health EPI Mini W518i Portable ECG Recording User Manual
N/A	EPI Mini Brochure

SECTION 12
STERILIZATION AND SHELF LIFE

12.1 Sterilization

The ZIO SR Patch and Gateway are provided non-sterile; therefore sterilization is not applicable.

12.2 Shelf Life

The ZIO SR Patch utilizes identical adhesive, sensing and housing components as the predicate ZIO Patch (K121319). These components have been tested for 6-month shelf life using both (b)(4) (b)(4) This testing confirms that the product remains stable over the intended 6-month shelf life. The 6-month (b)(4) report (b)(4)

Battery longevity through a 6-month shelf life has been verified (b)(4) The verification report including these analyses can be found on-file at (b)(4)

SECTION 13
BIOCOMPATIBILITY

13.1. Biocompatibility

The ZIO SR Patch utilizes the identical patient-contact components and manufacturing processing as the predicate ZIO Patch (K121319). To assess biocompatibility, the patient-contact materials were subjected as a (b)(4) in ISO 10993-1. (b)(4) All three tests passed and reports are on-file at iRhythm.

13.1.1. Patient Contacting Components & Materials

(b)(4)

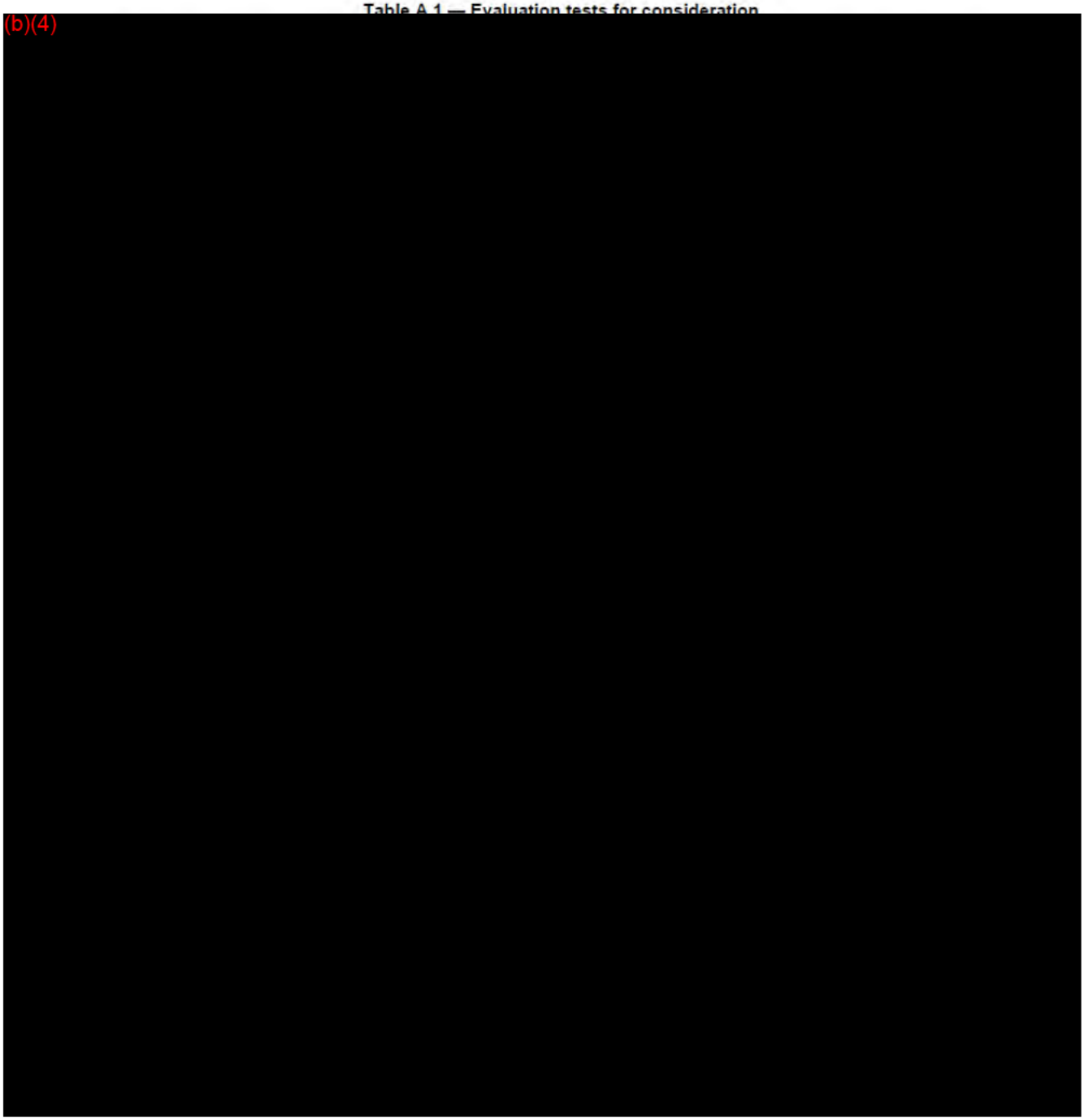
SECTION 13
BIOCOMPATIBILITY

13.1.2. Contact Classification - (ISO 10993-1.2009 - BIOLOGICAL EVALUATION OF MEDICAL DEVICES EVALUATION AND TESTING)

ISO 10993-1

Table A.1 — Evaluation tests for consideration

(b)(4)



SECTION 13
BIOCOMPATIBILITY

(b)(4)

SECTION 14
SOFTWARE

14.1 Level of Concern Determination

The Level of Concern determination for the ZEUS System contained within the ZIO® SR Monitoring Service is consistent with the determination from the 510(k) submission for the predicate ZEUS System (**K142681)**. It is considered to be "Moderate" when assessed using Tables 1 and 2 in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005. The ZEUS System does not qualify as Blood Establishment Computer Software, is not intended for use in combination with a drug of biologic, nor is it an accessory to a medical device that has a Major Level of Concern. Prior to mitigation of hazards, use of the ZEUS System could not result in death or serious injury to a patient or an operator of the device. As such, this device does not pose a Major Level of Concern. Based on the design and use of the product, there is the remote possibility that use of the device could directly or indirectly result in minor injury to the patient or operator prior to mitigations and, as such, is considered to pose a Moderate Level of Concern.

Due to the Moderate Level of Concern, descriptions of the following software-related documentation was reviewed and updated for the software changes included in the ZIO® SR versions of ZEUS System software.

- Software Description
- Device Hazard Analysis
- Software Requirements Specifications
- Architecture Design Chart
- Software Design Specification
- Traceability Analysis
- Software Development Environment Description
- Verification and Validation Documentation
- Software Revision Level History
- Unresolved Anomalies

(b)(4)

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

SECTION 15
FIRMWARE

15.1 Level of Concern Determination

The Level of Concern determination for firmware, or "embedded software," on the ZIO SR Patch and Gateway is consistent with the determination from the 510(k) submission for the predicate ZIO Patch device. It is considered to be "Moderate" when assessed using Tables 1 and 2 in the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005. There is a remote possibility that malfunction or latent design flaws could lead to erroneous diagnosis or delay in delivery of appropriate medical care that could lead to minor injury of the patient. As such, the firmware is considered to pose a Moderate Level of Concern.

Due to the Moderate Level of Concern, descriptions of the following software-related documentation are included in this package.

- Software Description
- Device Hazard Analysis
- Software Requirements Specifications
- Architecture Design Chart
- Software Design Specification
- Traceability Analysis
- Verification and Validation Documentation
- Software Development Environment Description
- Software Revision
- Unresolved Anomalies

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

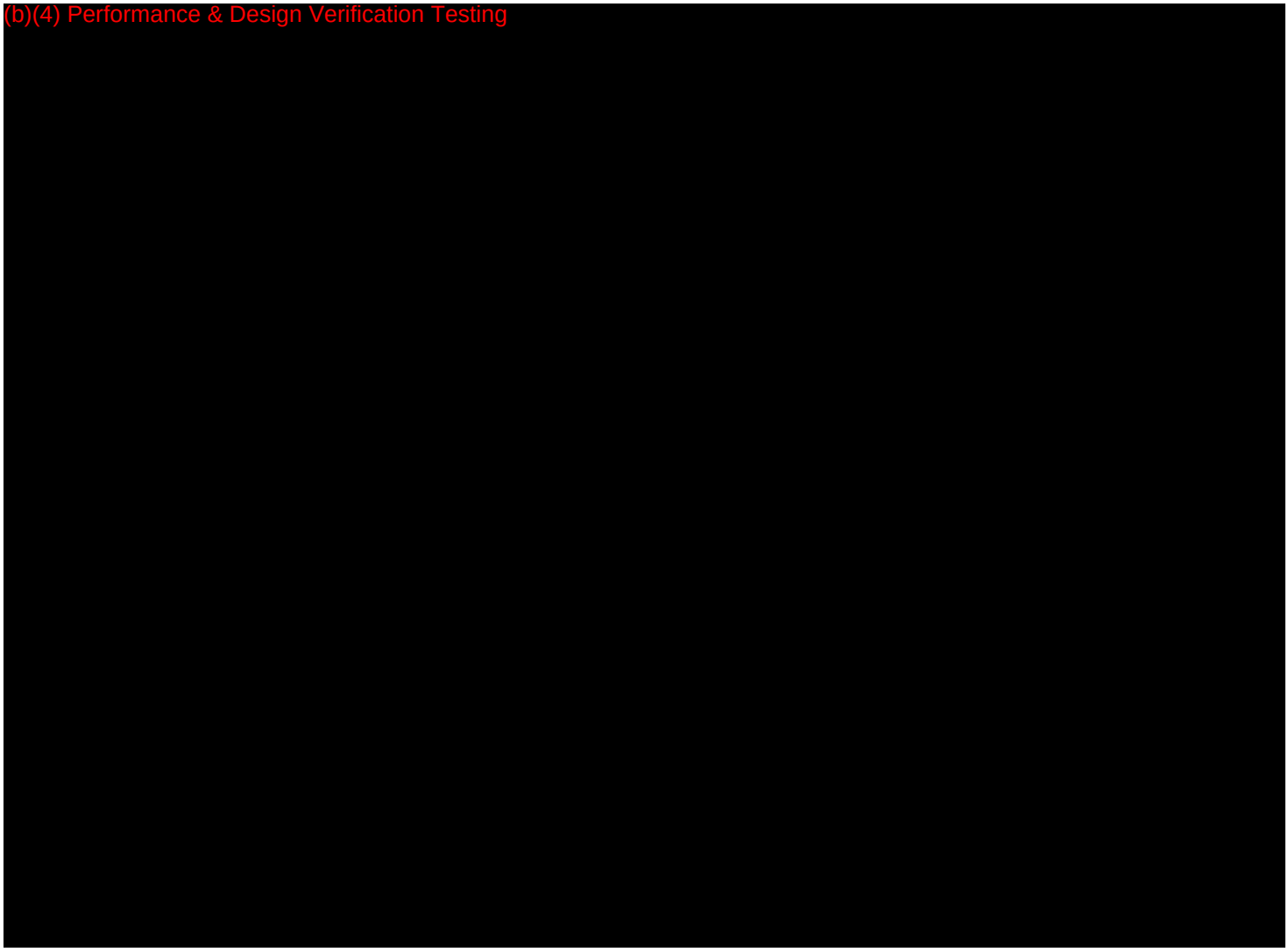
(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

SECTION 16
PERFORMANCE & DESIGN VERIFICATION TESTING

(b)(4) Performance & Design Verification Testing



SECTION 16
PERFORMANCE & DESIGN VERIFICATION TESTING

(b)(4)

[redacted]

SECTION 17
DESIGN CONTROL SUMMARY
DECLARATION OF DESIGN CONTROLS

(b)(4)

SECTION 17
DESIGN CONTROL SUMMARY
DECLARATION OF DESIGN CONTROLS

(b)(4)

[redacted]

SECTION 17
DESIGN CONTROL SUMMARY
DECLARATION OF DESIGN CONTROLS

(b)(4)

[redacted]

SECTION 17
DESIGN CONTROL SUMMARY
DECLARATION OF DESIGN CONTROLS

IRHYTHM TECHNOLOGIES, INC.

ZIO® SR ECG Monitoring Service

DECLARATION OF CONFORMITY WITH DESIGN CONTROLS

iRhythm Technologies, Inc. declares as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met; and

iRhythm Technologies, Inc. is in conformance with the design control procedure requirements as specified in 21 CFR 820.30. Design Control records are available for review.

(b)(6) [redacted]

December 9, 2014
Date

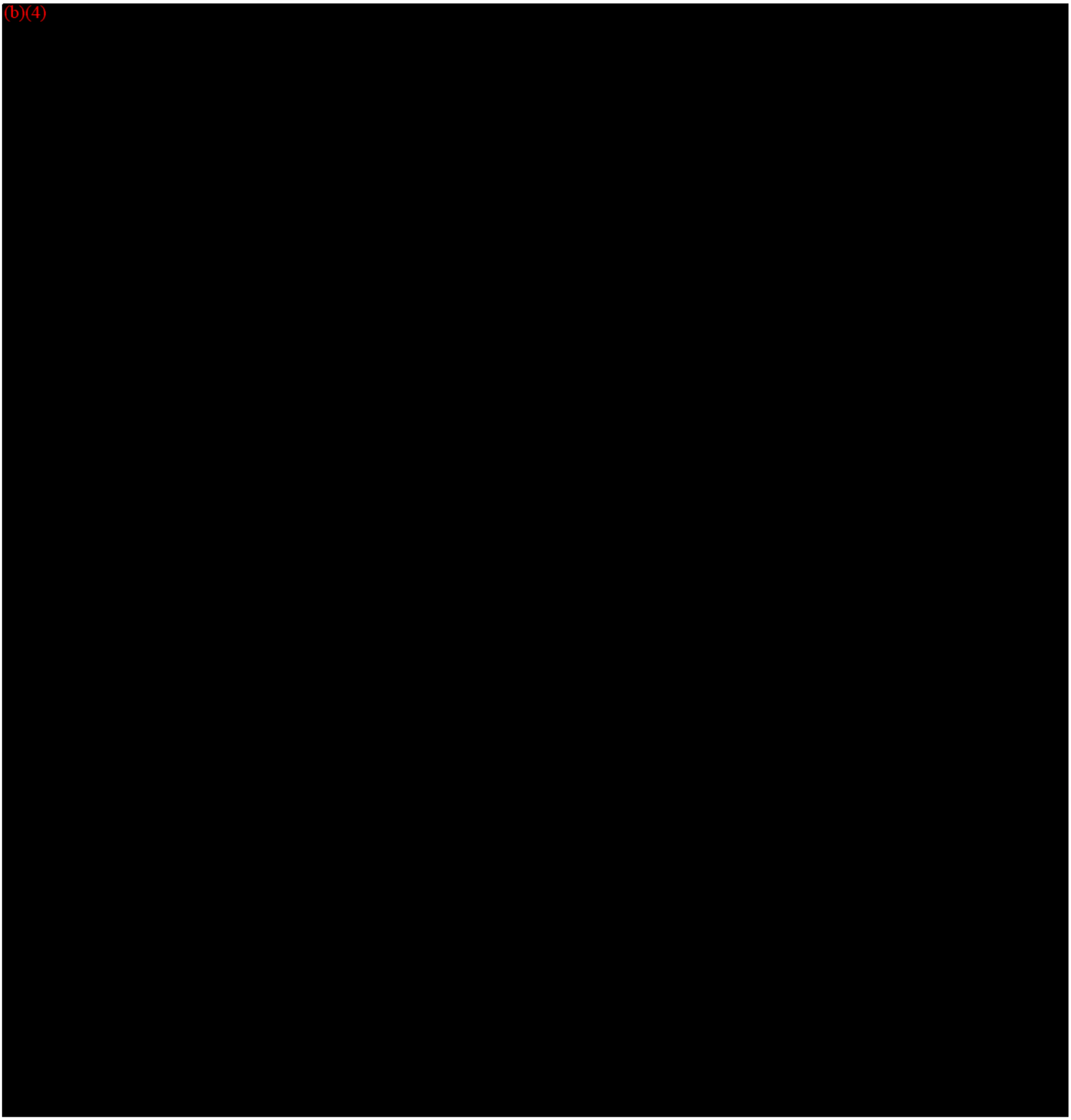
Executive Vice President, Research & Development
iRhythm Technologies, Inc.

APPENDIX A
RISK MANAGEMENT FILE

CONTENT:

(b)(4)

(b)(4)



(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

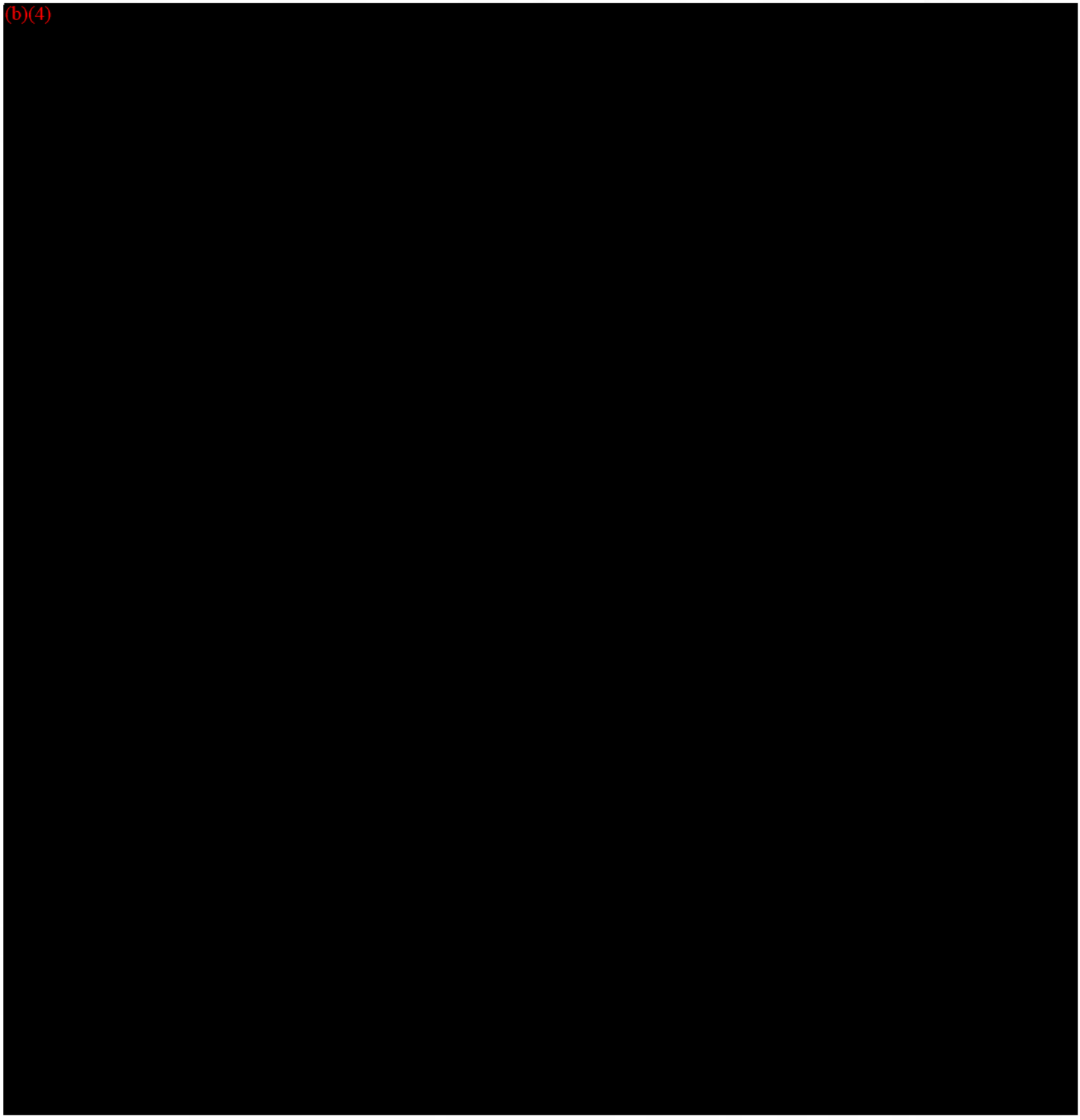
(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Risk Management Report

(b)(4)



(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

iRhythm	Document #: (b)(4)	Effective: On Approval	Rev: (b)(4)	Date: November 20, 2014
	Title: (b)(4) System Hazard Analysis			

(b)(4)

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Risk Management Report

(b)(4)

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

iRhythm

ZSRTRM.01 ZIO SP ECG Monitoring Service
Traceability Matrix

	USER NEEDS REQUIREMENTS	SYSTEM REQUIREMENTS	VERIFICATION TEST CASES
(b)(4)			

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

(b)(4) Traceability Matrix

APPENDIX B
LABELING SAMPLES

CONTENT:

ZIO SR ECG MONITORING PROPOSED LABELING

Part Number	Description
K100A201C.A	ZIO SR Product Box (Central)
N100A3021.02	ZIO SR Patch Bottom Label (common ZIO XT Patch)
N100A3022.01	ZIO SR Patch Barcode Sticker (common ZIO XT Patch)
K102A3006.A	ZIO SR Gateway Back Label
K100A4010.A	ZIO SR Clinical Reference Manual
K100A4030.A	ZIO SR Patient Instructions and Button Log
K100A2007.A	ZIO SR Skin Prep & Placement Card

PREDICATE DEVICE LABELING – ZIO PATCH

Part Number	Description
N100A202C.01	ZIO XT Patch Product Box (Central)
N100A3021.02	ZIO XT Patch Bottom Label (common ZIO SR Patch)
N100A3022.01	ZIO XT Patch Barcode Sticker (common ZIO SR Patch)
N100A4010.01	ZIO XT Patch Clinical Reference Manual
N100A4032.01	ZIO XT Patient Instructions and Button Log
N100A2007.03	ZIO XT Patch Skin Prep & Placement Card

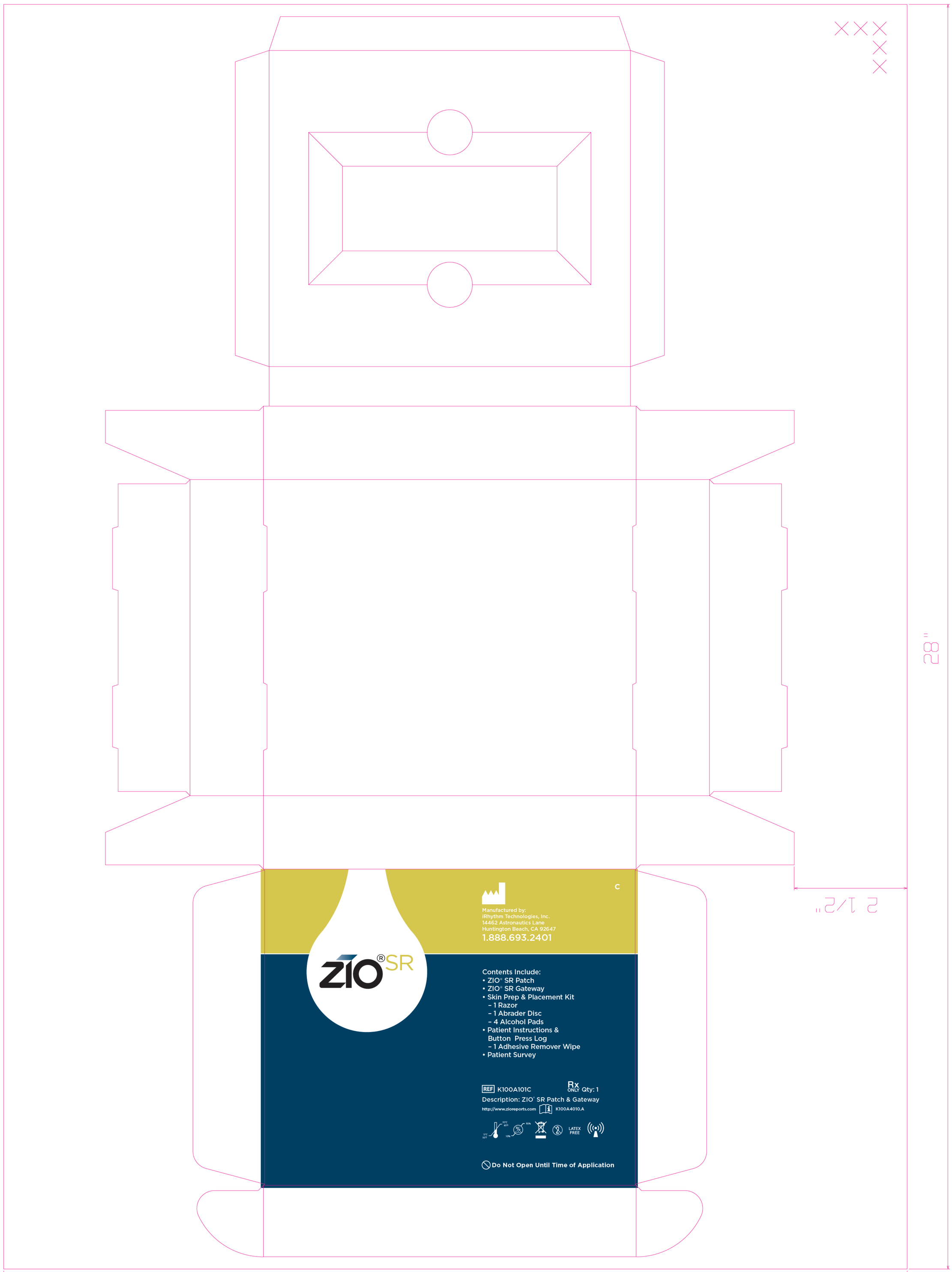
APPENDIX B
LABELING SAMPLES

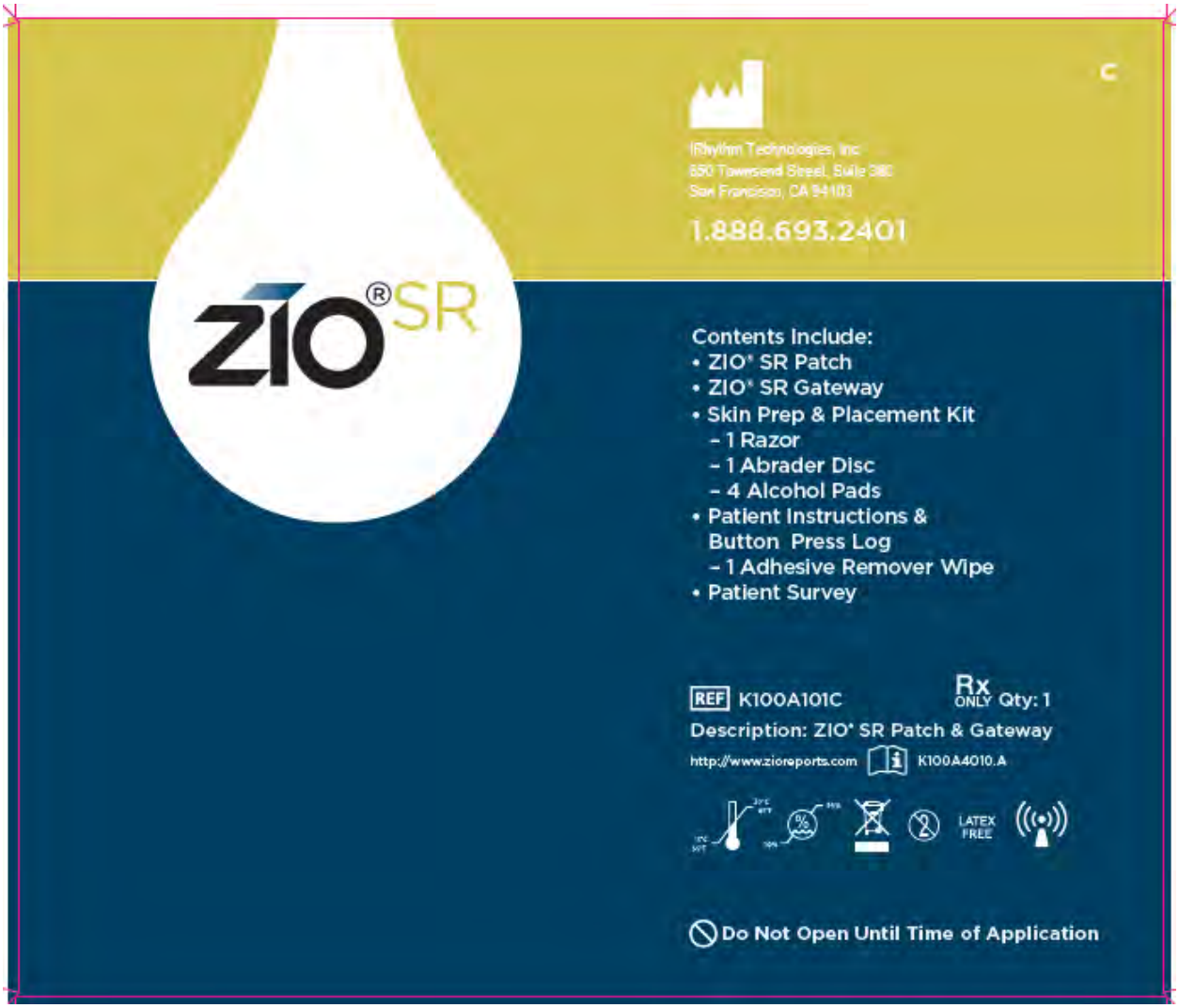
PREDICATE DEVICE LABELING - ZEUS SYSTEM

Part Number	Description
D100A4080	ZIO Reports XT Operator Manual
S100A4001	ZEUS Data Sheet

PREDICATE DEVICE LABELING - EPI MINI

Part Number	Description
LPI-0007-01	EPI Mobile Health EPI Mini W518i Portable ECG Recording User Manual
N/A	EPI Mini Brochure





(b)(4) Design Specifications

(b)(4) Design Specifications

2.5 x 2.5"
.1 Corner Radius

1-888-693-2401

ZIO®SR

Return to: **iRhythm Technologies**
2 Marriott Drive
Lincolnshire, IL 60069-9904

KEEP IN SIGHT AND IN ARM'S REACH

K102A3006-A

PROPOSED

Clinical Reference Manual

TABLE OF CONTENTS

DESCRIPTION

The ZIO® SR ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system consisting of four components: (1) ZIO SR Patch ECG Recorder, (2) ZIO SR Patient Gateway, (3) Proprietary algorithm software and (4) ZIO SR Report.

The ZIO® SR Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic data transmission for up to 14 days. The ZIO® SR Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of an ECG strip. The wireless transfer of data is enabled by the ZIO® SR Gateway, which requires proximity and reception but no patient interaction. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom-rhythm correlation in the ZIO SR Report. Alternatively, the patient can go to www.myzio.com to enter symptom logs and view received transmissions online.

At the conclusion of the wear period (up to 14 days), the patient removes the ZIO® SR Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of symptomatic or continuous ECG data at iRhythm's Clinical Center (iCC) the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report.

Upon explicit request from a clinician responsible for the patient's healthcare, segments of ECG data from the continuous recording on the Patch can also be wirelessly retrieved during the wear period.

INDICATIONS FOR USE

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

CONTRAINDICATIONS

- Do not use the ZIO® SR for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use the ZIO® SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO® SR in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use the ZIO® SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
Tel. +1.888.693.2401 (USA Only)
Fax. +888.693.2402

SYMBOLS

Consult instructions for use

Caution

Prescription use only

Manufacturer

Date of manufacture

Serial Number

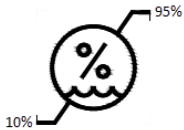
Use by

Do Not Reuse

Splash-proof equipment

Drip-proof equipment

Temperature limitations



Humidity limitations

Separate collection

Do not use if package is damaged

Type BF applied part

RF Transmitter

Keep Dry

QTY:

Net quantity of contents

WARNINGS

- Do not use the ZIO® SR Patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO® SR Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO® SR on patients residing in areas with limited to no cellular reception.

⚠ If skin irritation such as severe redness, itching or allergic symptoms develop, remove the ZIO® SR Patch from the patient's chest. Call iRhythm Customer Support at **1-888-693-2401**

Rx ONLY **CAUTION:** Federal (USA) law restricts the sale of this device to or on the order of a physician.

PRECAUTIONS

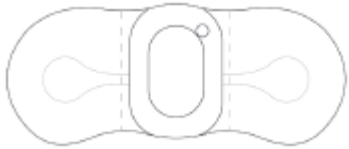
- The ZIO® SR Patch includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR Patch has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR Patch if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR Patch on pediatric patients (younger than 18 years old) has not been established.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe

tissue injury if ingested.

- Safety and effectiveness of the ZIO® SR Patch on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

PACKAGE CONTENTS

1 ZIO® SR Patch

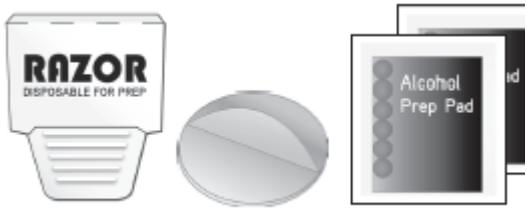


1 ZIO® SR Gateway, containing:

- 1 postage-paid return envelope

1 Skin Prep & Placement Kit containing:

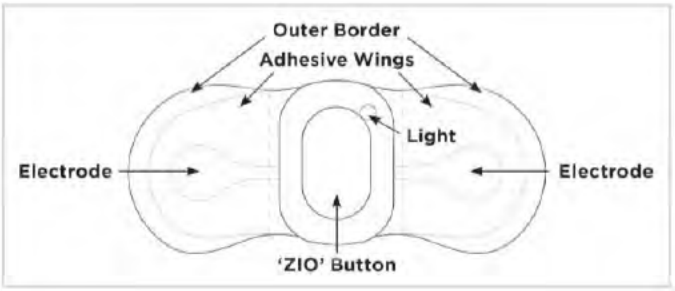
- 1 disposable razor
- 1 abrader disc
- 4 alcohol pads



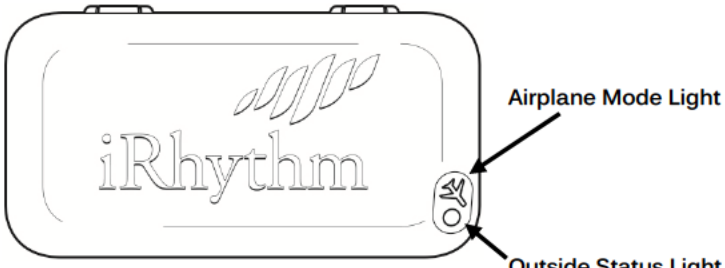
1 Patient Instructions & Button Press Log containing:

- 1 adhesive remover wipe

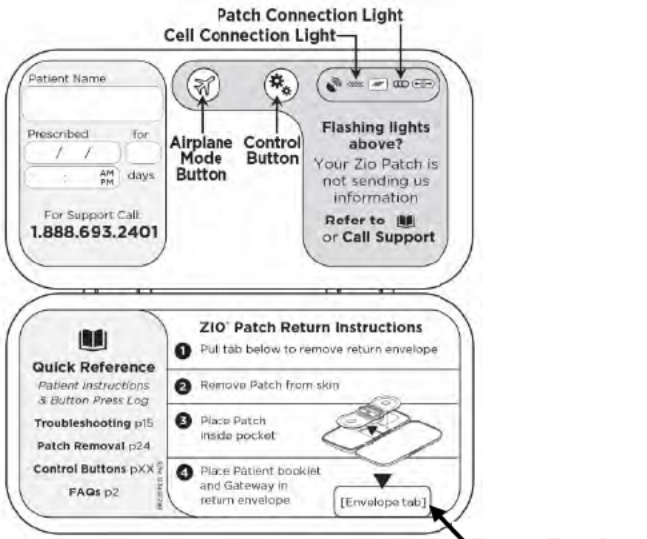
DEVICE DIAGRAMS



ZIO® Patch



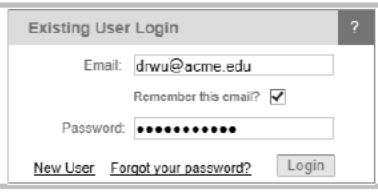
ZIO® Gateway Exterior



ZIO® Gateway Interior

ACCOUNT SETUP

To allow effective use of the ZIO service, an account on iRhythm's Patient Management system (www.zioreports.com) has been assigned to the clinic. The following steps should be performed to verify account access .

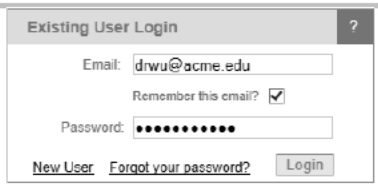
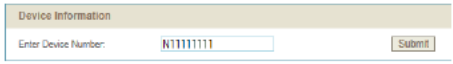
1. Open up Internet Explorer and go to www.zioreports.com	
2. Enter your email address and password to securely login into zioreports.com	

Ensure you can access iRhythm Patient Management system via provided username and password. If you are unable to access zioreports.com please contact iRhythm Customer Support at 1-888-693-2401

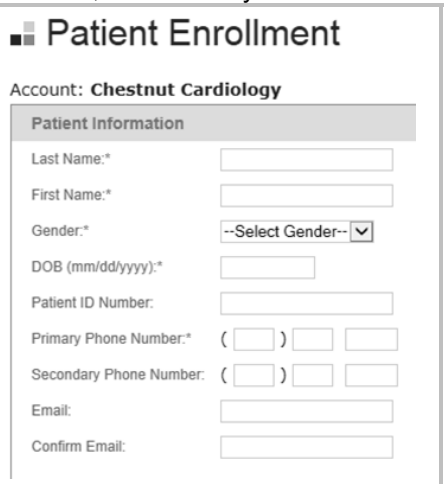
DURING PATIENT VISIT

REGISTRATION

1) Register patient online at www.zioreports.com.

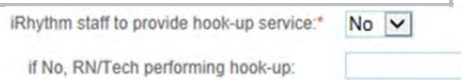
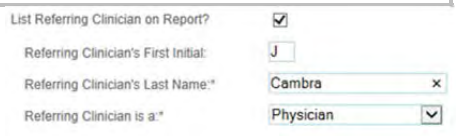
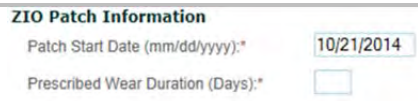
a) Open up Internet Explorer and go to www.zioreports.com	
b) Enter your email address and password to securely login into zioreports.com	
c) Select Register New Patient Option (Patient->Register New Patient)	
d) Enter in the Serial # and the Submit button	

e) Enter the following Patient Information
   i. Last Name (Required)
   ii. First Name (Required)
   iii. Gender (Required)
   iv. DOB (Required)
   v. Patient ID Number
   vi. Primary Phone Number (Required)
   vii. Secondary Phone Number
   viii. Email
   ix. Confirm Email (Required if Email provided)



f) Enter the Patient Address
   i. Street Address 1 (Required)
   ii. Street Address 2
   iii. City (Required)
   iv. State (Required)
   v. Zip Code (Required)
   vi. Patient PHI restricted use indicator

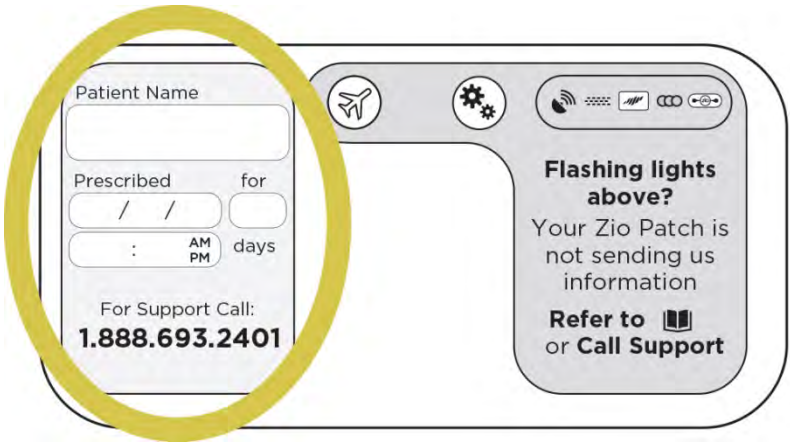
g) Enter the following Prescribing Information
   i. Physician Office (Required)
   ii. Prescribing Physician/Non-Physician (Required)
   iii. Primary Indication

(Required) – Enter associated ICD 9 code. iv. ICD or Pacemaker? [Yes/No] (Required)	
h) Enter Patch Hookup Information – iRhythm Staff performing hook-up? i. If Yes – then select 'Yes' ii. If No – then select 'No' and enter Rn/Tech name	
i) If it is desired to include the Referring Physician on the Zio® SR Patch Report enter a check next to "List Referring Clinician on Report" and enter the following information: i. Referring Clinician's First Name ii. Referring Clinician Last Name (Required) iii. Referring Clinician is a (Required)	
j) Enter the following Patch Wear information i. Patch Start Date (Required) ii. Prescribed Wear Duration (Required)	

k) Complete the patient registration by clicking 'Submit' button	

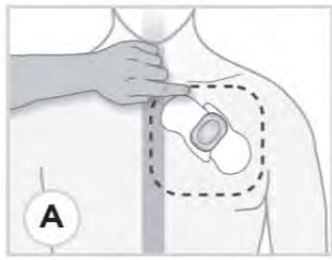
2) Remove the ZIO® SR Patch and ZIO Gateway from the packaging.

3) Inside the ZIO Gateway on the label, write the patient's name, start date, time and prescription duration using Pen or Marker. Instruct the patient to write the date when they remove the ZIO® SR Patch for return.



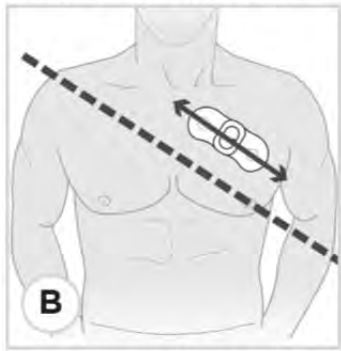
APPLICATION INSTRUCTIONS

1. Have the patient **stand** with their arms resting at their sides during the ZIO® Patch application.
   - If the patient cannot stand, have them sit up straight with their arms relaxed at their side.

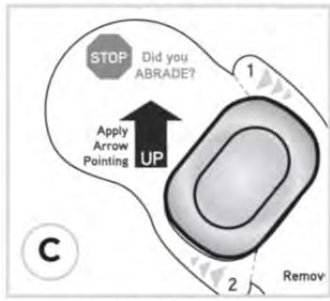


Prep & Placement Area

2. Determine placement area without removing the backing.
   - You may hold the ZIO® Patch up to the patient's **left** chest and use it as a guide to determine the placement area *(Fig. A)*.
     - o Place on flattest part of the left chest
     - o About 1 finger width below the collar bone, centered over left pectoral muscle
     - o Edge of the ZIO® Patch next to the sternum
     - o Avoid armpit and breast tissue
   - Angle so the arrow on the top label points upwards *(Fig C)*



Placement Angle



Arrow Points Up

Alternative placement may be necessary depending on the patient's anatomy. It is acceptable to modify the placement, but quality of ECG and record duration may be affected.

3. Prepare the patient's skin using the materials from the *Skin Prep & Placement Kit*:

   ***Note** that the preparation area will need to extend larger than where the ZIO® Patch will be applied.*

   a. Remove the razor by holding the cover on the sides and pulling down on the handle *(Fig. D)*.

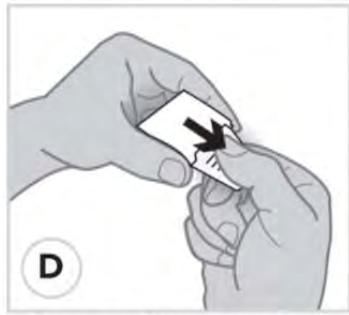
   b. **Shave** the placement area if hair is present. DO NOT add pressure to the razor; shave across the skin lightly.

      - ***NOTE:** If a cut should occur, treat the site and only continue once bleeding has stopped. After it has stopped, do not place electrode over cut.*
      - ***NOTE:** Dispose of razor in proper sharps container.*

   c. Applying pressure, **abrade** the entire area using 40 broad strokes ***NOTE:** This is essential for skin-patch adhesion and high ECG signal quality.*

   d. **Clean** the area thoroughly with four alcohol pads, using both sides of pads as needed. Allow skin to dry for 1 minute.

      - Be sure to clean off any perspiration, lotion or



How to Remove Razor

Abrade Skin

sunscreen.

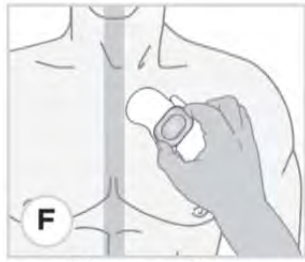
- Let dry for 1 minute.
- Skin must be completely dry before applying the ZIO SR Patch

The order of steps c and d are important! All skin cells / debris from the abrader must be removed for the ZIO SR patch to stick.

The steps above are critical to achieve good signal quality and adhesion.

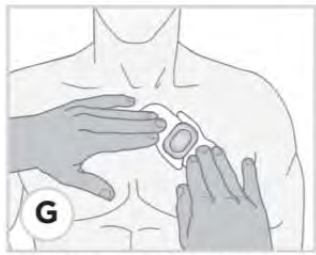
---

4. Hold device in the center and remove clear backings. Keep top label on. Do not touch adhesive.
5. Apply the ZIO® SR Patch to the patient's chest, making sure to place it in the prepared area *(Fig. F)*.



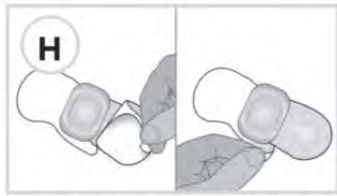
Place on Chest

6. Press firmly across the wings of the device for approximately 2 minutes *(Fig. G)*.
   This helps skin-patch bonding because the adhesive is pressure-sensitive.



Press for 2 Minutes

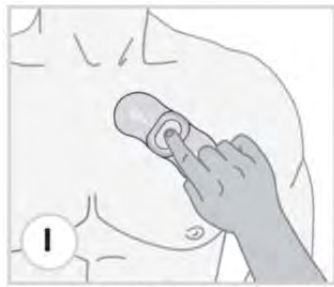
7. Remove the top label *(Fig. H)*.
   - Peel off the 2 parts of the top label, one at a time. As you peel, use your other hand to press down on the patch to keep it in place.



Remove Top Label

   a) **Press firmly for 2 minutes** across the entire device, working adhesive into the skin, which helps skin-patch bonding.

   b) Firmly press the 'ZIO' button and release *(Fig. I)*. The green light will flash 5 times indicating that the monitoring has started.



Press Button to Turn On

8. Open the gateway clasp and press the "Control" button *(Fig. J)* to power on the gateway. Watch for orange flashing light that changes to 5 green flashes. Green flashes indicate that the gateway and patch have connected and the wireless connection is good.

Press button to turn on

9. After you have seen green lights on both patch and gateway:
   - Help the patient practice pressing the patch button. This will familiarize the patient with the action of pressing the button when symptoms are felt. *Button presses within the first five minutes of activation will not be captured, however the device will continue to record.*

REVIEW WITH YOUR PATIENT

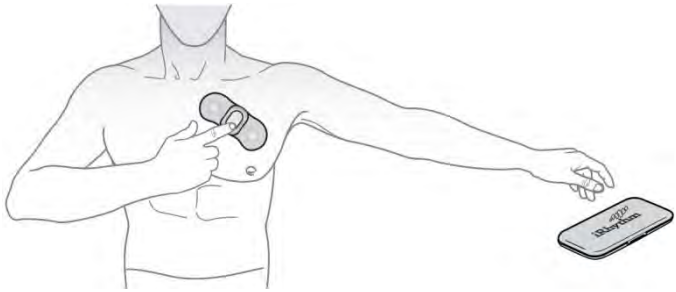
Using the ZIO® SR Patch and Gateway

1. The ZIO® Patch is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient). The gateway should be kept within arm's reach and in view to maintain a wireless connection. Ensure the patient understands the purpose and importance of each device.
2. The ZIO® Patch should not be removed before the end of the prescribed period unless skin irritation or itching is severe or hives or blisters develop (see Removal Instructions on page 12). If this occurs, the patient should call Customer Support at 1-888-693-2401.
3. If symptoms are felt the patient should press the 'ZIO' button on the device *(Fig. K)*.
   - This will mark the ECG recording, indicating that the patient felt a symptom.
   - The ZIO® Patch will **not** show a light when the patient presses the button.
   - A click should be felt and/or heard, indicating that the button has been pressed and a symptom has been marked.
4. Each time the patient presses the 'ZIO' button to mark a symptom an entry should be made in the Patient Instructions & Button Press Log *(Fig. L)* or at myzio.irhythmtech.com.

Location of Button; Press to Mark Symptom

Button Press Log Page

5. The gateway device sends heart rhythm data wirelessly when the patient presses the 'ZIO' button on the patch. In order for the gateway device to function properly:
   - The patient should keep the gateway within arm's length and line of sight as long as they are wearing the ZIO SR patch.



   - The patient may carry the device in a purse or coat pocket in order to maintain proximity while they are out of the home.
   - The patient should ensure that the gateway is located in an area with adequate cellular reception. (Note: the ZIO® SR device is not suitable for patients who live in rural areas with no cellular coverage.)

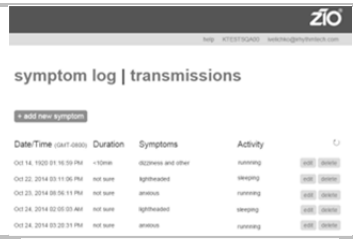
Note: Both Patch and Gateway device do not show lights when functioning properly

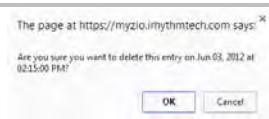
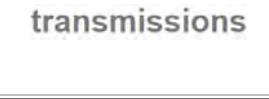
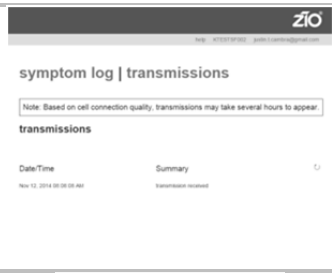
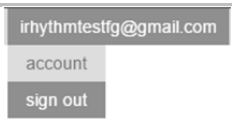
---

Transmission times may vary depending on the patient maintaining proximity to gateway and ensuring cellular reception.

Using the MyZIO Website

1. Open up Internet Explorer and go to myzio.irhythmtech.com	
2. To register select “new user”	
3. Enter the following Registration Information: i. Patient Email Address (Required) ii. Password (Required) iii. Confirm Password (Required) iv. Last Name (Required) v. First Name (Required) vi. Patch Serial Number (Required)	
4. Complete the myzio.irhythmtech.com registration by clicking ‘get started!’ button	
5. To enter Symptoms login to myzio.irhythmtech.com by providing your email address and password used during	

registration and click the 'sign in' button	
6. To enter a symptom select the "+ add new symptom" button.	
7. Enter the following Symptom Information: i. Date & Time of the Symptom (Required) ii. What were you doing? (i.e. Running, Walking,…) iii. How long did it last? (Required) iv. What did you feel? – Enter as many that apply. Use other if the symptom is not listed.	
8. Complete the Symptom Journal entry by clicking 'save entry' button.	
9. To edit a symptom, locate the symptom of interest from the Main page, and click the 'edit' button.	
10. Make the desired changes to the Symptom journal entry and click 'save entry' to save edits made.	
11. To delete a symptom, locate	

the symptom of interest from the Main page, and click the 'delete' button.	
12. To confirm the deletion, click the 'OK' button.	
13.To view list of Transmissions received, select the 'transmissions' tab.	
14. From the transmissions page the list of transmissions received are listed by date/time. *Note Based on cell connection quality and proximity to the gateway, transmissions may take several hours to appear.*	
15. To logout, select the tab with your email address and select 'sign out'	

Traveling with the ZIO® SR System

1. The ZIO® Patch can be worn through security screenings. A security statement, as shown below, is provided in the Patient Instructions & Button Press Log.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

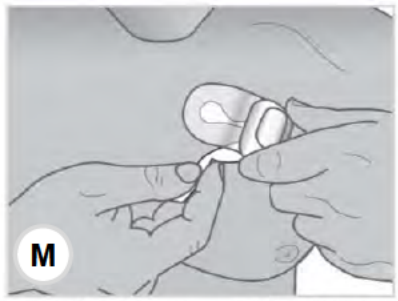
1.888.693.2401

24 hours/day, 7 days/week.

2. The ZIO® SR system allows the patient to power the cellular radio on and off with an Airplane Mode:
   a. To turn on Airplane Mode (when the cellular radio needs to be shut off), the patient should open the gateway and press and hold the "Airplane Mode" button for 3 seconds until the inside status lights flash orange momentarily. The outside airplane light will flash continuously while in Airplane Mode.
   b. To exit Airplane Mode (and turn the cellular radio back on), the same "Airplane Mode" button should be held for 3 seconds until the inside status lights flash green momentarily to show success. The outside airplane light will stop flashing and the cellular radio is turned on.

Removal of the ZIO SR Patch & Return of the ZIO® System

1. At the end of the wear period, detach the adhesive remover wipe from the back page of the *Patient Instructions & Button Press Log*.
2. Gently tilt the center of the ZIO® Patch up. Using the adhesive remover, sweep the wipe between the skin and the Patch while peeling the right side from the center out. Repeat for the other side, peeling from the center out *(Fig. M)*.
3. Wash skin with mild soap, rinse with water, and pat dry.

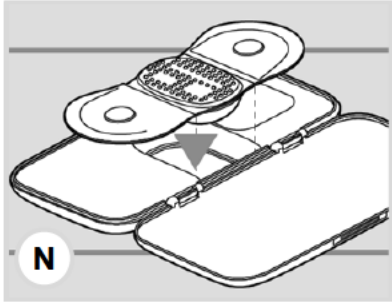


Adhesive Remover Aids Removal

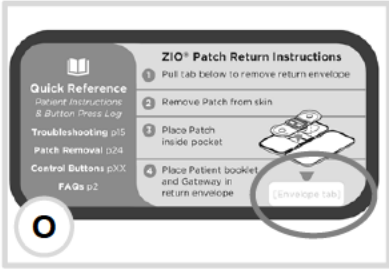
If patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, have them use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

---

4. Place the ZIO® Patch in the gateway and close the gateway such that the clasp clicks. *(Fig.N)*



5. Pull tab in the gateway to remove return envelope. *(Fig.O)*



6. Place Patient booklet and gateway in return envelope. Seal the envelope and mail it back via the U.S. postal service as soon as possible.

Analysis of the full continuous record cannot be performed until receipt of the patch. Encourage the patient to mail back the patch, gateway and patient booklet on the day of patch removal.

DURING MONITORING

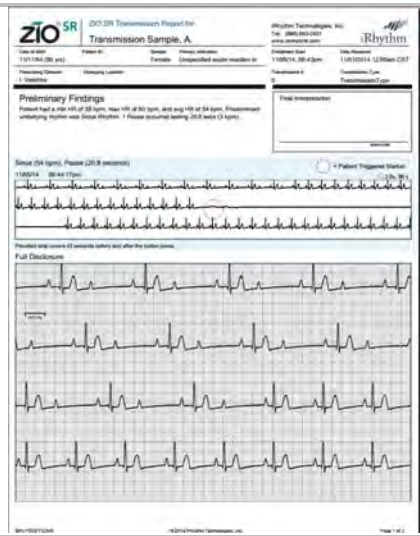
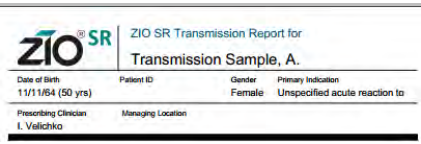
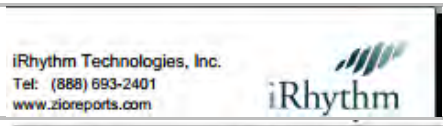
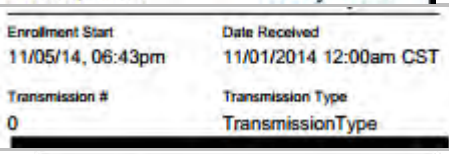
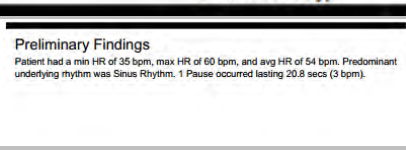
During monitoring the ZIO® device will record continuous beat to beat ECG information and transmit patient triggered ECG to provide accurate arrhythmia detection. Note that expected event transmission delays may vary significantly depending on how effectively the patient maintains patch-gateway proximity and gateway cellular reception. Transmission reports will be provided after receipt and analysis of patient triggered ECG strips.

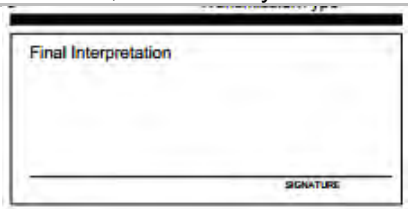
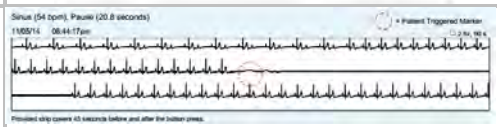
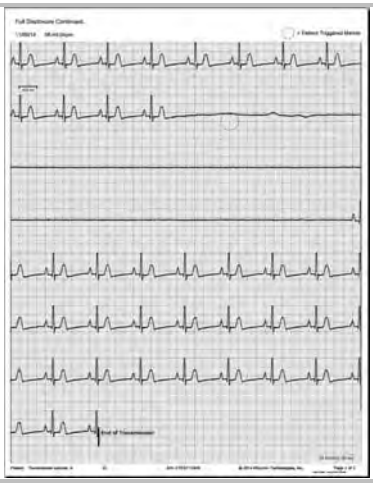
In special circumstances, when patient data needs to be accessed by the Physician during the wear period an Urgent Data Request can be made. In order to make an Urgent Data Request, the clinician should call iRhythm at 1-888-693-2401.

REPORTS

ZIO® SR TRANSMISSION REPORT

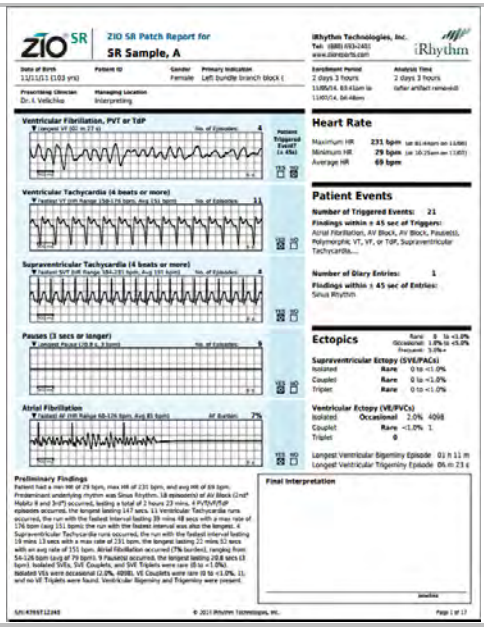
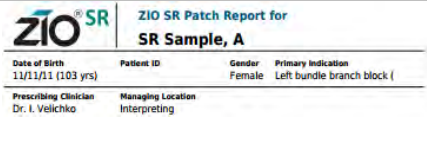
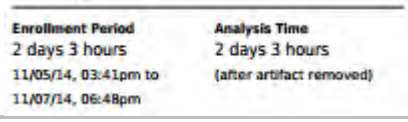
The transmission report is a snapshot of cardiac data during monitoring period.

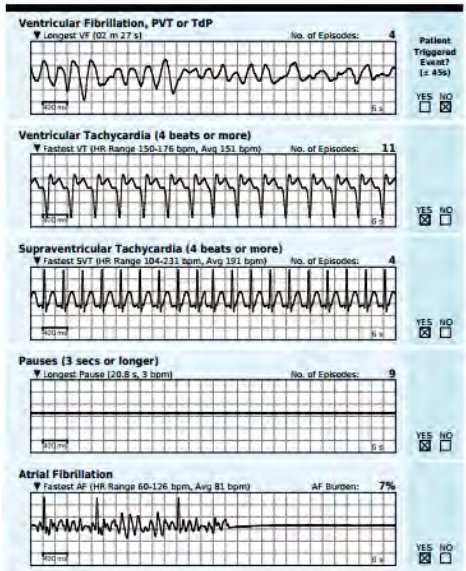
Each transmission report contains a 90 second ECG record centered on the Patient's button press time.	
It contains:	
"ZIO SR Transmission Report for" label followed by the Patient Demographics and prescription information:	 ZIO® SR ZIO SR Transmission Report for Transmission Sample, A. Date of Birth 11/11/64 (50 yrs) Patient ID Gender Female Primary Indication Unspecified acute reaction to Prescribing Clinician I. Velichko Managing Location
iRhythm contact information:	 iRhythm Technologies, Inc. Tel: (888) 693-2401 www.zioreports.com iRhythm
Enrollment and Event Transmission information:	 Enrollment Start 11/05/14, 06:43pm Date Received 11/01/2014 12:00am CST Transmission # 0 Transmission Type TransmissionType
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm)	 Preliminary Findings Patient had a min HR of 35 bpm, max HR of 60 bpm, and avg HR of 54 bpm. Predominant underlying rhythm was Sinus Rhythm. 1 Pause occurred lasting 20.8 secs (3 bpm).

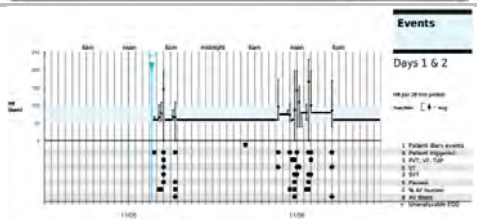
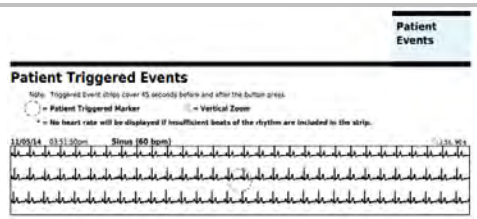
An area to include clinician's interpretation (when configured):	
A 200 mm/30 seconds resolution of the 90 second Event Transmission with a marker indicating the button press:	
A 25mm/sec resolution of the 90 seconds Event Transmission with a marker indicating the button press:	

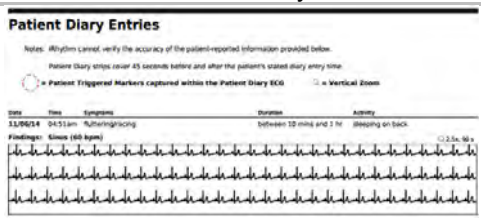
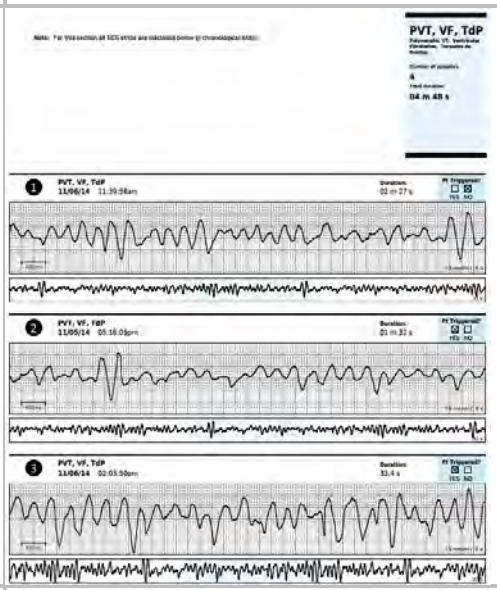
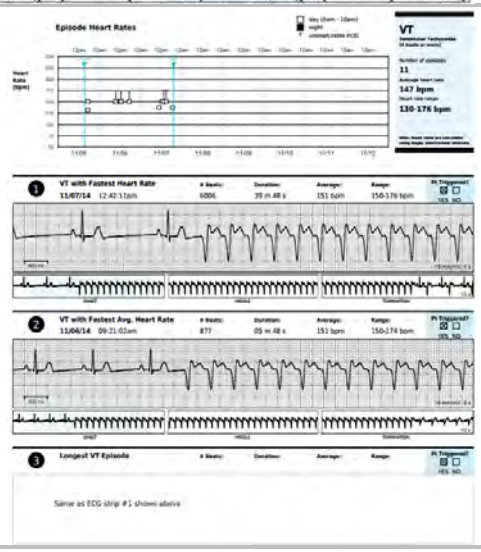
ZIO® SR PATCH CONTINUOUS REPORT

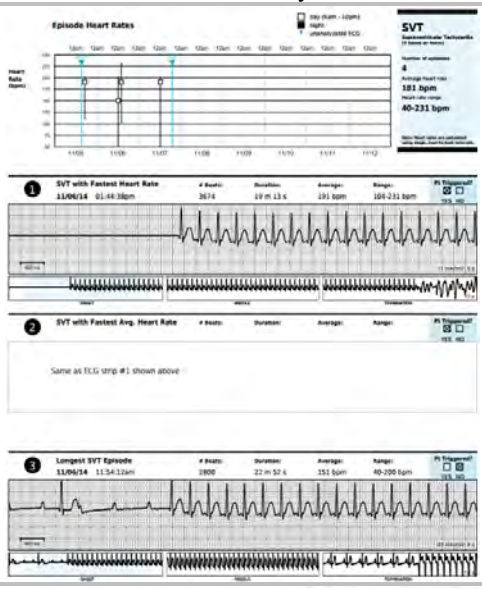
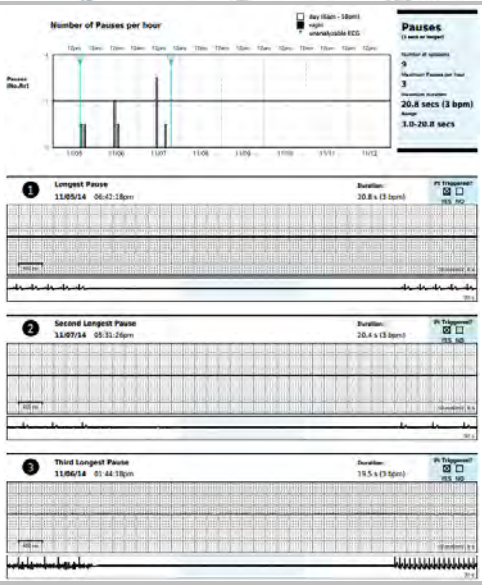
The ZIO® SR patch report is a comprehensive summary of symptomatic and asymptomatic arrhythmia findings that includes pertinent statistics, wear and analysis time, patient triggered and diary events.

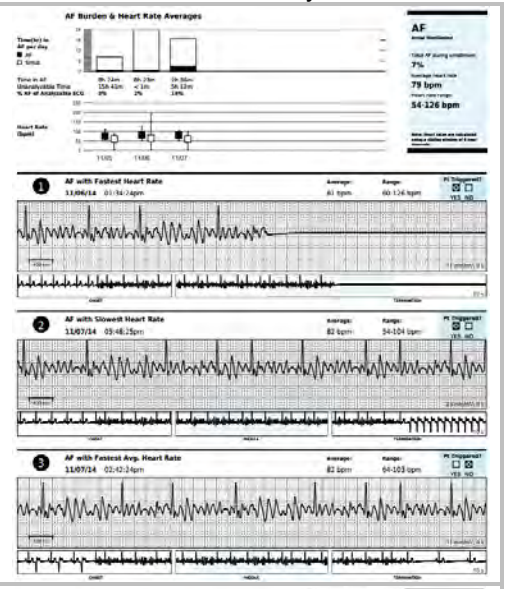
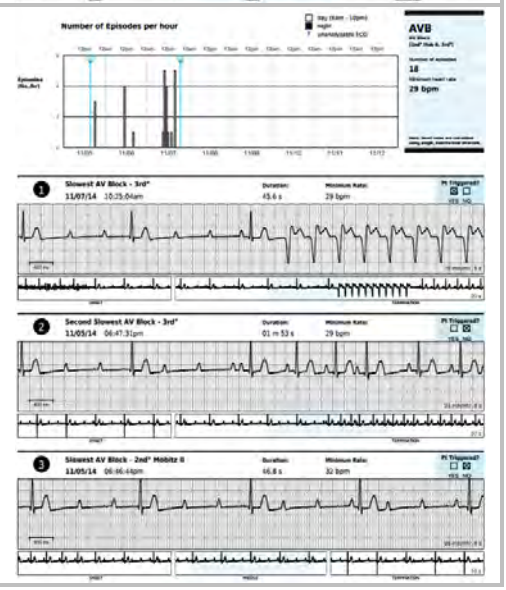
The front page includes a summary of all the finding:	
It contains:	
"ZIO SR Patch Report for" label followed by the Patient Demographics and prescription information:	
iRhythm contact information:	
Enrollment and Analysis information:	

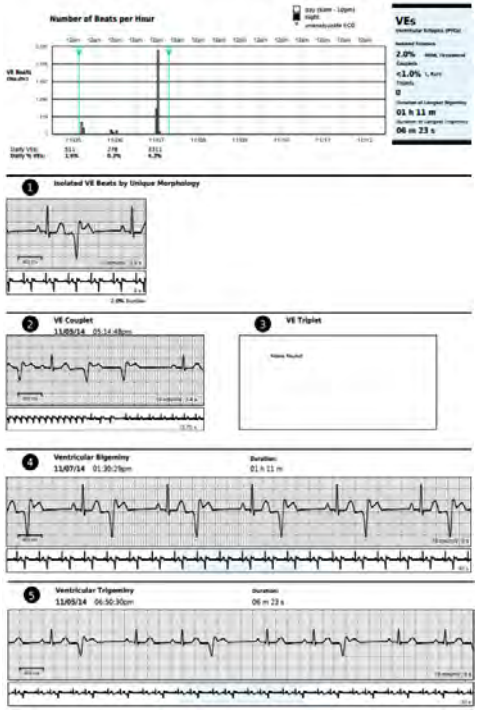
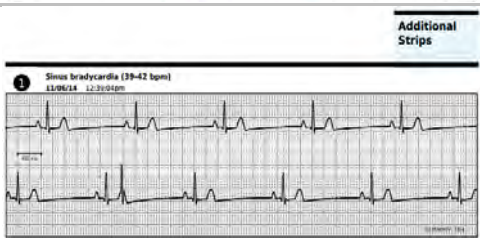
Arrhythmia Summary section:	
Heart Rate Summary section:	**Heart Rate** Maximum HR **231 bpm** (at 01:44pm on 11/06) Minimum HR **29 bpm** (at 10:25am on 11/07) Average HR **69 bpm**
Events (Patient Triggered and Diary Entry) summary:	**Patient Events** **Number of Triggered Events: 21** **Findings within ± 45 sec of Triggers:** Atrial Fibrillation, AV Block, AV Block, Pause(s), Polymorphic VT, VF, or TdP, Supraventricular Tachycardia,... **Number of Diary Entries: 1** **Findings within ± 45 sec of Entries:** Sinus Rhythm

Ectopics Summary section (including VEs, SVEs, Ventricular Bigeminy and Trigeminy):	**Ectopics** Rare: 0 to <1.0% Occasional: 1.0% to <5.0% Frequent: 5.0%+ **Supraventricular Ectopy (SVE/PACs)** Isolated **Rare** 0 to <1.0% Couplet **Rare** 0 to <1.0% Triplet **Rare** 0 to <1.0% **Ventricular Ectopy (VE/PVCs)** Isolated **Occasional** 2.0% 4098 Couplet **Rare** <1.0% 1 Triplet **0** Longest Ventricular Bigeminy Episode 01 h 11 m Longest Ventricular Trigeminy Episode 06 m 23 s
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm):	**Preliminary Findings** Patient had a min HR of 29 bpm, max HR of 231 bpm, and avg HR of 69 bpm. Predominant underlying rhythm was Sinus Rhythm. 18 episode(s) of AV Block (2nd° Mobitz II and 3rd°) occurred, lasting a total of 2 hours 23 mins. 4 PVT/VF/TdP episodes occurred, the longest lasting 147 secs. 11 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 39 mins 48 secs with a max rate of 176 bpm (avg 151 bpm); the run with the fastest interval was also the longest. 4 Supraventricular Tachycardia runs occurred, the run with the fastest interval lasting 19 mins 13 secs with a max rate of 231 bpm, the longest lasting 22 mins 52 secs with an avg rate of 151 bpm. Atrial Fibrillation occurred (7% burden), ranging from 54-126 bpm (avg of 79 bpm). 9 Pause(s) occurred, the longest lasting 20.8 secs (3 bpm). Isolated SVEs, SVE Couplets, and SVE Triplets were rare (0 to <1.0%). Isolated VEs were occasional (2.0%, 4098), VE Couplets were rare (0 to <1.0%, 1), and no VE Triplets were found. Ventricular Bigeminy and Trigeminy were present.
An area to include clinician's interpretation (when configured):	**Final Interpretation** SIGNATURE
Events Chart with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each 20 minutes segment:	
90 seconds (-/+ 45 secs.) 200 mm/30 seconds resolution ECG strips around patient button presses with a marker indicating the button press:	

90 seconds (-/+ 45 secs.) 30 seconds resolution ECG strips around patient diary entries and a button press marker whenever it occurred during a diary entry:	
Chapter with details of Ventricular Fibrillation, Polymorphic Ventricular Tachycardia & Torsade de Points (VF/PVT/ TdP):	
Chapter with details of Ventricular Tachycardia (VT):	

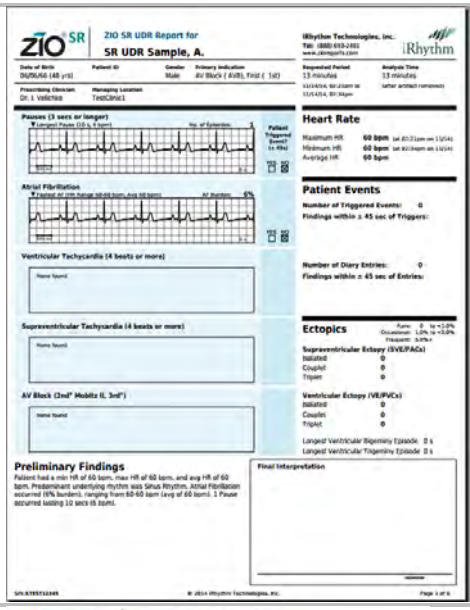
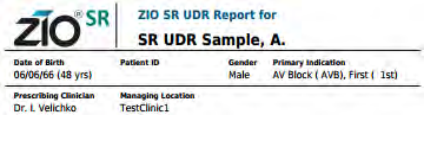
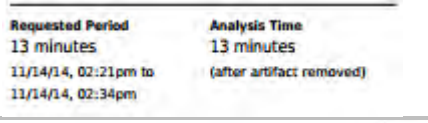
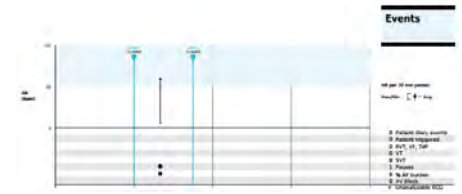
Chapter with details of Supraventricular Tachycardia (SVT):	
Chapter with details of Pause(s):	

Chapter with details of Atrial Fibrillation/Flutter (AF/AFL):	
Chapter with details of AV Block (AVB):	

Chapters with details of Ectopics (VEs and SVEs):	
Chapters for any additional ECG strips, which are either not included in the arrhythmia chapters or shown in different resolution:	

ZIO® SR URGENT DATA REQUEST (UDR) REPORT

The UDR report is an abbreviated version of the ZIO® report for a specific time period during the patient wear period requested by the clinician.

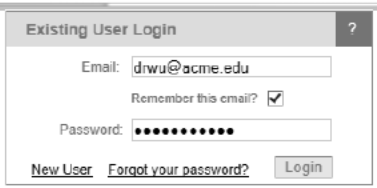
Each Urgent Data Request Report contains summary of all the findings within the requested data period. This report is very similar to the final summary report with differences mentioned below:	
"ZIO SR UDR Report for" label on the top of the Patient Demographics and prescription information:	
Requested Duration and Analysis information:	
Higher time resolution Events charts with indications for Start and End times of the data requests with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each	

20 minutes segment :	
Higher resolution arrhythmia chapter charts:	

ACCESSING REPORTS

1) Open up Internet Explorer and go to www.zioreports.com

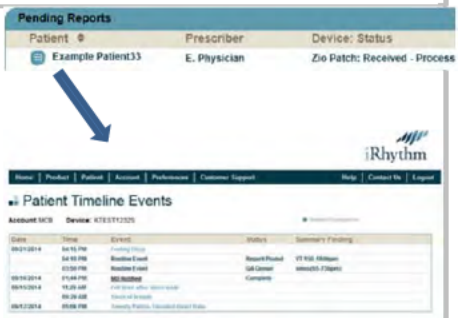
2) Enter your email address and password to securely login into zioreports.com



3) Select Register New Patient Option (Patient->Register New Patient)

4) From the Pending Reports list select the Timeline icon for the patient of interest

5) Within the Timeline, click the link to the appropriate report to open the attached report.



TROUBLESHOOTING

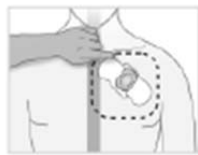
FOR CUSTOMER SUPPORT, CALL **1-888-693-2401**

FREQUENTLY ASKED QUESTIONS

Application

1. **The chest area was prepped and the device was applied. When the 'ZIO' button was pressed, it flashed orange (rather than green) five times.**
   Press down on the adhesive wings for a moment, so the device makes better contact with the skin. Then, press the 'ZIO' button again to attempt activation.
   If the devices does not activate (flash green) on the second attempt, please contact Customer Support at 1-888-693-2401.

2. **I think I placed the ZIO® SR Patch in the wrong position. Can I remove it and reposition it?**
   No. If the ZIO® SR Patch is over the heart in a slight diagonal as shown,
   the positioning should be acceptable.
   DO NOT attempt to reapply the ZIO® SR Patch.



3. **The top label was peeled off, but there still seems to be a white label stuck to the wings of the ZIO® SR Patch.**
   The top label may have separated. Peel the remaining white labels from the center of the ZIO® SR Patch outward.

4. **Are there tests or treatments that are not compatible with the ZIO® SR Patch?**
   Yes. The following are not recommended during wear of the ZIO® SR Patch:
   a. Magnetic Field(s): Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field

b. Neuromuscular Stimulators: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit
c. External Cardioversion/Defibrillation

NOTE: Data may not be interpretable during the time the stimulators are being used. Usage is at physician's discretion.

5. **Can the ZIO® SR Patch be left on a patient during Cardioversion/Defibrillation?**
   No, the ZIO® SR Patch should be removed if the patient requires Cardioversion or Defibrillation.

7. **I turned the gateway on but it is flashing orange?**
   Ensure that the patch has been turned on and is located within 10 feet of the gateway. If the gateway continues to flash orange for more than 2 minutes, please contact Customer Support at 1-888-693-2401.

Patient Questions

1. **How long is the patient supposed to wear the ZIO® SR Patch?**
   A patient can wear the ZIO® SR Patch for up to 14 days or as prescribed. Note: The ZIO® SR Patch will not record ECG data after 14 days.
   Based on individual wear experiences the patient's actual wear time may be shorter than prescribed.

2. **What is the ZIO® SR Patch doing?**
   The ZIO® SR Patch is recording every heartbeat. Pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

3. **What is the Zio SR Gateway doing?**
   The ZIO SR Gateway is sending heart rhythm data wirelessly when the ZIO button on the patch is pressed. The data is received at iRhythm and a report is provided to the patient's doctor while the patient may still be wearing the patch.

4. **Who should the patient call if they have questions about the ZIO SR Patch or Gateway?**
   The patient can read the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

5. **Who should the patient call if they have questions about the ZIO® SR Patch or if it falls off?**
   The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

6. **What should the patient do if they feel a symptom?**
   Press the 'ZIO' button and fill out a page of the *Patient Instructions & Button Press Log*.

7. **What if the patient forgets to press the 'ZIO' button when they feel a symptom?**
   While pressing the 'ZIO' button is important, the ZIO® SR Patch is recording every heartbeat.

8. **What if the patient presses the 'ZIO' button but forgets to write down the information on a Button Press Log page?**
   While the *Button Press Log* information is useful, pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

9. **What if the patient does not have symptoms?**
   That's okay. The ZIO® SR Patch records every heartbeat.

10. **What activities should the patient avoid while wearing the ZIO® SR Patch?**
    Activities that cause excessive sweating. This could cause the ZIO® SR Patch to slide, become loose, fall off, and shorten wear time.

11. **Can the patient exercise while wearing the ZIO® SR Patch?**
    Yes, but excessive sweating may shorten wear time.

12. **Can the patient shower with the ZIO® SR Patch on?**

Yes, but showers should be brief. Keep soaps and lotions away from the ZIO® SR Patch. If possible, face away from the water when showering. When towel-drying, the patient should hold the ZIO® SR Patch down with one hand so that it is not accidently knocked off. Instruct the patient to press the ZIO® SR Patch against their skin to secure it.

13. **Can the patient take a bath?**
    Yes, but the patient should keep the ZIO® SR Patch above water.

14. **Can the patient go swimming or in a hot tub?**
    No. The ZIO® SR Patch and ZIO® Gateway should not be submerged in water.

15. **Is it normal for the ZIO® SR Patch to move slightly from its original position?**
    Yes. The ZIO® SR Patch may move slightly from its original position. A blue gel may become visible under the wings of the ZIO® SR Patch.

16. **Is it normal to experience skin irritation or itchiness in the area of the ZIO® SR Patch?**
    Minor skin irritation and/or itching while wearing the ZIO® SR Patch may occur. If the irritation or itching is severe instruct the patient to remove the ZIO® SR Patch and call Customer Support at 1-888-693-2401.

17. **Is it normal for the ZIO® SR Patch wings to become cloudy in appearance?**
    Yes, the wings of the ZIO® SR Patch may become cloudy after a few days of wear.

18. **What should the patient do if they think they see blood under the ZIO® SR Patch?**
    Instruct the patient to call Customer Support at 1-888-693-2401. It is likely due to a small shaving cut when the device was applied to the chest.

19. **How will the patient know the ZIO® SR Patch is working?**

Once the ZIO® SR Patch is applied to the body, and the 'ZIO' button is pressed, a green light should flash, indicating that it was turned on. Afterwards, it will not flash or make noise when it is working properly.

20. **Will the ZIO® SR Patch flash while the patient is wearing it?**
No.If it is working properly, the ZIO® SR Patch will not flash or make noise. If the patient sees the ZIO® SR Patch flashing orange, this does not mean there is a problem with the patient's heart; it just means that the ZIO® SR Patch is not well attached. Instruct the patient to press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call Customer Support at 1-888-693-2401.

21. **Can a patient travel with the ZIO® SR Patch on?**
Yes. Please take the Patient Instruction and Button Press Log with you when traveling. If questioned during security screening there is a statement included in the *Patient Instruction & Button Press Log* for them to reference.

22. **When the patient removes the ZIO® SR Patch, it is flashing orange. Is this okay?**
The ZIO® SR Patch may blink orange after removal. It is okay to mail the device while it is blinking.

23. **Will the ZIO Gateway show any lights or make any sounds during normal use?**
No. If it is able to send data, the ZIO Gateway will not flash or make noise. If the patient sees the gateway flashing orange, this means there is a problem sending data wirelessly to the patch or to iRhythm.

24. **Does the patient need to do anything with the ZIO Gateway to send heart rhythm data wirelessly?**
The patient only needs to keep the Gateway within 6 feet of the patch and within range of good cellular reception. No action is

required for the Gateway to send symptomatic heart rhythm data other than pressing the ZIO button on the patch.

25. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway is not within 10 feet?**
    The patch will store the data until the Gateway is within range, then the data will be sent.

26. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway doesn't have cellular reception?**
    The gateway will store the data until it has cellular reception, then the data will be sent.

27. **What should the patient do if the ZIO Gateway is flashing orange?**
    Gateway flashing orange means that the patch cannot send us information wirelessly. The patient can attempt troubleshooting using the "Gateway Troubleshooting Guide" in the *Patient Instructions and Button Press Log* (see page 35 of this manual) or call Customer Support at 1-888-693-2401.

28. **Can the patient fly with the ZIO Gateway?**
    Yes. The gateway cellular radio can be turned off by pressing the airplane button inside the gateway for 3 seconds. The gateway cellular radio can be turned back on by pressing the airplane button for 3 seconds. While in "Airplane Mode" the airplane light on the outside face of the gateway will flash.

PATCH FLASHING LIGHTS KEY

If the light on the patch is flashing orange, pick the troubleshooting action based on the following:

- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

Flashing light location	Light flashing speed	Recommended action
	SLOW	Press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, call Customer Support at 1-888-693-2401.
	FAST	Call Customer Support at 1-888-693-2401.

GATEWAY FLASHING LIGHTS KEY

If the outside status light on the gateway is flashing orange, open the gateway and pick the troubleshooting action based on the following:

- Which inside lights are flashing orange?
- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

Flashing light location	Light flashing speed	Recommended action
	SLOW	Keep the gateway near to the patch for at least 10 minutes. If the light continues to flash, call Customer Support at 1-888-693-2401.
	SLOW	Move the gateway to an area with cellular reception and press the “Control” button for 3 seconds. If the gateway is able to connect and send the information, the light will flash green until it is done sending. Keep the gateway in the same location until the green flashing stops. If orange flashing does not stop even in an area with good cellular reception, call Customer Support at 1-888-693-2401.

	FAST	Call Customer Support at 1-888-693-2401.

IRHYTHM CLINICAL FACILITY CERTIFICATION

The ZIO® SR Patch heart monitor is analyzed at the iRhythm Clinical Center. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R.section 410.33) can be found at the iRhythm website www.irhythmtech.com.

NOTICE OF PRIVACY PRACTICES (NOPP)

iRhythm is committed to protecting the privacy of your personal information. We are required by the U.S. - EU Safe Harbor Framework to maintain the privacy of your personal information, and to notify you of our privacy practices, our legal duties, and your rights concerning your personal information.

Why?	As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information ("PHI"). This notice describes our privacy practices, our legal duties, and your rights concerning your PHI. We will follow the privacy practices described in this notice while it is in effect. We reserve the right to revise this notice and to make the new notice provisions effective for all PHI we maintain. If we revise this notice, we will post the revised notice on this page.
What?	In providing diagnostic services, the types of information we collect may include: - Name - Gender - Date of Birth - Medicare and Secondary Insurance Information - Address and Phone Number - Prescribing Physician and Office - Primary Indication - ECG Recording - Symptoms and Activities You Report, by Time and Date - Activity Level During Monitoring - Patient Identification Number - Clinical Information and Diagnostic Results
How?	By providing diagnostic services to our patients, we regularly collect information through: - Phone conversations - Patient submitted documents - Prescribing physician submitted documents - ZIO® Event card transmissions - Return of ZIO® XT Patches

How We May Use Your Information			
We have the right to use and disclose health information for your treatment, to secure payment for your health care, and to operate our business.			
Without Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
To You	We must disclose your PHI to you, as described in the "Your Rights" section of this notice.	Yes	Yes
For Payment	We may use and disclose PHI to obtain payment for services provided to you. We may also disclose your PHI to a health care provider or health plan so that the provider or plan may obtain payment of a claim or engage in other payment activities.	Yes	Yes
For Treatment	We may use and disclose PHI to provide and manage your diagnostic services. That may include consulting with other health care providers about your diagnostic services. For example, we will release the results of your diagnostic services to your prescribing physician, to the physician treating you, or in a medical emergency, if applicable.	Yes	No
For Health Care Operations	We may use or disclose PHI to conduct quality assessment and improvement activities, to conduct fraud and abuse investigations, to engage in care coordination or case management, or to communicate with you about health related benefits and services or treatment alternatives that may be of interest to you. We may also disclose PHI to a health care provider or health plan	Yes	No

	subject to federal privacy laws, as long as the provider or plan has or had a relationship with you and the PHI is disclosed only for certain health care operations of that provider or plan. We may also disclose PHI to other entities with which we have contracted to perform or provide certain services on our behalf (e.g., business associates).		
For Business Operations	We may use both De-Identified and Limited Data Sets (a data set that, per the Health Insurance Portability and Accountability Act of 1996 regulations, has had patient-identifiable data removed except for dates of service) for development of future products, devices or services. Once information is De-Identified through an approved method, the data is stripped of individual identifiers, at which point iRhythm may share this information without restriction externally to support research, market development, trend analysis, etc. Information containing Limited Data Sets may be provided externally to support market and product development. However, iRhythm will obtain the required data use agreements when transferring Limited Data Sets to external parties.	Yes	Yes
For Public Health And Safety	We may use or disclose PHI to the extent necessary to avert a serious and imminent threat to the health or safety of you or others. We may also disclose PHI for public health and government health care oversight activities and to report suspected abuse, neglect or domestic violence to government authorities	Yes	No
As Required By Law	We may use or disclose PHI when we are required to do so by law.	Yes	No

For Process And Proceedings	We may disclose PHI in response to a court or administrative order, subpoena, discovery request, or other lawful process.	Yes	No
For Law Enforcement	We may disclose PHI to a law enforcement official with regard to crime victims and criminal activities.	Yes	No
Special Government Functions	We may disclose the PHI of military personnel or inmates or other persons in lawful custody under certain circumstances. We may disclose PHI to authorized federal officials for lawful national security activities.	Yes	No
For Research, Death, And Organ Donation	We may use or disclose PHI in certain circumstances related to research, death or organ donation.	Yes	No
For Workers' Compensation	We may disclose PHI as permitted by workers' compensation and similar laws.	Yes	No
With Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
You may give us written authorization to use your PHI or disclose it to anyone for any purpose not otherwise permitted or required by law. If you give us such authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosure permitted by your authorization while it was in effect.		Yes	Yes
While the law permits us in certain circumstances to disclose your PHI to family, friends and others, we will do so only with your authorization. In the event you are unable to authorize		Yes	Yes

such disclosure, but emergency or similar circumstances indicate that disclosure would be in your best interest, we may disclose your PHI to family, friends or others to the extent necessary to help with your health care coverage arrangements.		

Your Rights	
Access	With limited exceptions, you have the right to review in person, or obtain copies of, your PHI. We may charge you a reasonable fee as allowed by law to obtain this information.
Amendment	With limited exceptions, you have the right to request that we amend your PHI.
Disclosure Accounting	You have the right to request and receive a list of certain disclosures made of your PHI. If you request this list more than once in a 12-month period, we may charge you a reasonable fee as allowed by law to respond to any additional request.
Use/Disclosure Restriction	You have the right to request that we restrict our use or disclosure of your PHI for certain purposes. We are not required to agree to a requested restriction. We will agree to restrict use or disclosure of your PHI provided that the law allows and we determine the restriction does not impact our ability to operate our business, provide diagnostic services, and comply with the law. Even when we agree to a restriction request, we may still disclose your PHI in a medical emergency and use or disclose your PHI for public health and safety and other similar public benefit purposes permitted or required by law.
Confidential Communication	You have the right to request that we communicate with you in confidence about your PHI at an alternative address.
Privacy Notice	You have the right to request and receive a copy of this notice at any time. For more information or if you have questions

	about this notice, please contact us using the information listed at the end of this notice.
Complaints / Violations	
If you are concerned that we may have violated your privacy rights, you may inquire with us using the contact information listed at the end of this notice. You may also submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address for the U.S. Department of Health and Human Services upon request. We support your right to protect the privacy of your PHI. We will not retaliate in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.	
To Limit Our Sharing Or Submit Complaints	Call 1-888-693-2401 - our Customer Service staff will assist you
Questions?	Call 1-888-693-2401
Who We Are	
Who Is Providing This Notice?	This privacy notice is being provided by iRhythm Technologies, Inc., and applies to the diagnostic services offered in connection with prescribed health care.
What We Do	
How Does iRhythm Protect My PHI?	To protect your PHI from unauthorized access and use, iRhythm has implemented security safeguards that comply with federal law to secure physical and electronic information.
Company Contact Details	
Address:	iRhythm Technologies, Inc. 650 Townsend Street Suite 380

	San Francisco, CA 94103 Attn: Privacy Official www.irhythmtech.com
Phone:	415.632.5700
Fax:	415.632.5701

DEVICE SPECIFICATIONS

PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	1 day

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Cellular RF Transmit/Receive	800 / 1900 MHz CDMA Effective Radiated Power ≤ 300mW

POWER CHARACTERISTICS

Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.0 x 0.5 inches
Patch Weight	24.7 g

Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g

ENVIRONMENTAL CHARACTERISTICS

Operational Temperature	36 to 104 degrees
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IPX4
Gateway IP Classification	IPX2

ESSENTIAL PERFORMANCE

The ZIO SR device records and transmits ECG for analysis after receipt of data. In the event it cannot record or transmit in a timely fashion, the ZIO SR alerts the patient that functionality is impaired.

HEART RATE CALCULATIONS

Episode Heart Rates	Max	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (i.e., minimum of all instantaneous heart rates within the episode)
	Avg	The average episode heart rate (i.e., average of all instantaneous heart rates within the episode)
Overall Rhythm Heart Rates	Max	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (i.e., minimum of all rhythm episode minimum heart rates exclusive of Pause heart rates within the record)
	Avg	The average overall heart rate (i.e., duration-weighted average of all rhythm episode heart rates within the record)

PAUSE DETERMINATION

Pause is defined as an RR interval greater than 3 seconds.

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The ZIO SR needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The ZIO SR should not be used adjacent to or stacked with other equipment.
- WARNING: The ZIO SR may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.

Table 1: Guidance and manufacturer's declaration— electromagnetic emissions

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ZIO® SR device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ZIO® SR device is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZIO® SR device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$80 MHz to 800 MHz $d = 2.3\sqrt{P}$800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 3, Continued

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

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

- Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZIO® SR is used exceeds the applicable RF compliance level above, the ZIO® SR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZIO® SR Patch.
- Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the ZIO® SR

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**80 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

PATIENT INSTRUCTIONS & BUTTON PRESS LOG

NAME:

PHYSICIAN:

START DATE: / /

TO BE COMPLETED BY PATIENT:

DATE REMOVED: / /

The ZIO SR patch records every heartbeat and the ZIO SR gateway sends a section of data for analysis each time the patch button is pressed.

☺ IT IS OKAY IF …

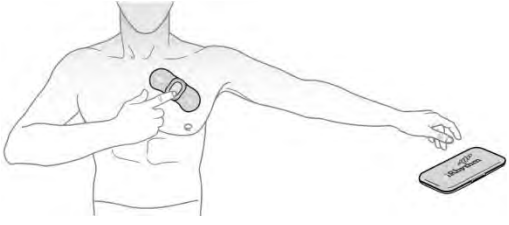
- The patch peels or lifts at the edges.
- You experience some itching.
- There are no lights on your patch and gateway.

CALL 1.888.693.2401 IF …

- The patch falls off.
- You feel severe itching or irritation.
- Patch or gateway lights are flashing.
  - ➔ This does not mean there is a problem with your heart
  - ➔ Turn to p.7 and p.8 to troubleshoot

During Recording:

Wear the patch during your normal daily activities, even while showering and sleeping. Keep the gateway in arm's reach and in view to stay connected.



Each time you feel a symptom, press the patch button and then record your symptom in a *Button Press Log* in this booklet or online at www.myzio.com.

When you are done wearing the patch:

Turn to the end of this booklet for removal and return instructions.

ZIO DO's

DO your normal activities while wearing the patch	**BUT...**
DO shower with your patch on	**BUT...**
DO try to keep your gateway with you, in arm's reach and in view	**BUT...**
DO try to keep the gateway in a place with cellular signal	**BUT...**
DO carry the gateway with you when you can	**BUT...**
DO travel with your patch and gateway	**BUT...**
DO put your patch inside the gateway and send it to iRhythm for analysis	**BUT...**

ZIO DON'Ts

DON'T do activities that cause heavy sweating

DON'T put your patch under water or let the gateway get wet

DON'T worry if it is out of range for a while

DON'T worry if it is out of range for a while

DON'T leave the gateway within 6 feet of 2.4 GHz devices like wireless routers, baby monitors and TV senders

DON'T forget to turn off airplane mode (p. 10)

DON'T put other objects in the gateway

WARNING

If at any time you feel the need for immediate medical care, call 911. The ZIO® SR device will not provide any medical assistance and cannot contact medical personnel for you.

PATCH TROUBLESHOOTING GUIDE

If the patch light is flashing orange slowly (once every 3 seconds):

→ Your patch is not making good contact. Press evenly on the patch for 3 to 5 minutes. If flashing continues, call 1-888-693-2401.

If the patch light is flashing orange fast (three times per second):

→ Your patch is not recording. Call 1-888-693-2401.

GATEWAY TROUBLESHOOTING GUIDE

Open your gateway and look inside...

If the gateway light is flashing orange slowly (once every 3 seconds):

→ The gateway lost connection to your patch. Keep the gateway near to the patch for at least 10 minutes. If flashing continues, call Customer Support at 1-888-693-2401.

If any gateway light is flashing orange fast (three times per second):

→ Your gateway is not working. Call Customer Support at 1-888-693-2401.

GATEWAY TROUBLESHOOTING GUIDE

Open your gateway and look inside...

SLOW

If the gateway light is flashing orange slowly (once every 3 seconds):

→ The gateway does not have cell signal. Move the gateway to a place with good cell signal, near a window or outside and hold the button for 3 seconds until the light flashes green.

- Keep the gateway there until green flashing stops.
- If it does not flash green, move the gateway to a new place and try again.

If orange flashing continues, call Customer Support at 1-888-693-2401.

TRAVELING WITH YOUR ZIO® SR

The patch can be worn through security screenings. A security statement is provided on the opposite page.

Airplane Mode ON (to turn off the cell radio):

1) Open the gateway
2) Press and hold the ✈ button for 3 seconds until the inside lights flash orange quickly. The outside airplane light will flash as long as the gateway is in “Airplane Mode.”

Airplane Mode OFF (to turn on the cell radio):

1) Open the gateway
2) Press and hold the ✈ button for 3 seconds until the inside lights flash green quickly. The outside airplane light will flash stop flashing.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

How long am I supposed to wear the patch?

Wear the patch for as long as your doctor prescribed but no longer than 14 days. NOTE: Each person's wear experience is different and actual wear time may be shorter than prescribed.

What is the patch doing?

The patch is recording every heartbeat. Your doctor will use the data from the patch to look at your heart rhythm and determine the right course of action.

What is the gateway doing?

The gateway is wirelessly sending a section of heart rhythm data from the patch each time the patch button is pressed. The data is received at iRhythm for analysis and a report is provided to your doctor.

What should I do if I feel a symptom?

Press the button and fill out a page of the *Button Press Log* in this booklet or on www.myzio.com. Make sure to keep the gateway in arm's reach and in view

What if I forget to press the button when I feel a symptom?

While pressing the button is important to "tag" and wirelessly send an event, the patch is recording every heartbeat.

What if I press the button but forget to write down the information in this booklet?

While the *Button Press Log* information is useful, pressing the button indicates that you felt your symptoms at that time.

What if I don't have symptoms?

That's okay. The patch records every heartbeat.

Do I need to do anything with the gateway to send heart rhythm data wirelessly?

No, you only need to keep the gateway in arm's reach and in view to stay connected wirelessly after you press the patch button. The gateway should also be kept in a place with good cell signal.

How do I know the patch and the gateway are working?

When they were turned on, the staff at your doctor's office made sure that the patch and gateway were working. When they are working with no problems, the patch and gateway will not flash or make noise.

Will the gateway show any lights or make any sounds?

No. As long as it is able to send data, the gateway will not flash or make noise.

What if I press the patch button while the gateway is not in range?

The patch will store the data until the gateway is in range, then the data will be sent.

What happens if I press the patch button while the gateway doesn't have cell signal?

The gateway will store the data until it has cell signal, then the data will be sent.

What kinds of devices can affect wireless connection with the gateway?

Other wireless devices that use 2.4 GHz signals such as baby monitors, TV senders, and wireless routers can interrupt communication between patch and gateway if used within 6 feet.

What should I do if the patch falls off?

Call Customer Support at 1-888-693-2401.

What should I do if the patch peels or lifts at the edges?

Press and hold along the edges to re-stick.

Can I exercise while wearing the patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the patch on?

Yes, but showers should be short. Keep soaps and lotions away from the patch. When towel-drying, hold the patch down with one hand. Press the patch against your skin to secure it.

Can I take a bath?

Yes, but keep the patch above water.

Can I go swimming or in a hot tub?

No. The patch should not be put under water and heavy sweating will reduce shorten wear time.

Is it normal for the ZIO® SR Patch wings to become cloudy?

Yes, the wings of the patch may become cloudy after a few days of wear.

Is it normal for the patch to move slightly from its original position?

Yes. The patch may move slightly from its original position. A blue gel may be seen under the wings of the patch.

Is it normal to experience skin irritation or itchiness in the area of the patch?

Most patients do not experience skin irritation or itchiness. However, some patients have reported minor skin irritation and/or itching while wearing the patch. If the irritation or itching is severe or hives or blisters develop please call Customer Support at 1-888-693-2401.

What activities should I avoid?

Activities that cause heavy sweating should be avoided. Sweat can cause the patch to slide, become loose, fall off, and shorten wear time.

I think I see blood under my patch. What should I do?

Call Customer Support at 1-888-693-2401. It is probably due to a small shaving cut when the patch was applied to your chest.

What if the patch flashes orange while I am wearing it?

If you see the patch flashing orange, this does not mean there is a problem with your heart; it just means that the patch is not well attached. Press evenly on the patch for 3 to 5 minutes. If the flashing continues or comes back, call Customer Support at 1-888-693-2401.

What should I do if my gateway is flashing orange?

If you see the gateway flashing orange, this does not mean there is a problem with your heart; it just means that the patch cannot send information wirelessly. Turn to page 8 to troubleshoot or call Customer Support at 1-888-693-2401.

Can I travel with the patch on?

Yes. If questioned during security screening, show the statement on page 11.

Can I fly with the gateway?

Yes. The gateway cellular radio can be turned off by pressing the airplane button inside the gateway for 3 seconds. The gateway cellular radio can be turned back on by pressing the airplane button for 3 seconds. While in “airplane

mode" the airplane light on the outside face of the gateway will flash. See page 10.

How do I return the patch and gateway?

You can drop off the sealed envelope at the Post Office, in a USPS (blue) mailbox or give it to your mail carrier. Turn to the end of this booklet for removal and return instructions.

I have removed the patch and it is flashing orange. Is this okay?

The patch may flash orange after removal. It is okay to mail the device while it is flashing. Turn to the end of this booklet for return instructions.

Who should I call if I have questions about the patch or gateway?

Call Customer Support at 1-888-693-2401.

BUTTON PRESS LOG

I pressed the button on...

05 / 29 / 13 (mm / dd / yy) 07 : 45 [X] AM [ ] PM

...because I felt:

- [ ] anxious
- [ ] arm or neck pain/tingling
- [ ] chest pain or pressure
- [X] dizziness
- [ ] fainted
- [X] light headed
- [ ] pounding
- [X] fluttering or racing
- [ ] short of breath
- [ ] skipped beat(s), irregular beats
- [ ] other (describe):

...for this duration:

- [X] 1 min or less
- [ ] 10 mins or less
- [ ] 1 hour or less
- [ ] More than 1 hour

...while I was

describe activity: getting out of bed

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m ☐ AM ☐ PM

...because I felt:

- ☐ anxious
- ☐ arm or neck pain/tingling
- ☐ chest pain or pressure
- ☐ dizziness
- ☐ fainted
- ☐ light headed
- ☐ pounding
- ☐ fluttering or racing
- ☐ short of breath
- ☐ skipped beat(s), irregular beats
- ☐ other (describe):

...for this duration:

- ☐ 1 min or less
- ☐ 10 mins or less
- ☐ 1 hour or less
- ☐ More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m ☐ AM ☐ PM

...because I felt:

- ☐ anxious
- ☐ arm or neck pain/tingling
- ☐ chest pain or pressure
- ☐ dizziness
- ☐ fainted
- ☐ light headed
- ☐ pounding
- ☐ fluttering or racing
- ☐ short of breath
- ☐ skipped beat(s), irregular beats
- ☐ other (describe):

...for this duration:

- ☐ 1 min or less
- ☐ 10 mins or less
- ☐ 1 hour or less
- ☐ More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

ZIO® SR DATA ANALYSIS

Your ZIO® SR data is analyzed at the iRhythm Clinical Centers. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R. section 410.33) can be found at the iRhythm website www.irhythmtech.com.

PATIENT IDENTIFICATION

Before placing your device in the prepaid envelope, please write your name on the line above the return address. By writing your name on the envelope you are providing another method of identification for the patch and gateway and are consenting to the potential viewing of your name on the envelope. You may choose to not write your name on the envelope.

NOTICE OF PRIVACY PRACTICES

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your

Protected Health Information (PHI). Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

INDICATIONS FOR USE

The ZIO SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the inteded user to render a dianosis based on clinical judgment and experience.

CONTRAINDICATIONS

- Do not use the ZIO® SR for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient.
- Do not use the ZIO® SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO® SR in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.

- Do not use the ZIO® SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

WARNINGS

- Do not use the ZIO® SR patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO® SR. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO® SR on patients residing in areas with limited to no cellular reception.

⚠ If skin irritation such as severe redness, itching or allergic symptoms develop, remove the patch.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician

Prescription-use only

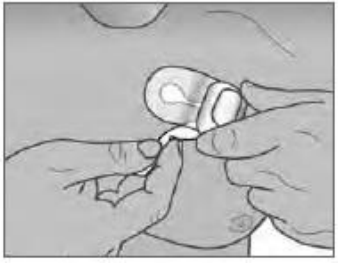

RF Transmitter


Keep Dry

PRECAUTIONS

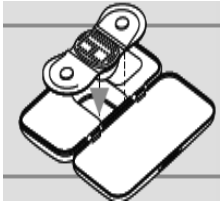
- The ZIO® SR includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the ZIO® SR on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

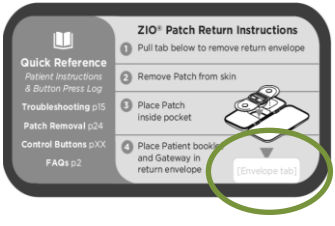
REMOVING AND RETURNING THE PATCH



1) Use the adhesive remover to the right. Tilt the center of the patch up and sweep between your skin and the patch while lifting one side from the center out. Repeat for the other side, lifting from the center out. Wash skin with mild soap, rinse with water, and pat dry.

2) Place the patch inside the gateway as shown





3) Pull tab in the gateway to remove envelope. Place the patch, gateway and this booklet inside the envelope and seal. Mail to iRhythm.

iRhythm Technologies, Inc.
Clinical Centers
650 Townsend St., Suite 380
San Francisco, CA 94103

2 Marriott Drive
Lincolnshire, IL 60069
363 N. Sam Houston Parkway East, Suite 125
Houston, TX 77060

1.888.693.2401 | irhythmtech.com | @iRhythmTech

FOR SUPPORT, CALL **1.888.693.2401**

SKIN PREP IS IMPORTANT FOR GOOD ECG SIGNAL QUALITY AND ADHESION.

FLIP OPEN

FLIP OPEN

iRhythm

iRhythm Technologies, Inc.
650 Townsend St., Suite 380
San Francisco, CA 94103
irhythmtech.com

K100A2008

FAQs

Why do I need to abrade the skin?

Abrading removes the top layer of skin, which is necessary for long-term adhesion and good signal quality.

Why do I need to clean the skin?

The alcohol wipes help remove surface oils that may be on the skin. It is important to clean the skin after the Abrade step to ensure adhesion and good signal quality.

What is this top liner?

The top liner helps keep the ZIO® SR Patch rigid and straight as it is applied to the patient. It prevents the adhesive from folding and sticking together.

I think I have a defective device What should I do?

If you suspect a defect, please contact customer service. Unless instructed otherwise, please send the devices back to iRhythm Technologies, Inc.

TROUBLESHOOTING

The patch flashes orange 5 times after attempting to turn on.

Press down on the adhesive sides for a moment, so the device makes better contact with the skin. Then, press the button.

If the device still does not activate (flash green), contact customer service.

The gateway flashes orange but won't flash green.

Make sure the patch is on and bring the gateway close to the patch. The flashing should change to green before stopping.

K100A2007-A

ZIO® SR

SKIN PREP & PLACEMENT KIT

ZIO®SR

SKIN PREP & PLACEMENT KIT

FOR SUPPORT, CALL
1.888.693.2401

Perforation

This panel is hidden/inside when folded (tab tucked into slit)

4 IMPORTANT STEPS TO GET STARTED WITH THE ZIO® SR PATCH

PLACE SERIAL NUMBER LABEL HERE

PATIENT NAME

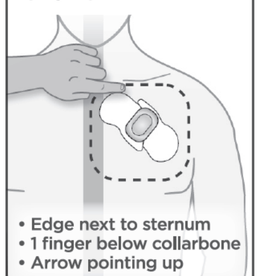
1 PLAN & POSITION

ENROLL

ZioReports.com

POSITION

Place patient in a relaxed, upright position



- Edge next to sternum
- 1 finger below collarbone
- Arrow pointing up

TEAR ALONG PERFORATION AND KEEP UNTIL PATIENT IS ENROLLED

RAZOR

ABRADER

ALCOHOL

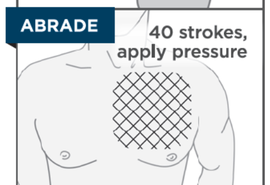
2 PREP SKIN

SHAVE

How to remove razor

ABRADE

40 strokes, apply pressure



CLEAN

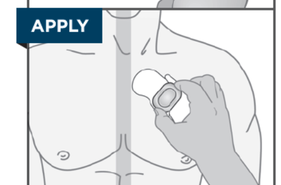
Let skin dry for 1 minute

3 APPLY PATCH

REMOVE

Clear adhesive backings

APPLY



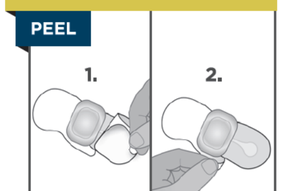
PRESS

... for 2 minutes

4 FINISH & ACTIVATE

PEEL

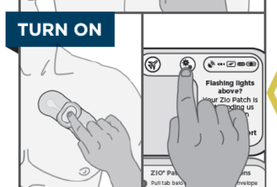
1. 2.



PRESS

... for 2 minutes

TURN ON



PRESS PATCH BUTTON TO ACTIVATE
PATCH SHOULD FLASH GREEN

THEN OPEN GATEWAY AND PRESS ✲* BUTTON TO ACTIVATE
GATEWAY SHOULD FLASH ORANGE, CHANGING TO 5 GREEN FLASHES.

SEE REVERSE FOR FAQs AND TROUBLESHOOTING

FOR SUPPORT, CALL
1.888.693.2401

PRACTICE BUTTON PRESS WITH PATIENT.

0.55″

TUCK IN LOCKING TAB AND
SECURE WITH TAPE BEFORE MAILING

ZIO XT

DO NOT OPEN THIS SIDE!

ZIO XT

Name:

Package Contains Lithium-ion Batteries (no lithium metal)

BUSINESS REPLY MAIL
FIRST-CLASS MAIL PERMIT NO. 78003 LINCOLNSHIRE, IL
POSTAGE WILL BE PAID BY ADDRESSEE

ATTN: ZIO® XT PATCH INTAKE
IRHYTHM NATIONAL CLINICAL CENTER
2 MARRIOTT DRIVE
LINCOLNSHIRE IL 60069-9904

NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

ZIO XT

C

OPEN THIS SIDE

TUCK IN LOCKING TAB AND
SECURE WITH TAPE BEFORE MAILING

PRINTED WITH VEGETABLE-BASED INKS • LOW VOC

100% Recycled Content

KEEP THIS BOX!

YOU WILL RETURN THE ZIO® XT PATCH IN THIS BOX.

ZIO® XT

C

Manufactured by:
iRhythm Technologies, Inc.
14462 Astronautics Lane
Huntington Beach, CA 92647
1.888.693.2401

LOCKING TAB

ZIO® XT

LOCKING TAB

Contents Include:
- ZIO® XT Patch
- Skin Prep & Placement Kit
  - 1 Razor
  - 1 Abrader Disc
  - 2 Alcohol Pads
- Patient Instructions & Button Press Log
  - 1 Adhesive Remover Wipe
  - 1 Box Seal
- Patient Survey

REF N100A102C Rx Only Qty: 1

Description: ZIO® XT Patch

http://www.zioreports.com N100A202C.01

-20°C -4°F 40°C 104°F 10% 95% LATEX FREE

Use within ONE day of opening.

(b)(4) Design Specifications

(b)(4) Design Specifications

ZIO® XT

CLINICAL REFERENCE MANUAL

TABLE OF CONTENTS

INDICATIONS FOR USE

The ZIO® XT Patch is a prescription-only, single patient use, continuously recording ECG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

CONTRAINDICATIONS

The ZIO® XT Patch has no known contraindications.

DESCRIPTION

The Zio® XT Patch is a single-patient-use ECG recorder that provides a continuous, single-channel recording for up to 14 days. The Zio® XT Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report.

After conclusion of the wear period (up to 14 days), the patient removes the Zio® XT Patch and returns it via US Mail to an iRhythm data processing center. After receipt, the data is analyzed by iRhythm's proprietary Zio® System before a Certified Cardiographic Technician reviews the results and generates a report of the key findings.

WARNINGS

- Do not use the ZIO® XT Patch on patients with known allergic reaction to adhesives or hydrogels or with a family history of adhesive skin allergies.
- Do not use the ZIO® XT Patch in combination with external cardiac defibrillators or high frequency surgical equipment.
- Do not use the ZIO® XT Patch near strong magnetic fields or devices such as MRI.
- Do not use the ZIO® XT Patch on patients with a neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® XT Patch on patients who do not have the competency to wear the device for the prescribed monitoring period.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician.

PRECAUTIONS

Patients with sensitive skin or known skin conditions should use the ZIO® XT Patch with caution.

If irritation such as redness, severe itching or allergic symptoms (i.e. hives) develop, instruct patients to remove the ZIO® XT Patch immediately and then call **1-888-693-2401** for iRhythm Customer Support.

The ZIO® XT Patch and associated ZIO® analysis system have not been tested on patients receiving any form of pacing therapy. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

The ZIO® XT Patch and associated ZIO® analysis system have not been tested on pediatric patients (younger than 18 years old). The ZIO® XT Patch may pose a hazard to pediatric patients if used inappropriately. Pediatric cardiac rhythms may not be accurately detected and may be incorrectly classified. The ZIO® XT Patch is sized appropriately for use on adult patients and may pose additional physical hazards to infants.

This is a prescription-only device. Keep device and packaging away from young children. Contents may be harmful if swallowed. This is not a toy. Unit contains Lithium Batteries (Button Cells) that are not accessible under normal use but, if exposed, are known choking hazards to small children.

The ZIO® XT Patch has been tested and is safe to use in conjunction with cellular phones and general household electronics.

Do not use if internal packaging has been previously opened.

ZIO® XT PATCH ANALYSIS

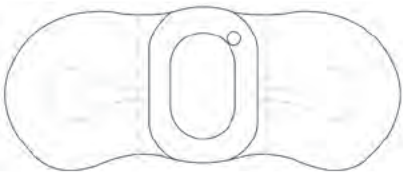
The ZIO® XT Patch heart monitor is analyzed at the iRhythm Clinical Centers in Lincolnshire, IL and San Francisco, CA. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R. section 410.33) can be found at the iRhythm website www.irhythmtech.com.

NOTICE OF PRIVACY PRACTICES

We are required by applicable federal and state law to maintain the privacy of Protected Health Information (PHI). Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and patients' rights concerning PHI.

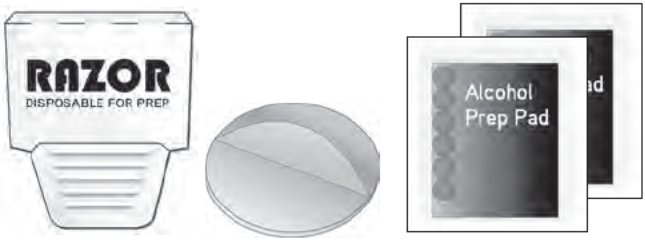
PACKAGE CONTENTS

1 ZIO® XT Patch



1 *Skin Prep & Placement Kit* containing:

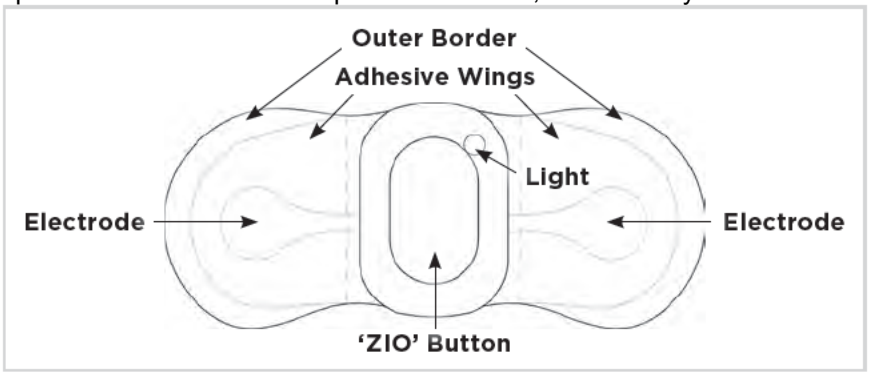
- 1 disposable razor
- 1 abrader disc
- 2 alcohol pads



1 *Patient Instructions & Button Press Log* containing:

- 1 adhesive remover wipe
- 1 box seal

1 Postage-paid return box



GETTING STARTED

The ZIO® XT Patch is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a physician for up to 14 days. **Each patient's wear duration may differ due to individual wear experiences.** Excessive sweating may decrease wear duration.

1. Enroll patient online at **www.zioreports.com**.

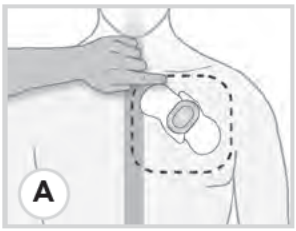
2. Remove the ZIO® XT Patch from the packaging.

3. On the front of *Patient Instructions & Button Press Log*, write the patient's name, physician, start date and time. Instruct the patient to write the date when they remove the ZIO® XT Patch for return.

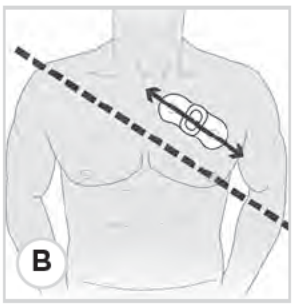
APPLICATION INSTRUCTIONS

1. Have the patient **stand** with their arms resting at their sides during the ZIO® XT Patch application.
   - If the patient cannot stand, have them sit up straight with their arms relaxed at their side.
   - Make sure chest area is free of perspiration.

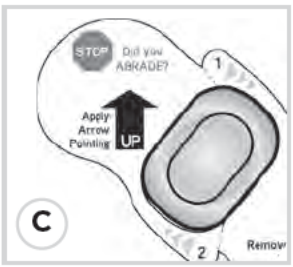
2. Determine placement area.
   - You may hold the ZIO® XT Patch up to the patient's **left** chest and use it as a guide to determine the placement area *(Fig. A)*.
     - About 1 finger width below the collar bone
     - Edge of the ZIO® XT Patch next to the sternum
   - The recommended placement is similar to a modified Lead II configuration *(Fig. B)*.
     - Electrodes should be placed parallel to a line drawn from right shoulder to left nipple
   - The writing on the top label should be parallel to the ground and the arrow should be pointing straight up when the ZIO® XT Patch is oriented correctly *(Fig. C)*.



Prep & Placement Area



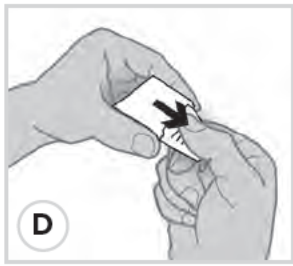
Placement Angle



Arrow Points Up

Alternative placement may be necessary depending on the patient's anatomy. It is acceptable to modify the placement, but quality of ECG and record duration may be affected.

- **Note that the preparation area will need to extend larger than where the ZIO® XT Patch will be applied.**
  - Due to the nature of the adhesive, the ZIO® XT Patch may move slightly during the monitoring period. A blue gel may become visible under the wings of the ZIO® XT Patch.



How to Remove Razor

3. Prepare the patient's skin using the materials from the *Skin Prep & Placement Kit*:

Abrade Skin

a. Remove the razor by holding the cover on the sides and pulling down on the handle *(Fig. D)*. **Shave** the placement area if hair is present. DO NOT add pressure to the razor; shave across the skin lightly.
  - ***NOTE:*** *If a cut should occur, treat the site and only continue once bleeding has stopped. After it has stopped, do not place electrode over cut.*
  - ***NOTE:*** *Dispose of razor in proper sharps container.*

b. Applying pressure, **abrade** the entire area using 30 broad strokes *(Fig. E)*.
  - ***NOTE:*** *Be sure to abrade the full prep area.*

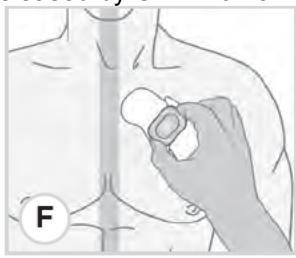
c. Using both alcohol pads, **clean** the area thoroughly. Allow skin to dry for 1 minute.

- At application, any hair, skin oil, residue or moisture present can interfere with the duration and quality of the test.

The steps above are critical to achieve good signal quality and adhesion.

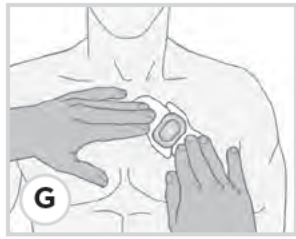
4. Holding the ZIO® XT Patch in the middle, over the top and bottom, pull off the clear backings.
  - Be sure not to touch the exposed adhesive.

5. Apply the ZIO® XT Patch to the patient's chest, making sure to place it in the prepared area *(Fig. F)*.



Place on Chest

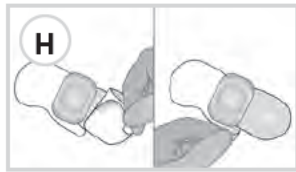
6. Apply continuous firm pressure across the wings of the device for approximately 2 minutes *(Fig. G)*.



Press for 2 Minutes

7. Remove the top label as illustrated *(Fig. H)*:

- Hold the tab labeled "1" and peel in the direction of the arrows, tearing along the perforations. Follow with tab "2."

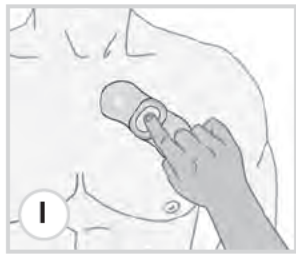


Remove Top Label

8. Firmly press the 'ZIO' button and release *(Fig. I)*. Watch for the **green** light to flash 5 times indicating that the monitoring has started.

9. After you see the green light:

- Help the patient practice pressing the 'ZIO' button. This will familiarize the patient with the action of pressing the button when symptoms are felt. Button presses within the first five minutes of activation will not be captured, however the device will continue to record.



Press Button to Turn On

PATIENT USAGE INSTRUCTIONS

Helpful hints to maximize wear time:

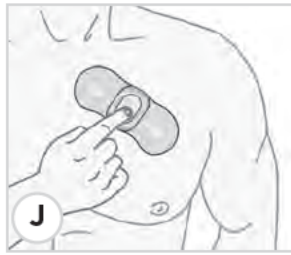
- The patient should try to avoid activities that cause excessive sweating as this may cause the ZIO® XT Patch to slide from its original position or fall off. For this reason, the patient may want to limit exercise while wearing the ZIO® XT Patch.
  - It is normal to experience some itching, especially during or immediately after exercise and/or excessive sweating. The itching should subside when the patient cools down. If the itching becomes severe, the patient should remove the ZIO® XT Patch and call **1-888-693-2401** for Customer Support.
- The patient should keep shower duration short, and if possible, face away from the water.
- The patient should not submerge the ZIO® XT Patch in water (e.g. pool or hot tub) as this may affect the adhesive strength. Patients may shower and bathe. During a bath, it is important for the patient to keep the device above water.
- The patient should keep soaps and lotions away from the ZIO® XT Patch.
- After showering the patient should:
  - Hold the ZIO® XT Patch down with one hand to secure it while towel drying so that it is not accidently knocked off.
  - Press the ZIO® XT Patch against skin to secure it.

REVIEW WITH YOUR PATIENT

1. The ZIO® XT Patch is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient). Ensure the patient understands the purpose and importance of the device.

2. The ZIO® XT Patch should not be removed before the end of the prescribed period unless skin irritation or itching is severe or hives or blisters develop (see Removal Instructions on page 12). Please call Customer Support, **1-888-693-2401**.

3. If symptoms are felt the patient should press the 'ZIO' button on the device *(Fig. J)*.
   - This will mark the ECG recording, indicating that the patient felt a symptom.
   - The ZIO® XT Patch will *not* show a light when the patient presses the button.
   - A click should be felt and/or heard, indicating that the button has been pressed and a symptom has been marked.



Location of Button; Press to Mark Symptom

Button Press Log Page

4. Each time the patient presses the 'ZIO' button to mark a symptom, an entry should be made in the *Patient Instructions & Button Press Log (Fig. K)*.

5. The ZIO® XT Patch can be worn through security screenings. A security statement is provided in the *Patient Instructions & Button Press Log*.

SECURITY SCREENING STATEMENT

(Included in the *Patient Instructions & Button Press Log*)

This person is wearing an iRhythm ZIO® XT Patch prescribed by their physician. This device is currently adhered to the patient's chest, where it is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Customer Support at **1-888-693-2401**, 24 hours/day, 7 days/week.

REMOVAL & RETURN INSTRUCTIONS

REVIEW WITH YOUR PATIENT

1. At the end of the wear period, detach the adhesive remover wipe from the back page of the *Patient Instructions & Button Press Log*.

2. Gently tilt the center of the ZIO® XT Patch up. Using the adhesive remover, sweep the wipe between the skin and the Patch while peeling the right side from the center out. Repeat for the other side, peeling from the center out ***(Fig. L)***.

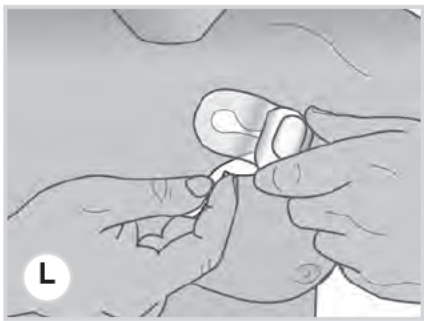
If patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, have them use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

---

3. Wash skin with mild soap, rinse with water, and pat dry.

4. Stick the ZIO® XT Patch flat to the area indicated on the last page of the *Patient Instructions & Button Press Log*.
   - The residual adhesive on the ZIO® XT Patch should be sufficient to affix the device to the page.

5. Place the entire booklet, including the ZIO® XT Patch, into the postage-paid return box, seal the box with tape, and drop it in a U.S. mailbox as soon as possible.



Adhesive Remover Aids Removal

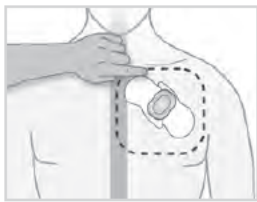
TROUBLESHOOTING

FOR CUSTOMER SUPPORT, CALL **1-888-693-2401**

APPLICATION

1. **The chest area was prepped and the device was applied. When the 'ZIO' button was pressed, it flashed orange (rather than green) five times.**
   Press down on the adhesive wings for a moment, so the device makes better contact with the skin. Then, press the 'ZIO' button again to attempt activation.
   If the devices does not activate (flash green) on the second attempt, please contact Customer Support at 1-888-693-2401.

2. **I think I placed the ZIO® XT Patch in the wrong position. Can I remove it and reposition it?**
   No. If the ZIO® XT Patch is over the heart in a slight diagonal as shown, the positioning should be acceptable. DO NOT attempt to reapply the ZIO® XT Patch.



3. **The top label was peeled off, but there still seems to be a white label stuck to the wings of the ZIO® XT Patch.**
   The top label may have separated. Peel the remaining white labels from the center of the ZIO® XT Patch outward.

4. **Are there tests or treatments that are not compatible with the ZIO® XT Patch?**
   Yes. The following are not recommended during wear of the ZIO® XT Patch:
   a. **Magnetic Field(s)**: Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field
   b. **Neuromuscular Stimulators**: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit
   c. **External Cardioversion/Defibrillation**

   NOTE: Data may not be interpretable during the time the stimulators are being used. Usage is at physician's discretion.

4. **Can the ZIO® XT Patch be left on a patient during Cardioversion/Defibrillation?**
   No, the ZIO® XT Patch should be removed if the patient requires Cardioversion or Defibrillation.

5. **Which tests and treatments are okay to have while the patient is wearing the ZIO® XT Patch?**
   Wear of the ZIO® XT Patch will not interfere during the following:

   a. Computed Tomography (CAT Scan)
   b. Electrocardiogram (EKG)
   c. Echocardiogram
   d. Electron-beam Computed Tomography (EBCT)
   e. Electroencephalogram (EEG)
   f. Mammogram
   g. Ultrasound
   h. Nuclear Stress Test
   i. Positron Emissions Tomography (PET SCAN)
   j. X-RAY
   k. Radiation

   NOTE: The image of the ZIO® XT Patch may be visible if chest fields are being imaged.

PATIENT QUESTIONS

1. **How long is the patient supposed to wear the ZIO® XT Patch?**
   A patient can wear the ZIO® XT Patch for up to 14 days or as prescribed. **Note:** The ZIO® XT Patch will not record ECG data after 14 days.

   Based on individual wear experiences the patient's actual wear time may be shorter than prescribed.

2. **What is the ZIO® XT Patch doing?**
   The ZIO® XT Patch is recording every heartbeat. Pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

3. **Who should the patient call if they have questions about the ZIO® XT Patch or if it falls off?**
   The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

4. **What should the patient do if they feel a symptom?**
   Press the 'ZIO' button and fill out a page of the *Patient Instructions & Button Press Log*.

5. **What if the patient forgets to press the 'ZIO' button when they feel a symptom?**
   While pressing the 'ZIO' button is important, the ZIO® XT Patch is recording every heartbeat.

6. **What if the patient presses the 'ZIO' button but forgets to write down the information on a *Button Press Log* page?**
   While the *Button Press Log* information is useful, pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

7. **What if the patient does not have symptoms?**
   That's okay. The ZIO® XT Patch records every heartbeat.

8. **What activities should the patient avoid while wearing the ZIO® XT Patch?**
   Activities that cause excessive sweating. This could cause the ZIO® XT Patch to slide, become loose, fall off, and shorten wear time.

9. **Can the patient exercise while wearing the ZIO® XT Patch?**
   Yes, but excessive sweating may shorten wear time.

10. **Can the patient shower with the ZIO® XT Patch on?**
    Yes, but showers should be brief. Keep soaps and lotions away from the ZIO® XT Patch. If possible, face away from the water when showering. When towel-drying, the patient should hold the ZIO® XT Patch down with one hand so that it is not accidently knocked off. Instruct the patient to press the ZIO® XT Patch against their skin to secure it.

11. **Can the patient take a bath?**
    Yes, but the patient should keep the ZIO® XT Patch above water.

12. **Can the patient go swimming or in a hot tub?**
    No. The ZIO® XT Patch should not be submerged in water.

13. **Is it normal for the ZIO® XT Patch to move slightly from its original position?**
    Yes. The ZIO® XT Patch may move slightly from its original position. A blue gel may become visible under the wings of the ZIO® XT Patch.

14. Is it normal to experience skin irritation or itchiness in the area of the ZIO® XT Patch?

Patients have reported minor skin irritation and/or itching while wearing the ZIO® XT Patch. If the irritation or itching is severe or hives or blisters develop instruct the patient to call Customer Support at 1-888-693-2401.

15. Is it normal for the ZIO® XT Patch wings to become cloudy in appearance?

Yes, the wings of the ZIO® XT Patch may become cloudy after a few days of wear.

16. What should the patient do if they think they see blood under the ZIO® XT Patch?

Instruct the patient to call Customer Support at 1-888-693-2401. It is likely due to a small shaving cut when the device was applied to the chest.

17. How will the patient know the ZIO® XT Patch is working?

Once the ZIO® XT Patch is applied to the body, and the 'ZIO' button is pressed, a green light should flash, indicating that it was turned on. Afterwards, it will not flash or make noise when it is working properly.

18. Will the ZIO® XT Patch flash while the patient is wearing it?

No. If it is working properly, the ZIO® XT Patch will not flash or make noise. If the patient sees the ZIO® XT Patch flashing orange, this does not mean there is a problem with the patient's heart; it just means that the Patch is not well attached.

Instruct the patient to press evenly on the ZIO® XT Patch for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call Customer Support at 1-888-693-2401.

19. Can a patient travel with the ZIO® XT Patch on?

Yes. If questioned during security screening there is a statement included in the *Patient Instruction & Button Press Log* for them to reference.

20. When the patient removes the ZIO® XT Patch, it is flashing orange. Is this okay?

The ZIO® XT Patch may blink orange after removal. It is okay to mail the device while it is blinking.

DEVICE SPECIFICATIONS

PERFORMANCE CHARACTERISTICS	
ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	1 day

ELECTRICAL CHARACTERISTICS	
Frequency Response	0.5 Hz to 30 Hz
Input Impedance	≥ 10 Mohm
Differential Range	± 1.65 mV
A/D Sampling Rate	200 Hz
Resolution	10 bits

POWER SPECIFICATIONS	
Battery Type	2 Lithium Manganese Dioxide Coin Cells
Battery Life	14 days

PHYSICAL CHARACTERISTICS	
Dimensions	5.20 x 2.02 x 0.53 inches
Weight	24.5 g

ENVIRONMENTAL SPECIFICATIONS	
Operational Temperature	36 to 104 degrees F
Operational Altitude	-1,000 to 10,000 ft
Storage Temperature	-4 to +104 degrees F
Recommended Long-Term Storage Temperature	55 to 86 degrees F
Storage Humidity	10% to 95% (non-condensing)
Storage Altitude	-1,000 to 14,000 ft

STANDARD COMPLIANCE
AAMI/ANSI EC38
IEC 60601-1

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The ZIO® XT Patch needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: This device should not be used adjacent to or stacked with other equipment.

Table 1: Guidance and manufacturer's declaration—electromagnetic emissions

The ZIO® XT Patch device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® XT Patch device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ZIO® XT Patch device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ZIO® XT Patch device is suitable for use in all establishments, including domestic establishments.

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® XT Patch device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® XT Patch device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® XT Patch device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® XT Patch device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ZIO® XT Patch, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

Table 3, Continued

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

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

- [a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZIO® XT Patch is used exceeds the applicable RF compliance level above, the ZIO® XT Patch should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZIO® XT Patch.
- [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the ZIO® XT Patch

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**80 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

NOTES

NOTES

FOR SUPPORT, CALL **1.888.693.2401**

iRhythm

iRhythm Technologies, Inc.
Clinical Centers
650 Townsend Street, Suite 380
San Francisco, CA 94103

2 Marriott Drive
Lincolnshire, IL 60069

1.888.693.2401 | irhythmtech.com | @iRhythmTech

ZIO XT

PATIENT INSTRUCTIONS & BUTTON PRESS LOG

NAME: _____

PHYSICIAN: _____

START DATE: / / TIME: _____

REMOVAL: ☐ Physician prescribed duration of _____ days

☐ Patient to wear as long as possible (up to 14 days)

TO BE COMPLETED BY PATIENT

DATE REMOVED: / /

ZIO XT

IT IS OKAY IF...

- The ZIO® XT Patch peels or lifts at the edges. Try to press and hold along the edges to re-stick.
- You experience some itching.

4.281"

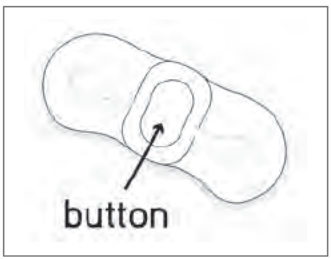
CALL 1.888.693.2401 IF...

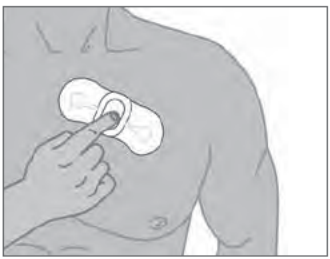
- The ZIO® XT patch falls off.
- You experience severe itching or irritation.
- The ZIO® XT Patch is flashing orange. This does not mean there is a problem with your heart; it just means that the Patch is not well attached.

TURN TO PAGE 2 FOR ADDITIONAL FAQs

During Recording:

Wear the Zio® XT Patch during your normal daily activities, even while showering and sleeping. The wear experience is different for all patients, depending on activity level, sweating and prep of the skin at application.





Each time you feel a symptom, press the button then complete a *Button Press Log* page.

At the End of the Enrollment Period:

Turn to the end of this booklet for removal and return instructions.

How long am I supposed to wear the Zio® XT Patch?

Wear the Zio® XT Patch according to your physician prescribed wear time but no longer than 14 days. **NOTE:** Based on individual wear experiences your actual wear time may be shorter than prescribed.

What is the Zio® XT Patch doing?

The Zio® XT Patch is recording every heartbeat. Your physician will use the data from the Zio® XT Patch to look at your heart rhythm and determine a proper course of action.

What should I do if the Zio® XT Patch falls off?

Call Customer Support at 1-888-693-2401.

What should I do if I feel a symptom?

Press the button and fill out a page of the *Button Press Log* in this booklet.

What if I forget to press the button when I feel a symptom?

While pressing the button is important, the Zio® XT Patch is recording every heartbeat.

What if I press the button but forget to write down the information in this booklet?

While the *Button Press Log* information is useful, pressing the button indicates that you felt your symptoms at that time.

What if I don't have symptoms?

That's okay. The Zio® XT Patch records every heartbeat.

Can I exercise while wearing the Zio® XT Patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the Zio® XT Patch on?

Yes, but showers should be brief. Keep soaps and lotions away from the Zio® XT Patch. When towel-drying, hold the Zio® XT Patch down with one hand. Press the Zio® XT Patch against your skin to secure it.

Can I take a bath?

Yes, but keep the Zio® XT Patch above water.

Can I go swimming or in a hot tub?

No. The Zio® XT Patch should not be submerged in water.

Is it normal for the Zio® XT Patch to move slightly from its original position?

Yes. The Zio® XT Patch may move slightly from its original position. A blue gel may become visible under the wings of the Zio® XT Patch.

Is it normal to experience skin irritation or itchiness in the area of the Zio® XT Patch?

Some patients have reported minor skin irritation and/or itching while wearing the Zio® XT Patch. If the irritation or itching is severe or hives or blisters develop please call Customer Support at 1-888-693-2401.

Is it normal for the Zio® XT Patch wings to become cloudy?

Yes, the wings of the Zio® XT Patch may become cloudy after a few days of wear.

What activities should I avoid?

Activities that cause excessive sweating can cause the Zio® XT Patch to slide, become loose, fall off, and shorten wear time.

I think I see blood under my Zio® XT Patch. What should I do?

Call Customer Support at 1-888-693-2401. It is likely due to a small shaving cut when the device was applied to your chest.

How do I know the Zio® XT Patch is working?

When it was applied, the staff at your physician's office made sure that the Zio® XT Patch was working correctly. If it is working properly, the Zio® XT Patch will not flash or make noise.

What if the Zio® XT Patch flashes orange while I am wearing it?

If you see the Zio® XT Patch flashing orange, this does not mean there is a problem with your heart; it just means that the Patch is not well attached.

Press evenly on the Zio® XT Patch for 3 to 5 minutes. If flashing persists or reoccurs, call Customer Support at 1-888-693-2401.

Can I travel with the Zio® XT Patch on?

Yes. If questioned during security screening, show the statement on the following page.

I have removed the Zio® XT Patch and it is flashing orange. Is this okay?

The Zio® XT Patch may blink orange after removal. It is okay to mail the device while it is blinking. Turn to the end of this booklet for return instructions.

How do I return the Zio® XT Patch?

You can drop off the package at the Post Office, in a USPS (blue) mailbox or give it to your mail carrier. Turn to the end of this booklet for removal and return instructions.

Who do I call if I have questions about the Zio® XT Patch?

Call Customer Support at 1-888-693-2401.

WARNING

If at any time you feel the need for immediate medical care, call 911. The Zio® XT Patch will not provide any medical assistance and cannot contact medical personnel for you.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® XT Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

BUTTON PRESS LOG

I pressed the button on...

mm/dd/yy: 05/29/13 hh:MM: 07:45 [X] AM [ ] PM

...because I felt:

- [ ] anxious
- [ ] arm or neck pain/tingling
- [ ] chest pain or pressure
- [X] dizziness
- [ ] fainted
- [X] light headed
- [ ] pounding
- [X] fluttering or racing
- [ ] short of breath
- [ ] skipped beat(s), irregular beats
- [ ] other (describe):

...for this duration:

- [X] 1 min or less
- [ ] 10 mins or less
- [ ] 1 hour or less
- [ ] More than 1 hour

...while I was

describe activity: getting out of bed

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

ZIO® XT PATCH ANALYSIS

Your Zio® XT Patch Heart monitor is analyzed at the iRhythm Clinical Centers in Lincolnshire, IL and San Francisco, CA. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R. section 410.33) can be found at the iRhythm website www.irhythmtech.com.

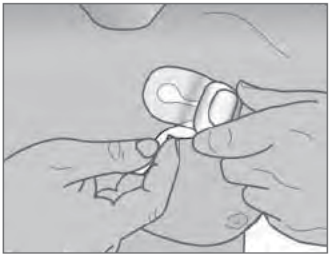
PATIENT IDENTIFICATION

After sealing the device into the Zio® XT Patch box, please write your name on the line above the return address. By writing your name on the box you are providing another method of identification for the Zio® XT Patch and are consenting to the potential viewing of your name on the Zio® XT Patch box. You may choose to not write your name on the Zio® XT Patch box.

NOTICE OF PRIVACY PRACTICES

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information (PHI). Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

REMOVING THE ZIO® XT PATCH

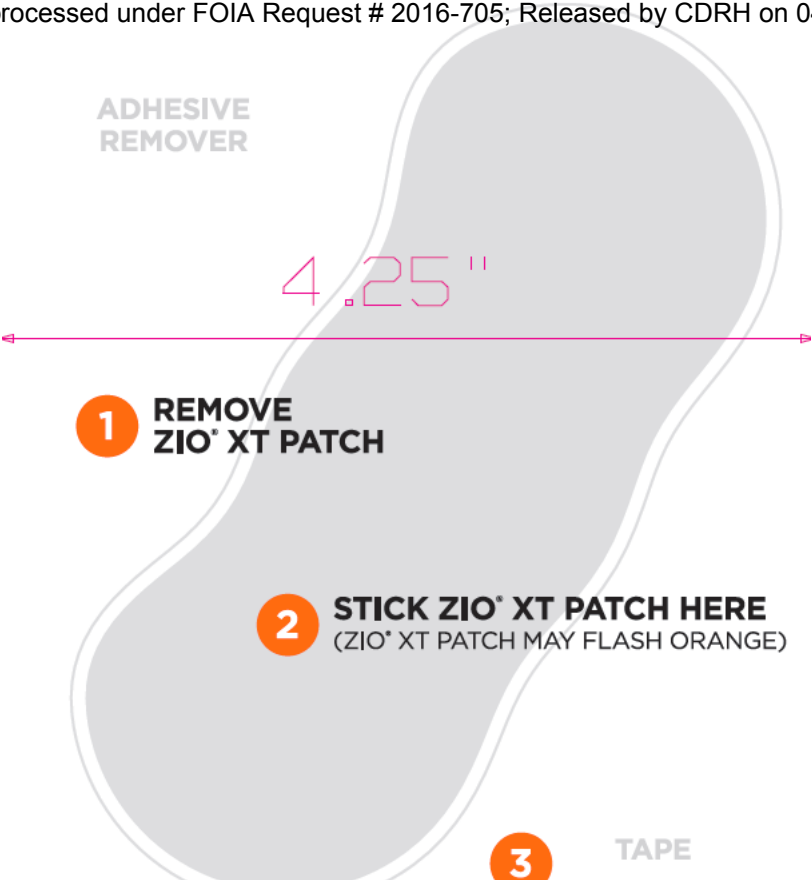


1 Gently tilt the center of the Patch up. Using the adhesive remover to the right, sweep between your skin and the Patch while peeling one side from the center out. Repeat for the other side, peeling from the center out. Wash skin with mild soap, rinse with water, and pat dry.

2 Stick the Zio® XT Patch to the area shown on the right. It will stick on its own.

3 Place this entire booklet, including the Patch, into the postage-paid return box. Seal the box shut with the tape provided. Mail it back via the U.S. postal service as soon as possible.

For support, call 1.888.693.2401



iRhythm

iRhythm Technologies, Inc.
Clinical Centers
650 Townsend St., Suite 380
San Francisco, CA 94103

2 Marriott Drive
Lincolnshire, IL 60069

1.888.693.2401 | irhythmtech.com | @iRhythmTech

FLIP OPEN

SKIN PREP IS IMPORTANT FOR GOOD ECG SIGNAL QUALITY AND ADHESION.

FLIP OPEN

iRhythm

iRhythm Technologies, Inc.
650 Townsend St., Suite 380
San Francisco, CA 94103
irhythmtech.com

N100A2008 | July 2013

FAQs

Why do I need to abrade the skin?

Abrading removes the top layer of skin, which is necessary for long-term adhesion and good signal quality.

Why do I need to clean the skin?

The alcohol wipes help remove surface oils that may be on the skin. It is important to clean the skin after the Abrade step to ensure adhesion and good signal quality.

What is this top liner?

The top liner helps keep the ZIO® XT Patch rigid and straight as it is applied to the patient. It prevents the adhesive from folding and sticking together.

I think I have a defective ZIO® XT Patch. What should I do?

If you suspect a defect, please contact customer service. Unless instructed otherwise, please send the device back to iRhythm Technologies, Inc.

TROUBLESHOOTING

ZIO® XT Patch flashes orange 5 times after attempting to turn on.

Press down on the adhesive sides for a moment, so the device makes better contact with the skin. Then, press the button.

If the device still does not activate (flash green), contact customer service.

I did not apply the ZIO® XT Patch in the exact place shown in the picture. Should I remove and reapply it?

No. If the ZIO® XT Patch is over the heart in a slight diagonal as shown in the picture, the positioning should be acceptable. DO NOT attempt to reapply the ZIO® XT Patch.

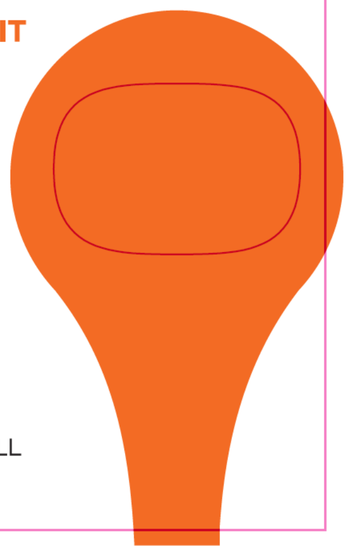
N100A2007.03 | April 2014

ZIO® XT

SKIN PREP & PLACEMENT KIT

ZIO® XT

SKIN PREP & PLACEMENT KIT



FOR SUPPORT, CALL
1.888.693.2401

Perforation

This panel is hidden/inside when folded (tab tucked into slit)

4 IMPORTANT STEPS TO GET STARTED WITH THE ZIO® XT PATCH

PLACE SERIAL NUMBER LABEL HERE

PATIENT NAME

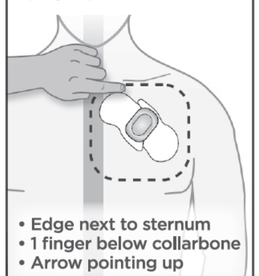
1 PLAN & POSITION

ENROLL

ZioReports.com

POSITION

Place patient in a relaxed, upright position



- Edge next to sternum
- 1 finger below collarbone
- Arrow pointing up

TEAR ALONG PERFORATION AND KEEP UNTIL PATIENT IS ENROLLED

RAZOR

ABRADER

ALCOHOL

2 PREP SKIN

SHAVE

How to remove razor

ABRADE

40 strokes, apply pressure

CLEAN

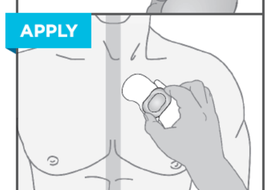
Let skin dry for 1 minute

3 APPLY PATCH

REMOVE

Clear adhesive backings

APPLY



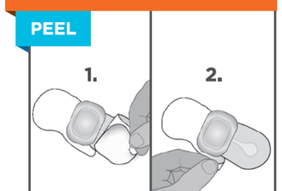
PRESS

... for 2 minutes

4 FINISH & ACTIVATE

PEEL

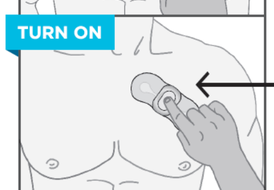
1. 2.



PRESS

... for 2 minutes

TURN ON



PRESS BUTTON TO ACTIVATE

ZIO® XT PATCH SHOULD FLASH GREEN. PRACTICE BUTTON PRESS WITH PATIENT.

SEE REVERSE FOR FAQs AND TROUBLESHOOTING

FOR SUPPORT, CALL
1.888.693.2401

0.55″

ZIO® Reports

XT Operator Manual

P/N: D100A4080.DRAFT
Release Date: 2014/09

DESCRIPTION

The ZIO® ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The ZIO ECG Monitoring System consists of two components: (1) ZIO Patch ECG Recorder and the (2) ZIO ECG Utilization Software, proprietary algorithm software.

The ZIO® XT Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The ZIO® XT Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report.

After conclusion of the wear period (up to 14 days), the patient removes the ZIO® XT Patch and returns it by mail to an iRhythm data processing center. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results, generates and posts a comprehensive ECG report of the key findings at www.zioreports.com.

INDICATIONS FOR USE

The ZEUS System is intended for use by qualified medical professionals for the assessment ambulatory electrocardiogram (ECG) data from adult patients 18 years or older. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

CONTRINDICATIONS

- The ZEUS System is not indicated for use on pediatric patients and patients with paced beats.

P/N: D100A4080.DRAFT
Release Date: 2014/09

iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
Tel. +1.888.693.2401 (USA Only)
+1.224.543.4200 (International)
Fax. +888.693.2401

SYMBOLS

Consult instructions for use

Caution

Prescription use only

Manufacturer

Serial Number

NOTICE OF PRIVACY PRACTICES

We are required by applicable federal and state law to maintain the privacy of Protected Health Information (PHI). Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and patients' rights concerning PHI.

P/N: D100A4080.DRAFT
Release Date: 2014/09

www.zioreports.com

Home Page Review

www.zioreports.com is accessible from any computer with an internet connection. The home page is where you will find general product information and log into the secure website to manage your account and your patient's ZIO electrocardiogram (ECG) Monitoring Service (ZIO Service).

P/N: D100A4080.DRAFT
Release Date: 2014/09

Administrator Account Access

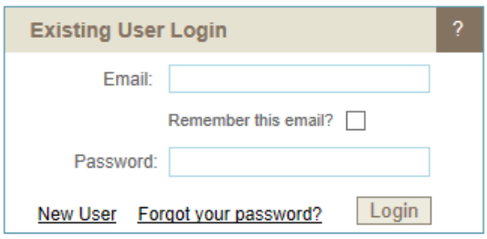
Contact Customer Service to create a NEW account user. The account user will have the administrator (admin) role. The admin role will have the following system level access:

- Create/edit Physician & Non-physician roles
- Patient registration
- View reports

Once you have completed the new account registration process, type www.zioreports.com in your web browser.

Type the account Email address and Password.

Click on **Login**.



The ZIO® Patient Report List page is accessed with the Account Name indicated on the top of page.

P/N: D100A4080.DRAFT
Release Date: 2014/09

Create / Edit Users

Logged in as the system Admin, configure the following users with the appropriate level of system access:

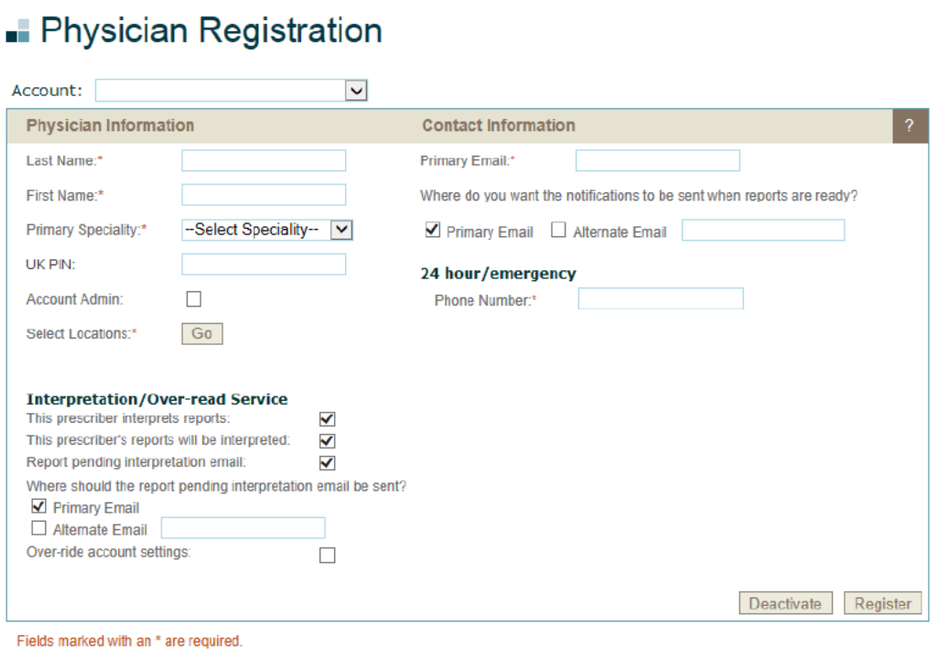
- Physician
- Non-physician

Select **Account**, and then **Add** to create a new physician or non-physician user.

Physician Selection

Complete the Physician Registration online form by providing the information as required. The information provided will configure the Physician's role, workflow, and method of communication.

If the Account has multiple locations, use the drop down to select and associate the physician to the appropriate location. A physician can be associated with multiple locations.

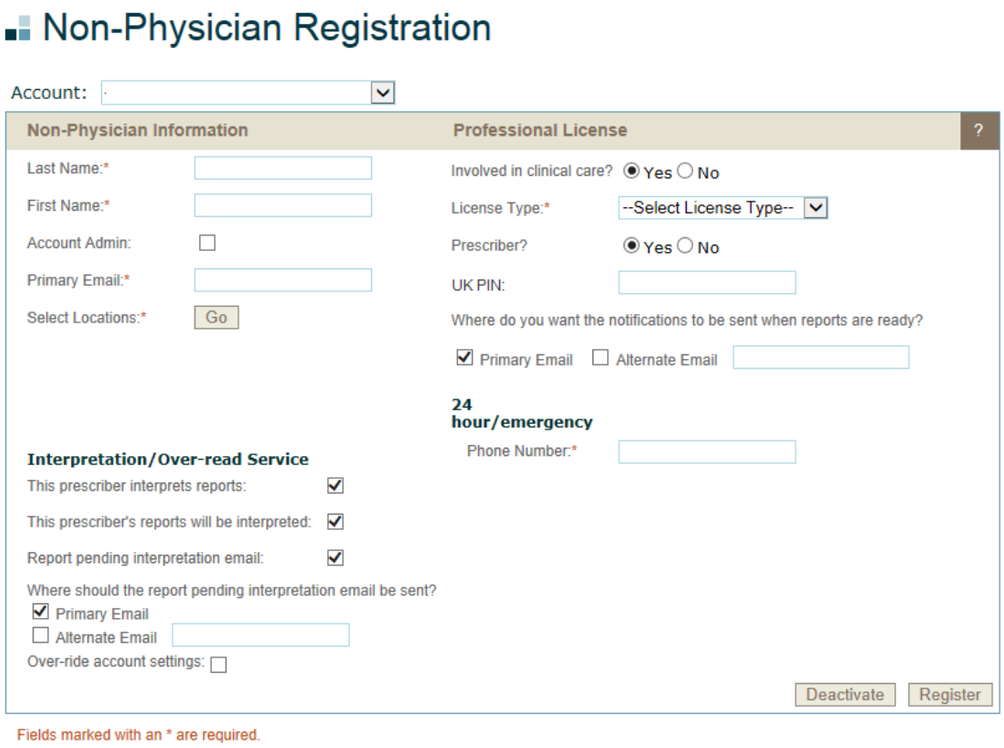


When complete, click the **Register** button.

Non-Physician Selection

Complete the Non-Physician Registration online form by providing the information as required. The information provided will configure the Non-Physician's role, workflow, and method of communication.

If the Account has multiple locations, use the drop down to select and associate the physician to the appropriate location.

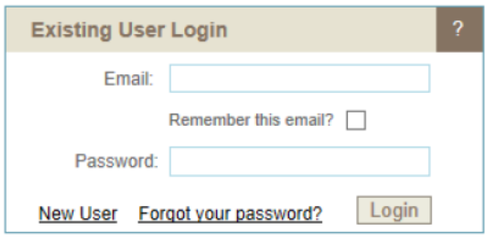


When complete, click the **Register** button.

User Account Access

Type the Email address and Password the account administrator created.

Click on **Login**.



On system access, the ZIO Patient Report List page will open.

View of the navigation selection bar will change depending on the user's assigned role.

Patient Registration

Patient registration is the first step in the ZIO Service workflow. Select **Patient** to view the dropdown menu, and then **Register New Patient**.

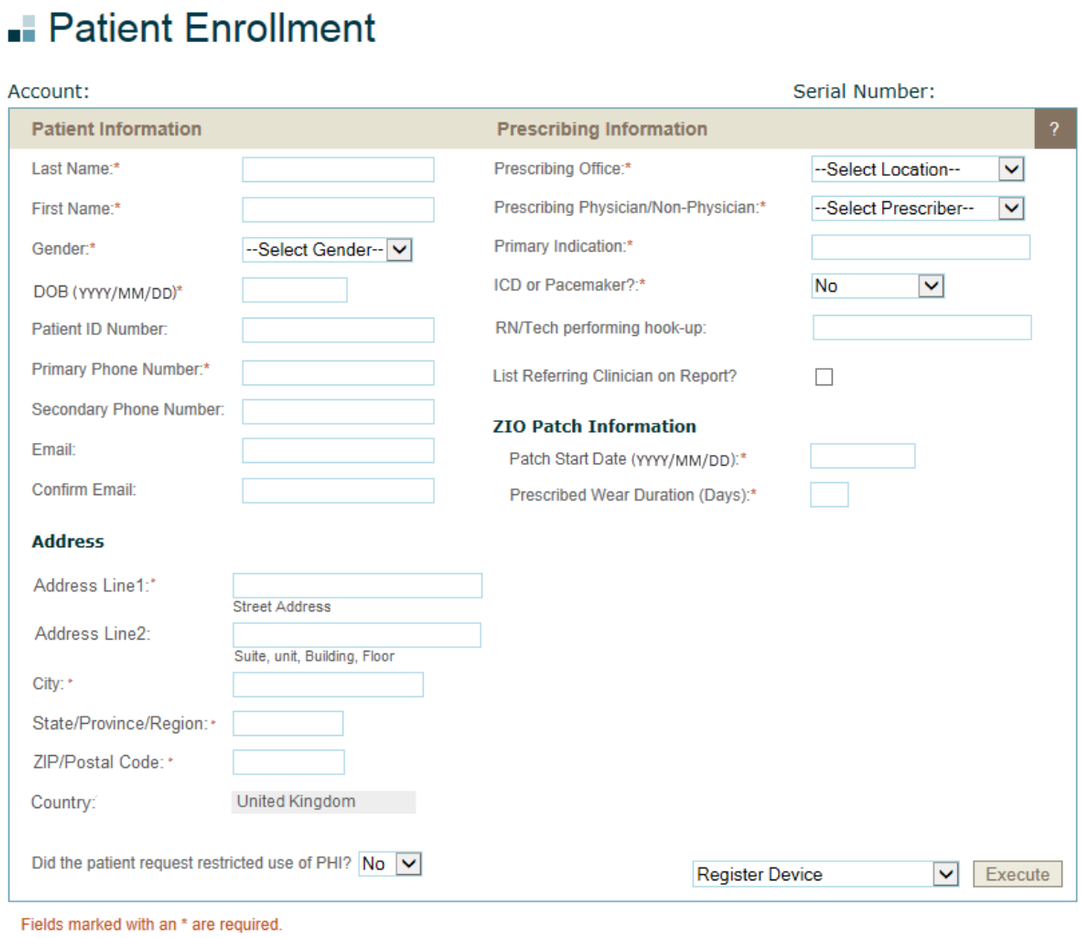
PRECAUTION

Patient registration of the ZIO Patch at the time the device is applied to the patient is necessary to prevent the possibility of incorrect patient registration. Incorrect patient registration may cause misdiagnosis and unnecessary therapy.

The Patient Registration prompting Device Information appears.

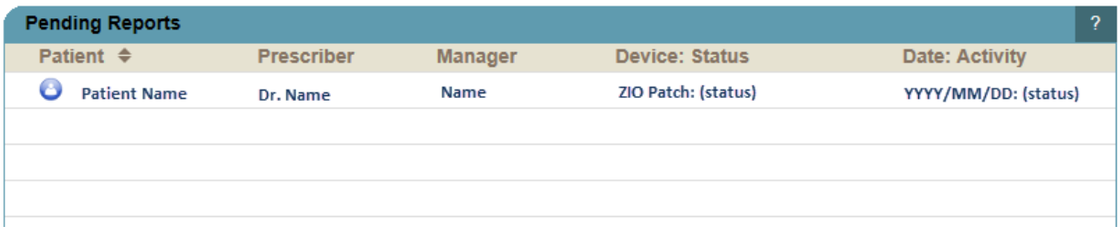
Type the device serial number (a 10-character alphanumeric code found on back of the device or the ZIO Patch packaging). Click **Submit**.

Complete the patient demographics and registration information as required.



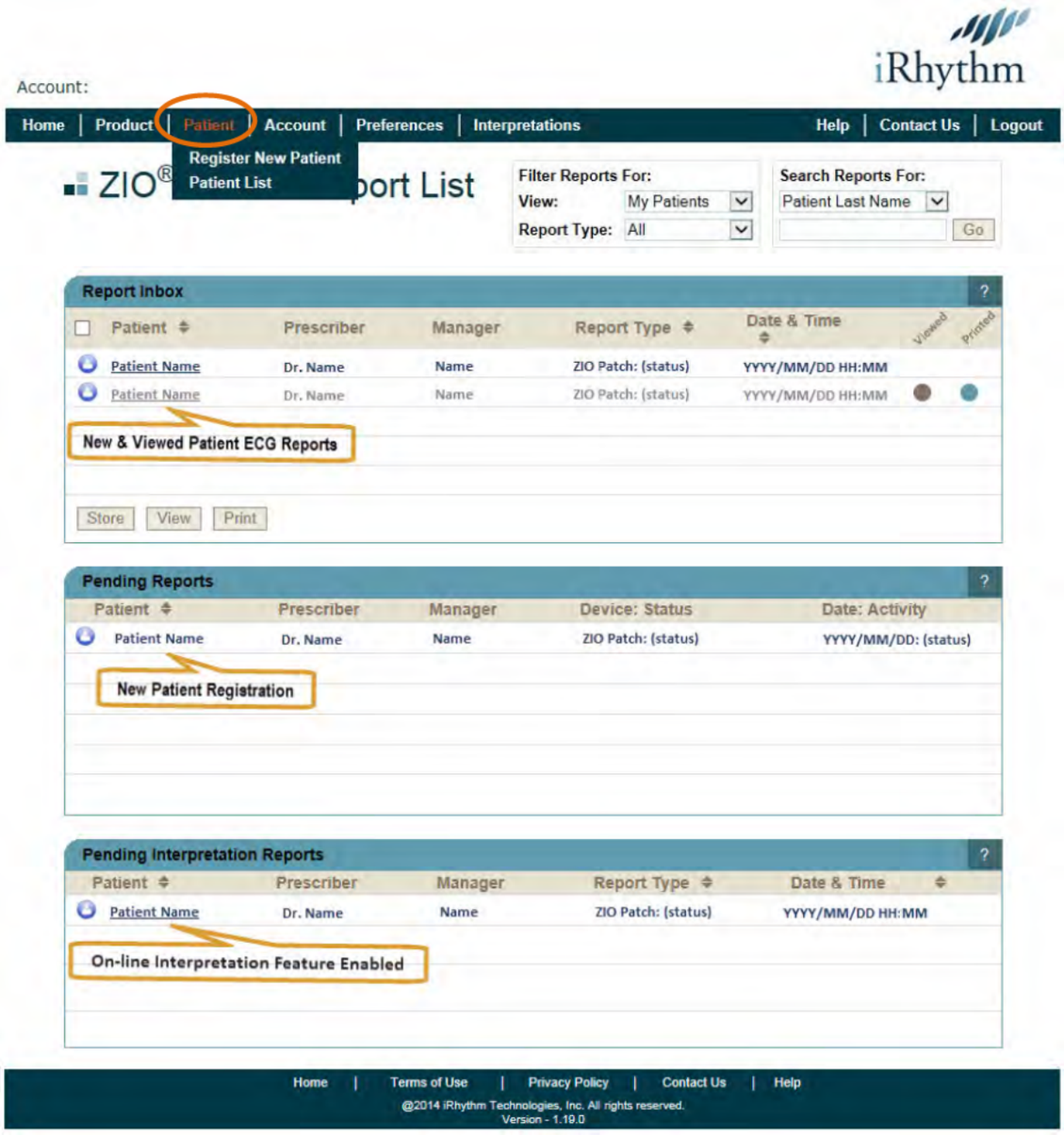
When complete, click the **Execute** button.

Once the patient is registered, patient information will appear in the Pending Reports section on the Patient List page.



Patient Reports

Select **Patient** to view the navigation dropdown. Select **Patient List**.



Report Inbox & Status

ZIO ECG Reports ready for viewing, printing and/or storing. Statuses include:

- **Routine**: Any standard report not meeting notification criteria
- **MD Notified**: A report that meets account-specific MD notification criteria

P/N: D100A4080.DRAFT
Release Date: 2014/09

Pending Reports

ZIO ECG Reports are pending the return of the Patch from the patient or Patch processing. The following statuses are given:

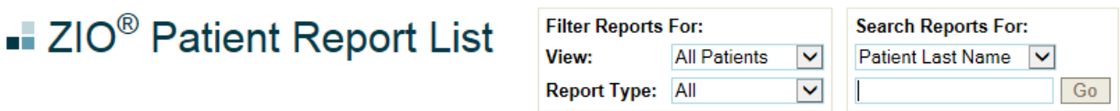
- **Pending Receipt:** Device is still with patient or is in transit to iRhythm
- **Received – Processing:** Device is at iRhythm where its data is being analyzed and report is being created

Pending Interpretation Reports

This feature is only visible to accounts that have requested online interpretation. See Online Interpretation Instructions.

Filter & Search Feature

To efficiently manage the account Patient Report List, a filter or specific Patient search can be performed to find a record. Use the dropdowns to select the criteria to apply a filter or select the search drop down and type the name to search.



iCon Legend

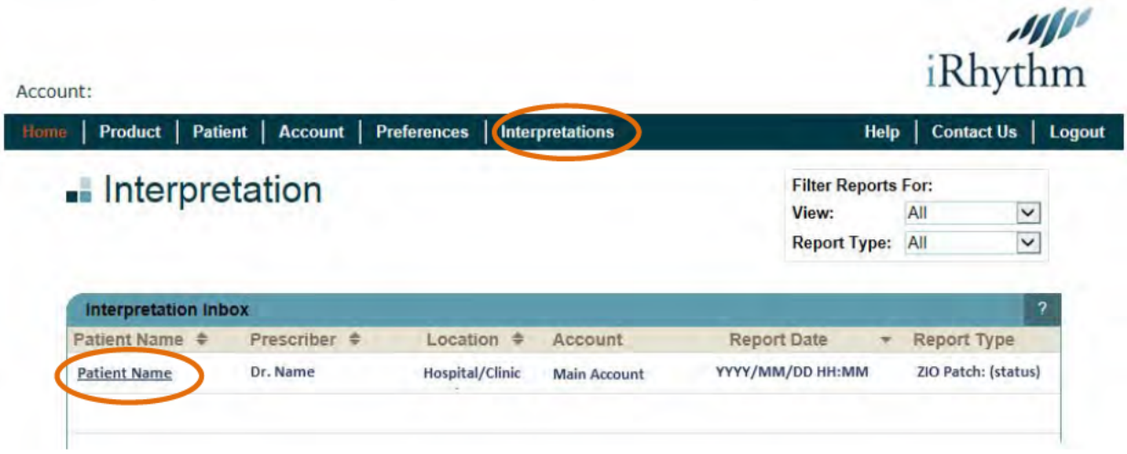
Click to view Patient demographics

Sort filter or search results by column

Online Interpretation Instructions

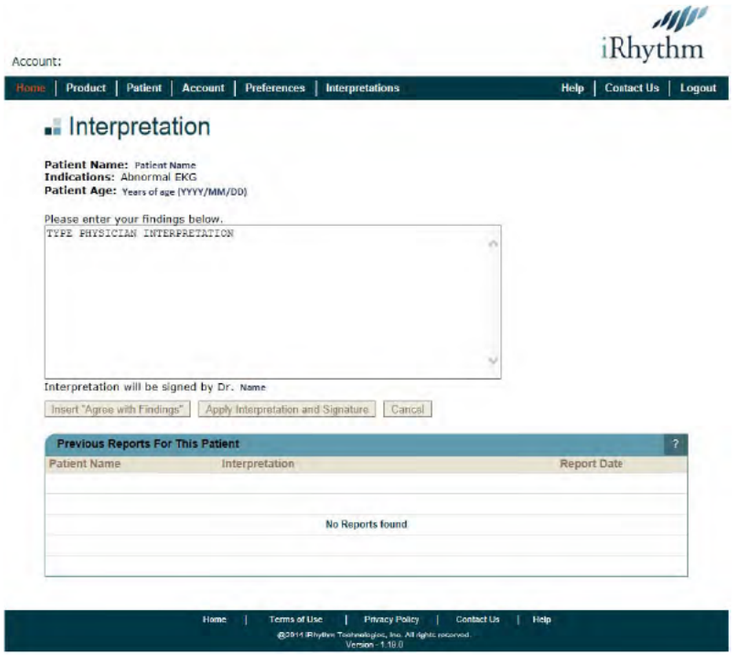
The online interpretation feature is only available to accounts that have requested this feature. It allows the Physician to record their findings in the system, apply a secure electronic signature, and append the original ECG Report with their findings.

Select **Interpretations** to navigate to the Interpretation Page.



Click on the patient's name in the Interpretation Inbox. The patient ECG Report will open in a second window or browser tab.

The patient report is for viewing only and not for recording the interpretation. The interpretation is recorded, and signed in the Interpretation Form.



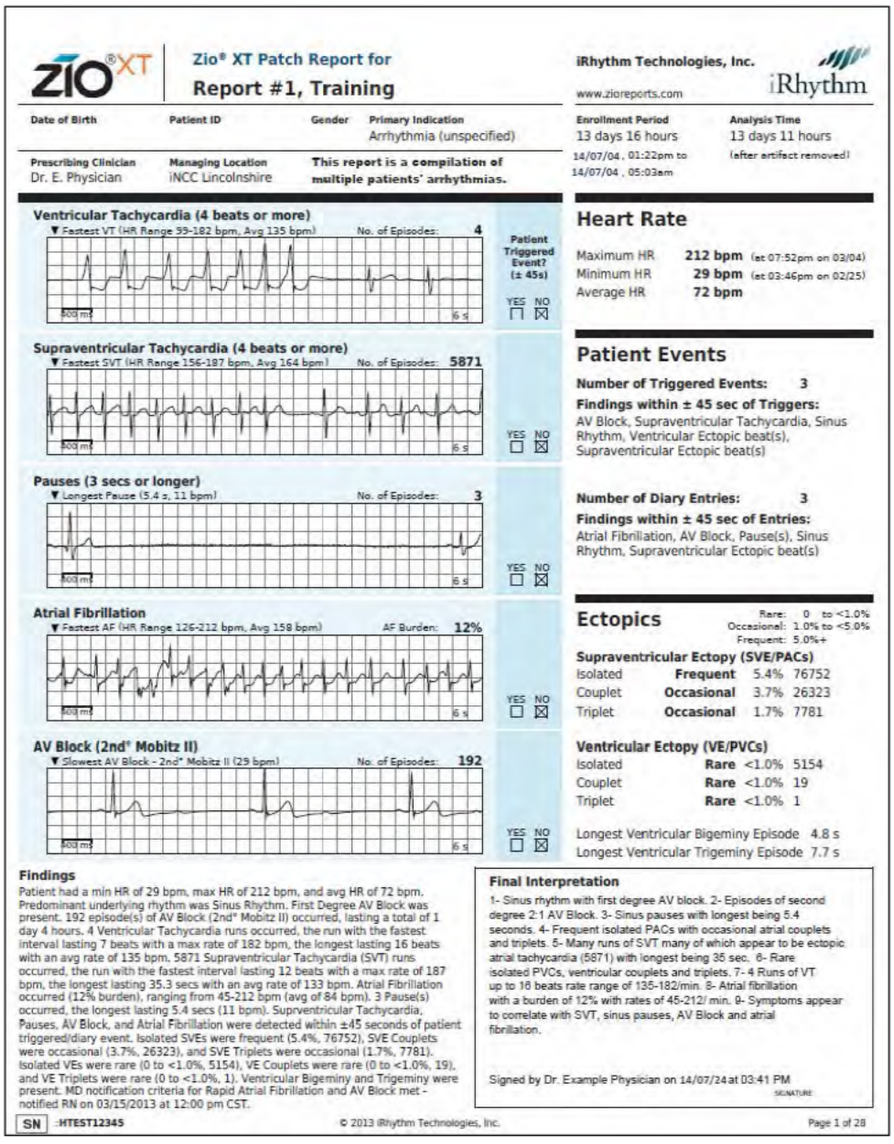
P/N: D100A4080.DRAFT
Release Date: 2014/09

The physician enters their interpretation of the ECG report or may insert **Agree with Findings** by clicking the button.

Should the physician choose to edit the findings, select the text in the Findings sections of the report and copy to the clipboard. Past the copied text into the interpretation section and make the necessary changes.

Once completed with interpretation details, click the **Apply Interpretation and Signature** button.

The Final Interpretation is amended to the patient's ECG report.



ZIO®XT Zio® XT Patch Report for
Report #1, Training

iRhythm Technologies, Inc.
www.zioreports.com

Date of Birth	Patient ID	Gender	Primary Indication
			Arrhythmia (unspecified)

Prescribing Clinician	Managing Location	
Dr. E. Physician	iNCC Lincolnshire	**This report is a compilation of multiple patients' arrhythmias.**

Enrollment Period	Analysis Time
13 days 16 hours 14/07/04 , 01:22pm to 14/07/04 , 05:03am	13 days 11 hours (after artifact removed)

Ventricular Tachycardia (4 beats or more)
▼ Fastest VT (HR Range 99-182 bpm, Avg 135 bpm) No. of Episodes: 4

Supraventricular Tachycardia (4 beats or more)
▼ Fastest SVT (HR Range 156-187 bpm, Avg 164 bpm) No. of Episodes: 5871

Pauses (3 secs or longer)
▼ Longest Pause (5.4 s, 11 bpm) No. of Episodes: 3

Atrial Fibrillation
▼ Fastest AF (HR Range 126-212 bpm, Avg 158 bpm) AF Burden: 12%

AV Block (2nd° Mobitz II)
▼ Slowest AV Block - 2nd° Mobitz II (29 bpm) No. of Episodes: 192

Patient Triggered Event? (± 45s) YES ☐ NO ☒

Heart Rate

Maximum HR	**212 bpm**	(at 07:52pm on 03/04)
Minimum HR	**29 bpm**	(at 03:46pm on 02/25)
Average HR	**72 bpm**	

Patient Events

Number of Triggered Events: 3
Findings within ± 45 sec of Triggers:
AV Block, Supraventricular Tachycardia, Sinus Rhythm, Ventricular Ectopic beat(s), Supraventricular Ectopic beat(s)

Number of Diary Entries: 3
Findings within ± 45 sec of Entries:
Atrial Fibrillation, AV Block, Pause(s), Sinus Rhythm, Supraventricular Ectopic beat(s)

Ectopics

Rare: 0 to <1.0%
Occasional: 1.0% to <5.0%
Frequent: 5.0%+

Supraventricular Ectopy (SVE/PACs)

Isolated	**Frequent**	5.4%	76752
Couplet	**Occasional**	3.7%	26323
Triplet	**Occasional**	1.7%	7781

Ventricular Ectopy (VE/PVCs)

Isolated	**Rare**	<1.0%	5154
Couplet	**Rare**	<1.0%	19
Triplet	**Rare**	<1.0%	1

Longest Ventricular Bigeminy Episode 4.8 s
Longest Ventricular Trigeminy Episode 7.7 s

Findings
Patient had a min HR of 29 bpm, max HR of 212 bpm, and avg HR of 72 bpm. Predominant underlying rhythm was Sinus Rhythm. First Degree AV Block was present. 192 episode(s) of AV Block (2nd° Mobitz II) occurred, lasting a total of 1 day 4 hours. 4 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 7 beats with a max rate of 182 bpm, the longest lasting 16 beats with an avg rate of 135 bpm, 5871 Supraventricular Tachycardia (SVT) runs occurred, the run with the fastest interval lasting 12 beats with a max rate of 187 bpm, the longest lasting 35.3 secs with an avg rate of 133 bpm. Atrial Fibrillation occurred (12% burden), ranging from 45-212 bpm (avg of 84 bpm). 3 Pause(s) occurred, the longest lasting 5.4 secs (11 bpm). Supventricular Tachycardia, Pauses, AV Block, and Atrial Fibrillation were detected within ±45 seconds of patient triggered/diary event. Isolated SVEs were frequent (5.4%, 76752), SVE Couplets were occasional (3.7%, 26323), and SVE Triplets were occasional (1.7%, 7781). Isolated VEs were rare (0 to <1.0%, 5154), VE Couplets were rare (0 to <1.0%, 19), and VE Triplets were rare (0 to <1.0%, 1). Ventricular Bigeminy and Trigeminy were present. MD notification criteria for Rapid Atrial Fibrillation and AV Block met - notified RN on 03/15/2013 at 12:00 pm CST.

Final Interpretation
1- Sinus rhythm with first degree AV block. 2- Episodes of second degree 2:1 AV Block. 3- Sinus pauses with longest being 5.4 seconds. 4- Frequent isolated PACs with occasional atrial couplets and triplets. 5- Many runs of SVT many of which appear to be ectopic atrial tachycardia (5871) with longest being 35 sec. 6- Rare isolated PVCs, ventricular couplets and triplets. 7- 4 Runs of VT up to 16 beats rate range of 135-182/min. 8- Atrial fibrillation with a burden of 12% with rates of 45-212/ min. 9- Symptoms appear to correlate with SVT, sinus pauses, AV Block and atrial fibrillation.

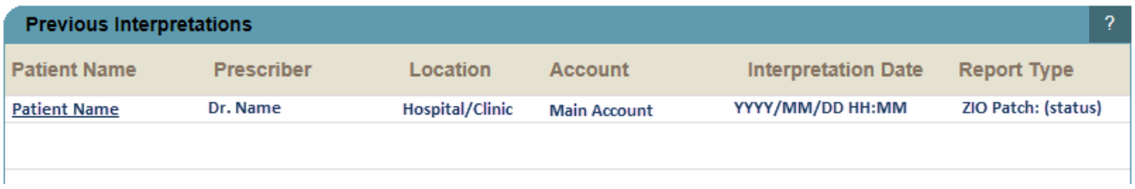
Signed by Dr. Example Physician on 14/07/24 at 03:41 PM
SIGNATURE

SN :HTEST12345

Page 1 of 28

Previous Interpretations

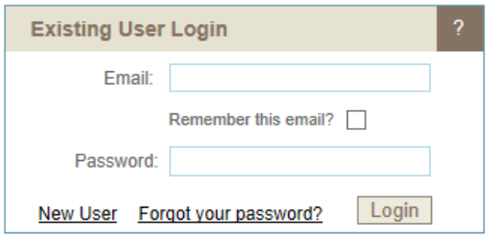
This section list of all previous ECG reports that have been interpreted for the patient. Click on the patient's name to open the report for review.



One Login – Multiple Location Users

Type the account Email address and Password.

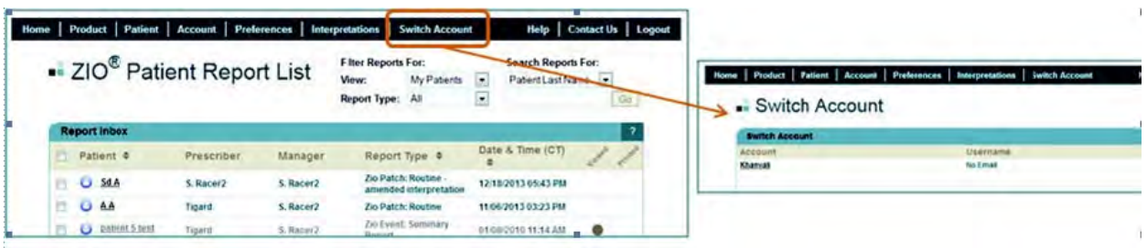
Click on **Login**.



On login, only the patients from the account associated with the login will be shown.

Example: If a user logins in with their Cole Cardiology username ("JohnD@ColeCardio.org"), he/she will only see Cole Cardiology patients on their landing page.

Select **Switch Account** navigation to view a list of the user's linked accounts. The users can select the account for which he/she wants to view and manage patient's ZIO Service.



Heart Rate Calculations

The heart rate calculation uses algorithm beat and rhythm output to compute heart rates at per beat (instantaneous), per rhythm episode, per time period, and per record levels. Instantaneous heart rates are the fundamental units of all reported heart rates, taking detected beat indices as well as its underlying rhythm into account; thus, they are the most representative metric to be used in performance verification.

Reported Heart Rates

Episode Heart Rates	Max	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (i.e., minimum of all instantaneous heart rates within the episode)
	Avg	The average episode heart rate (i.e., average of all instantaneous heart rates within the episode)
Overall Rhythm Heart Rates	Max	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (i.e., minimum of all rhythm episode minimum heart rates exclusive of Pause heart rates within the record)
	Avg	The average overall heart rate (i.e., duration-weighted average of all rhythm episode heart rates within the record)

PAUSE Determination

Pause is defined as an RR interval greater than 3 seconds.

ZEUS

THE ZIO™ ECG UTILIZATION SERVICE (ZEUS) SYSTEM

ZEUS provides highly accurate ECG analysis using beat-by-beat QRS detection. It is designed to work with single-lead ECG monitors, such as Zio™ monitoring devices, and can analyze up to 14 days of ECG data. Together, the Zio™ device family and ZEUS provide a simple, complete solution for clinicians using ambulatory ECG monitors.

LIMITATIONS WITH CURRENT ALGORITHMS

- Many cannot effectively analyze records with a single channel ECG
- Many cannot analyze recordings beyond 24 hours in length
- Many systems provide longer reports as more recordings are analyzed

ZEUS FEATURES

- A proprietary ECG algorithm to iRhythm Technologies, Inc.
- Designed to detect 10 categories of rhythms
- Analyzes lead ECG recordings up to 14 days
- Detects with a high degree of accuracy and faster turnaround time
- Unique patient report presenting patient data tailored specifically for clinicians
- Intended for post-processing recordings (not real-time analysis)
- Harness power of parallel processing to process data faster than traditional systems

ZEUS BENEFITS

- Capacity to detect a wide range of arrhythmias from patient reports
- Processing more data allows for the detection of more patients with asymptomatic arrhythmias compared to traditional analysis systems
- Reports display clinically relevant information for improved interpretation of ECG data
- No capital equipment investment necessary
- Saves staff time
- Website is user friendly interface for downloading reports

SYSTEM SPECIFICATIONS

ZEUS ANALYSIS IDENTIFIERS

- Identification of fiducial points
- Beat-by-beat analysis
- Heart rate analysis
- Rhythm recognition

ZEUS RHYTHM CATEGORIES DETECTED

Type of Rhythm	# of Episodes Tested	Sensitivity (%)	Positive Predictivity (%)	Post QA Sensitivity (%)
Atrial Fibrillation	207	99.5	81.0	99.5
AV Block	98	75.5	70.4	86.7
Pause (>3s)	105	96.2	96.2	98.2
Supraventricular Tachycardia	103	96.1	83.3	100
Ventricular Tachycardia	89	98.9	88.9	100
Ventricular Trigeminy	75	96.0	97.5	96.0
Ventricular Bigeminy	154	96.8	95.8	97.5
Sinus Rhythm	2146	97.3	91.4	97.3
Ventricular Fibrillation	42	78.6	82.4	90.5

INDICATIONS FOR USE

The ZEUS System is intended for use by qualified medical professionals for the assessment ambulatory electrocardiogram (ECG) data from adult patients 18 years or older. The system is intended to be marketed as a service that downloads and analyzes up to 14 days of ECG data. Analysis metrics are provided in a report which is available for clinician review and printing. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

CONTRAINDICATIONS

* Do not use the ZIO® XT Patch for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient.
* Do not use the ZIO® XT Patch in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
* Do not use the ZIO® XT Patch on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
* Do not use the ZIO® XT Patch on patients who do not have the competency to wear the device for the prescribed monitoring period.

iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 | San Francisco, CA 94103 | Tel: (415) 632-5700

S100A4001 |

EPI Mobile Health EPI Mini W518i Portable ECG Recording User Manual

User Assistance Information

Company Contact Details

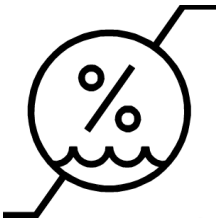
EPI Mobile Health Solutions (S) Pte Ltd
8 Ubi View, Serial System Building, #03-01
Singapore 408554
Tel: (+65) 6262 6868
Fax: (+65) 6363 3030
Email: info.enquiries@epi.com.sg
www.epi.com.sg

Inside this box you will find

1. EPI Mini W518i X 1
2. Charger (Model No: AU1050501e) X 1
3. USB cable X 1
4. User Manual X 1

Table of Contents

Symbols

Symbols	Meaning
	Follow Instructions for Use
	Caution. Please refer to safety-related notes accompanying this instrument
	Temperature limitation (Store at)
	Humidity limitation (Store at)
	Type BF applied part
	Serial Number

	Indicates separate collection for electrical and electronic equipment (WEEE).
IP20	Protected against ingress of solid foreign objects greater than or equal to 12.5 mm diameter per IEC 60529. Not protected against ingress of water
CE 0120	CE Marking indicating conformance to EC Directive No. 93/42/EEC concerning medical devices.
CE 2280	CE Marking indicating conformance to R&TTE directive 1999/5/EC
Rx only	Caution: Federal Law (USA) restricts this device to sale by or on the order of a healthcare practitioner
EC REP	Authorized Representative in the European Community
	Manufacturer name and address

Note: This device is registered in USA as Rx only for the US market.

For your safety, please follow all operating and safety instructions in this user guide

Indications for Use

EPI Mini W518 is a portable single lead electrocardiogram (ECG) recording device. It is capable of recording, storing and sending several leads using different configurations allowing mobile recording, storing and sending of ECGs on-the-go. This provides the user with instant access to information about their heart, within the limitations of a traditional 12 lead ECG. It serves the purpose of a mobile and highly portable ECG recording device. The device is used for ad-hoc recording of ECGs when cardiac symptoms are present to allow the detection of abnormal heart activity. The target patient population includes but it is not limited to users who are at risk of heart disease, have existing heart conditions and/or users who show symptoms suggestive of heart disease. The device is not meant to entirely replace the clinical 12 lead ECG machine.

ECG data is recorded for 30 seconds each time by the user. Recorded ECG data is stored on the EPI Mini and can be sent to a Smartphone via Bluetooth. ECG data sent from the EPI Mini is received and stored for viewing on the Smartphone using the EPI Mini mobile software application (mobile app). Users are able to view their ECGs using the mobile app, as well as resend or delete any of these data via the app to allow the doctor to monitor their conditions. The ECG data recorded by the device are not designed or intended for medical diagnosis. Conditions such as arrhythmia can only be diagnosed by a doctor through a special examination.

Warnings and Cautions

Contraindications

Users who have pacemakers or other stimulators implanted should not use this device to record any modified pre-cordial leads and should strictly be limited to using the modified limb leads for ECG recording (device should be kept at a minimal distance of 9 inches away from the implanted pacemaker or other stimulators)

For your safety, please take note of the following warnings.

Warnings

- ✓ Do not use this device in places with flammable substances like anaesthetic gas or pressurized oxygen.
- ✓ Do not self-diagnose ECG. Always consult your doctor. Self-diagnosis or self-treatment may lead to deterioration in your condition.
- ✓ Do not use this device around electromagnetic scanning like MRI scans.
- ✓ Do not use this device on people with sensitive skin or allergies.
- ✓ Do not attempt to use the device over or through clothing.
- ✓ Use only the original charger and the original USB data cable for charging. Use of other chargers and USB cables may cause unwanted electrical risk.
- ✓ Do not measure ECG when this device is charging.
- ✓ Do not plug the USB cable to this device during recording of ECG.
- ✓ Keep out of reach of infants and small children.

For your safety, please take note of the following cautions.

Cautions

- ✓ Do not use this device for any purpose other than obtaining an ECG.
- ✓ Do not record ECG where this device will be exposed to strong electromagnetic forces.
- ✓ Do not expose the unit to strong shocks or vibrations. Do not drop or step on the unit.
- ✓ Do not use for any purpose other than obtaining an electrocardiograph.
- ✓ Do not take measurements in a moving vehicle.
- ✓ If electrodes are dirty, please wipe with dry soft cloth before recording ECG.
- ✓ Only use this device in accordance with instructions provided from the manufacturer.
- ✓ The device will automatically shut down after 2 minutes of non-use.
- ✓ Do not induce excessive shock, vibration, external force onto this device.
- ✓ Do not disassemble, repair, or modify the unit.
- ✓ Charger input voltage is 100V – 220V. Do not disassemble the charger.
- ✓ Do not short-circuit the charger.

- ✓ The device and charger are not waterproof. Avoid direct exposure to water or dirt and prolonged exposure to sunlight.
- ✓ Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.
- ✓ Do not sterilize this device in an autoclave, ultraviolet sterilizer or gas sterilizer.
- ✓ When storing the device, avoid exposure to direct sunlight or heat.
- ✓ The device should be stored under the storage temperature range where the temperature is between 0°C and 40°C and the humidity is between 35% and 85%.
- ✓ The device should be stored in the room without acid, alkali and harmful gas.
- ✓ Avoid exposure to violent vibration, rain, sunshine and high humidity during transportation.
- ✓ Avoid extremes in temperature and humidity. This device and charger are designed to be used in environments where the temperature is between 5°C and 38°C and the humidity is between 35% and 85%.
- ✓ Follow local, state, and national governing ordinances and recycling instructions regarding disposal or recycling of the device and device components.
- ✓ In compliance with the European Directive on Waste Electrical and Electronic Equipment (WEEE) 2002/96/EC, do not dispose of this product as unsorted municipal waste. This device contains WEEE materials; please contact your distributor regarding take-back or recycling of the device.

Description of Device

There are 4 function keys.

1) **"Power"** button / **"Back"** button.

2) **"Enter"** button.

3) **"Up"** button.

4) **"Down"** button.

Note that the device will automatically shut down after 2 minutes of non-use to prolong battery life.

Environmental conditions that affect use

- ✓ EPI Mini is designed to be used in environments where the temperature is between 5°C and 38°C and the humidity is between 35% and 85%.
- ✓ To avoid interference with other electronic devices, please avoid placing other electronic equipment sensitive to radio frequency (RF) and magnetic fields too close to the EPI Mini. Consult the manufacturers of your electronic devices to solve any interference problems you experience.
- ✓ Standby time data provided by manufacturer is based on the ideal working environment. Actual time may vary and depends on the environment, and usage method.

Classification of degree of protection/Type BF

The EPI Mini's sensors are conductive in nature and classified as type BF applied parts. Should a leakage current occur, there is sufficient protection to prevent users from a serious electric shock.

Getting Started

Charging the device

Please charge EPI Mini before use. To charge EPI Mini, insert the original USB cable into the device and connect the other end to the USB port of the original charger. The screen will show a charging screen with all the normal functions disabled. Do not use the device during charging. The screen will show **"fully charged"** (Battery icon with 'F' in red font) when battery is fully charged.

Note: The rechargeable battery has a limited number of charge cycles and might eventually need to be replaced. Battery life varies based on use.

Pairing the device with your phone

1. Power on the EPI Mini by holding the “Power” button for 3 seconds
2. **Go to Settings** >> **System Info** >> **BT Address**, record the characters on the screen.
3. In your phone, go to **Menu** >> **Settings** >> **Bluetooth**. Select to scan for new devices. Select **“EPI Mini”** or corresponding BT Address to pair the device.

Download Application

Please download the application EPI mHealth from your Smartphone’s respective application (“app”) stores (i.e. Google Play Store, BlackBerry App World, Apple App Store).

You may also visit our website at www.epi.com.sg and refer to the Support section to download the application and other guides on how to setup the respective Smartphone.

Operating Instructions

Recording your ECG

1) Select the **"Record ECG"** tab in your EPI Mini. Press the **"Enter"** button and read the instructions on the screen. Hold the device as shown in the image below. Ensure that there is good surface contact with the electrodes leads and press the **"Enter"** button again to start recording.

.

2) After recording, ensure that the arrow is on **"Yes"** then press the **"Enter"** button to send the ECG. You should see **"Data Sent"** appearing on the EPI Mini, and **"Data Received"**, **"Connecting to Server"**, **"Data sent successfully"** appearing sequentially on the application of your Smartphone.

3) You should obtain a reply on your Smartphone within 10 minutes.

ECG Manager

In this function, you can send or delete previous ECGs.

Press the "**Up**" or "**Down**" button to the corresponding option and **"Enter"** button to select option.

To return to the previous menu, press the **"Back"** button.

Date/Time

To change the Date,

Go to Settings >>> **Date/Time** >>> **Set Date**

Press the "**Up**" or "**Down**" button to change the value.

Press the **"Enter"** button to move to the next value.

After the last value, press the "**Enter**" button to save changes.

To return to the previous menu, press the **"Back"** button.

To change the Time,

Go to Settings >>> **Date/Time** >>> **Set Time**

Press the "**Up**" or "**Down**" button to change the value.

Press the **"Enter"** button to move to the next value.

After the last value, press the "**Enter**" button to save changes.

Language

To change language,

Go to Settings >>> **Language.**

Press "**Enter**" button.

Press the "**Up**" or "**Down**" button to scroll.

Press "**Enter**" button to confirm the desired language.

To return to the previous menu, press the **"Back"** button.

User Settings

To edit User Profile,

Go to Settings >>> **User Settings** >>> **Edit User Profile**

Select profile to edit, use the "**Up**" or "**Down**" button to change the value, press **"Enter"** button to save changes.

To change User,

Go to Settings >>> **User Settings** >>> **Select User Profile**

Use the "**Up**" or "**Down**" button to select the desired user, press **"Enter"** button to confirm.

To return to the previous menu, press the **"Back"** button.

System Information

Go to Settings >>> **System Info.**

You can check your Firmware version by going to FW Version.

You can view the device name **"EPI Mini"** in Device Name.

You can view your Bluetooth address by going to **"BT Address"**.

To return to the previous menu, press the **"Back"** button.

Cleaning and Maintenance

- ✓ Clean your device with a soft and dry cloth.
- ✓ Do not use caustic or abrasive cleaning agents, or any cleaning agent containing ammonium chloride or isopropyl alcohol.
- ✓ Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids onto the device.
- ✓ Do not repair, disassemble and modify this device.
- ✓ This device does not require calibration during its expected life cycle.

Storage and Transport

- ✓ When storing the device, avoid exposure to direct sunlight or heat.
- ✓ The device should be stored under the storage temperature range. If the device will be stored for a long time, the recommended conditions are:

Temperature: 0°C to 40°C
Relative humidity: 35% to 85%

- ✓ The device should be stored in the room without acid, alkali and harmful gas.
- ✓ Avoid exposure to violent vibration, rain, sunshine and high humidity during transportation.

Troubleshooting Guide

Problem	Possible Cause	Recommended Solution
EPI Mini cannot be switched on	The battery is out of power.	Charge the battery.
EPI Mini cannot be charged	The charger is damaged.	Change charger.
Noisy ECG Signal	Fingers are dry.	Moisten hands with a damp towel.
	Integrated electrodes are dirty.	Refer to Cleaning and Maintenance.
	Excessive movement during measurement.	Check instructions and repeat measurement.
Error message “Failed to send Check BT connection with phone”	EPI Mini not connected to Smartphone.	Follow the instructions on “Pairing the device with your phone”.
Unable to send ECG to server	Smartphone not connected to Internet.	Check internet connection on your Smartphone.

Specifications

Product Name:	EPI Mini
Model:	W518i
Dimension:	75.4(L) mm x 46.4(W) mm x 15.0(H) mm
Weight:	58 g
Display:	2” 220X176 TFT-LCD
Power rating:	3.7V 80mA
Battery Life:	
Operating mode:	over 6 hours
Standby mode:	over 5 days
Wireless Communication:	Bluetooth 4.0 Low Energy
Operating Environment:	5°C to 38°C (41ºF to 100ºF)/ 35% to 85% RH
Storage Environment:	0°C to 40°C (32ºF to 104ºF) / 35% to 85% RH

Classifications per IEC 60601-1:

Degree of protection: Type BF-Applied Part 

Enclosure Degree of Ingress Protection: IP20

Note: Specifications are subject to change without prior notice

This product meets EMC standards IEC60601-1-2:2007. This standard is designed to provide reasonable protection against harmful interference in a typical medical installation. However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in healthcare and other environments, it is possible that high levels of such interference due to close proximity or strength of a source might disrupt the performance of this device. Using this device with or near other medical/electrical equipment could produce mutual interference. Be sure to read the Instruction Manual for correct installation and use. Also, be sure to read the Instruction Manuals for all other electronic equipment nearby.

Federal Communications Commission (FCC) Notice

This device has been tested and found to comply with the limits for a class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This device generates, uses, and can radiate radio frequency energy. If not installed and used in accordance with the instructions, it may cause harmful interference to radio or television reception, which can be determined by turning the device off and on. The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the distance between the device and the receiver.
- Connect the device to an outlet on a circuit different from the outlet where the receiver is connected
- Consult the dealer or an experienced radio/TV technician for assistance.

The device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the United States FCC. These limits are part of comprehensive guidelines and establish permitted levels of RF energy for the general population. The guidelines are based on the safety standards previously set by both U.S. and international standards bodies. This device has been shown to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-2005.

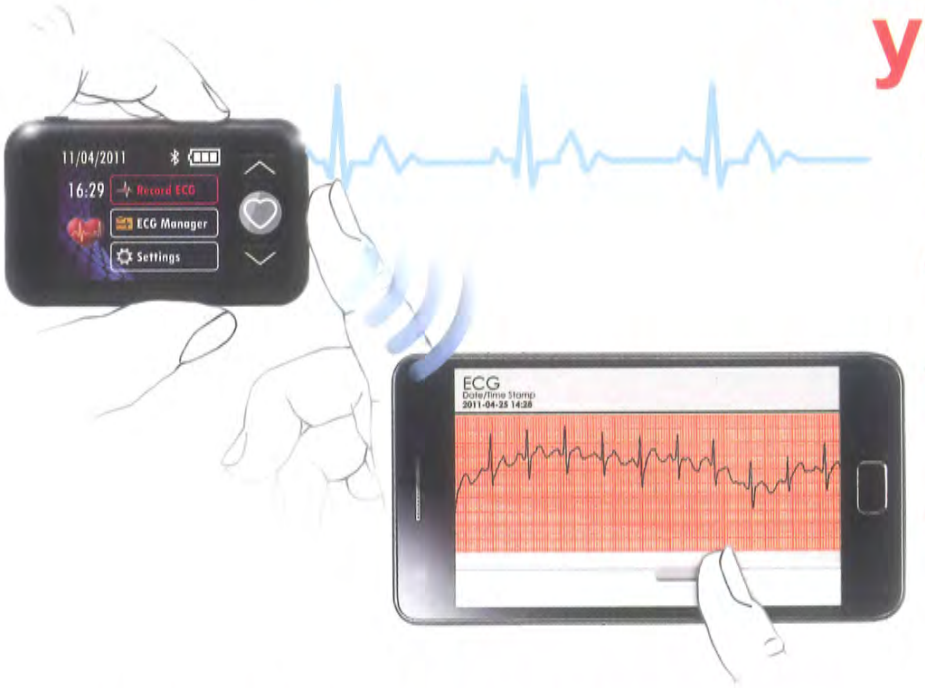
CAUTION:
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1)This device may not cause harmful interference, and
(2)This device must accept any interference received, including interference that may cause undesired operation

EPI Mini

epi

A Doctor in your Pocket!



- Records ECG anytime, anywhere at the touch of your fingers;
- Receives timely response of your ECG via SMS on your smartphone;
- Allows active tracking & monitoring of your health parameters using the virtual health folder. **
- Each EPI Mini can be used by up to 5 registered users

** Subscription to service applies

INTRODUCING:

EPI Mini, a revolutionary mobile health monitoring device that connects to a user's smartphone via Bluetooth, enables instantaneous recording of ECG and tracking of other health parameters. Through the 24/7 EPI Health Concierge service, users of EPI Mini are able to receive ECG interpretations in a timely manner. Simple to use, EPI Mini is designed for anyone to keep their health in check anytime, anywhere, simply at the touch of their fingers.

Health monitoring is not only relevant to users with known illnesses, but healthy individuals as well. The need to constantly monitor one's health to maintain a good quality of life is vital. With the aid of the online "Virtual Health Folder" service, users can access to their health records conveniently.

EPI Health Concierge Solution:

ECG readings will be automatically sent via your Smartphone to EPI Health Concierge.

Users are facilitated with the direct linkage to medical service in the event of an emergency.

Health Concierge

EPI concierge team will analyze and respond by sending the ECG results via sms.

Intensive clinical trials have proven our devices to be highly accurate in detecting abnormalities in ECG recordings:

- 98% accuracy when compared to the recordings of a 12-lead ECG which is commonly done in hospitals or clinics settings.
- 67% positive diagnosis of heart conditions in patients with palpitations as compared to Holter's 64%.

Contact Us:

EPI MOBILE HEALTH SOLUTIONS (S) PTE LTD

8 Ubi View, #03-01, Serial System Building, Singapore 408554

Tel: (65) 6262 6363 Fax: (65) 6363 3030

info.enquiries@epi.com.sg

APPENDIX C
PERFORMANCE TEST - BENCH

CONTENT:

ZIO SR ECG MONITORING PROPOSED LABELING

Report Number	Description
(b)(4)	SkyRunner Wireless Performance Test Report
(b)(4)	SkyRunner System (b)(4) Test Report
(b)(4)	(b)(4) (b)(4) Rev (b)(4) Testing of the Skyrunner
(b)(4)	(b)(4) Test Report
(b)(4)	(b)(4) (b)(4) Rev. (b) - SkyRunner - Package Performance Testing per ASTM D7386-12
(b)(4)	(b)(4) (b)(4) Performance Testing of the SkyRunner
(b)(4)	(b)(4) Lab Report (b)(4)
(b)(4)	(b)(4) Lab Report (b)(4)

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4)

[redacted]

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4)

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

APPENDIX D
SOFTWARE SUPPORTING DOCUMENTS

CONTENT:

ZEUS SYSTEM

Part Number	Description
(b)(4)	(b)(4) - Requirements Specification
(b)(4)	(b)(4) - Design Description
(b)(4)	(b)(4) - Design Description
(b)(4)	(b)(4) Architecture Overview
(b)(4)	(b)(4) - Verification Report

(b)(4)

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4)

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4)

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4)

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

(b)(4) Verification Report

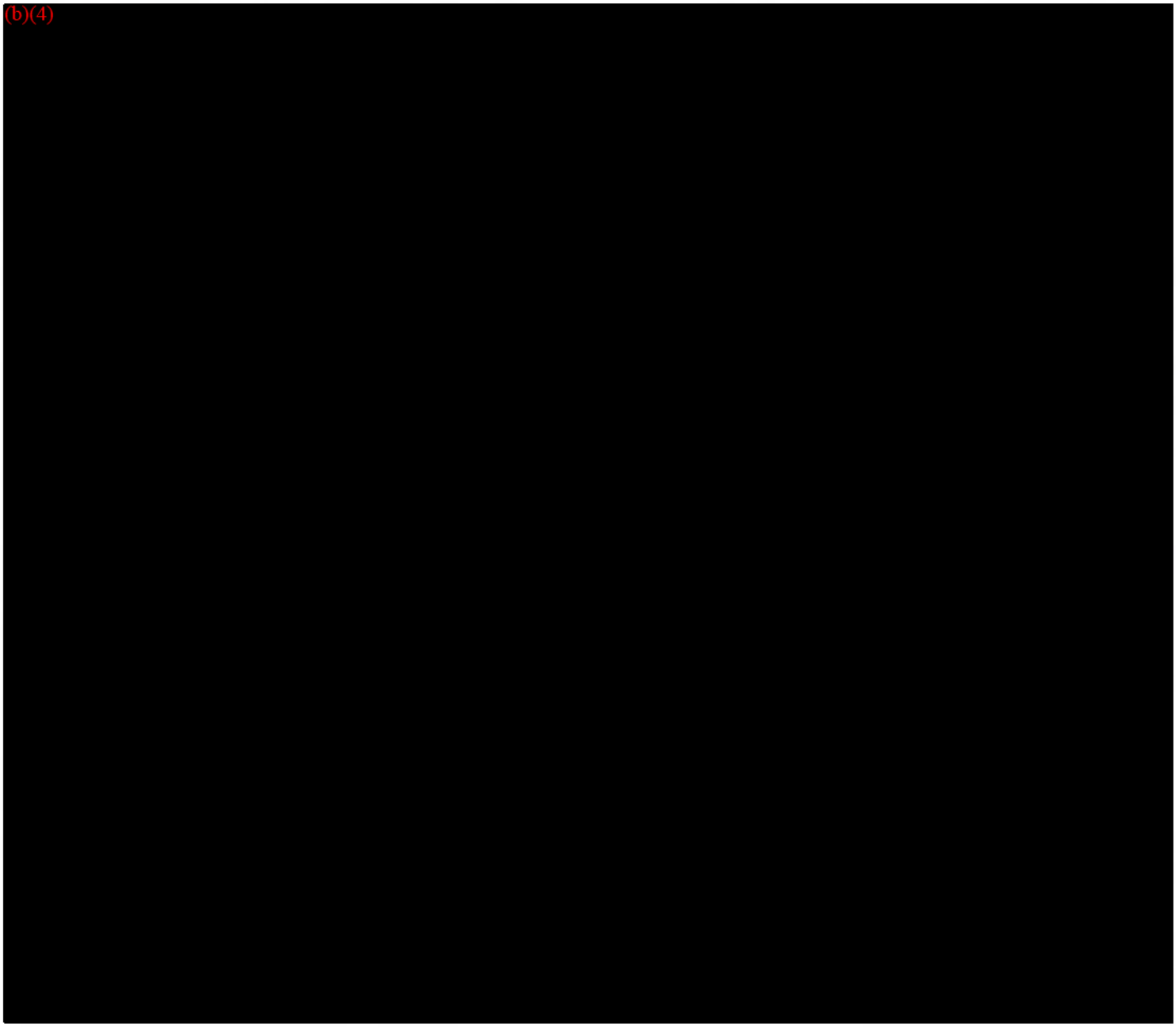
APPENDIX E
FIRMWARE SUPPORTING DOCUMENTS

CONTENT:

ZIO SR PATCH & GATEWAY

Part Number	Description
(b)(4)	SkyRunner Patch Firmware Requirements Specification
	SkyRunner Gateway Firmware Requirements Specification
	SkyRunner Patch Firmware Design Description
	SkyRunner Gateway Firmware Design Description
	SkyRunner BLE Firmware Design Description

(b)(4)



(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

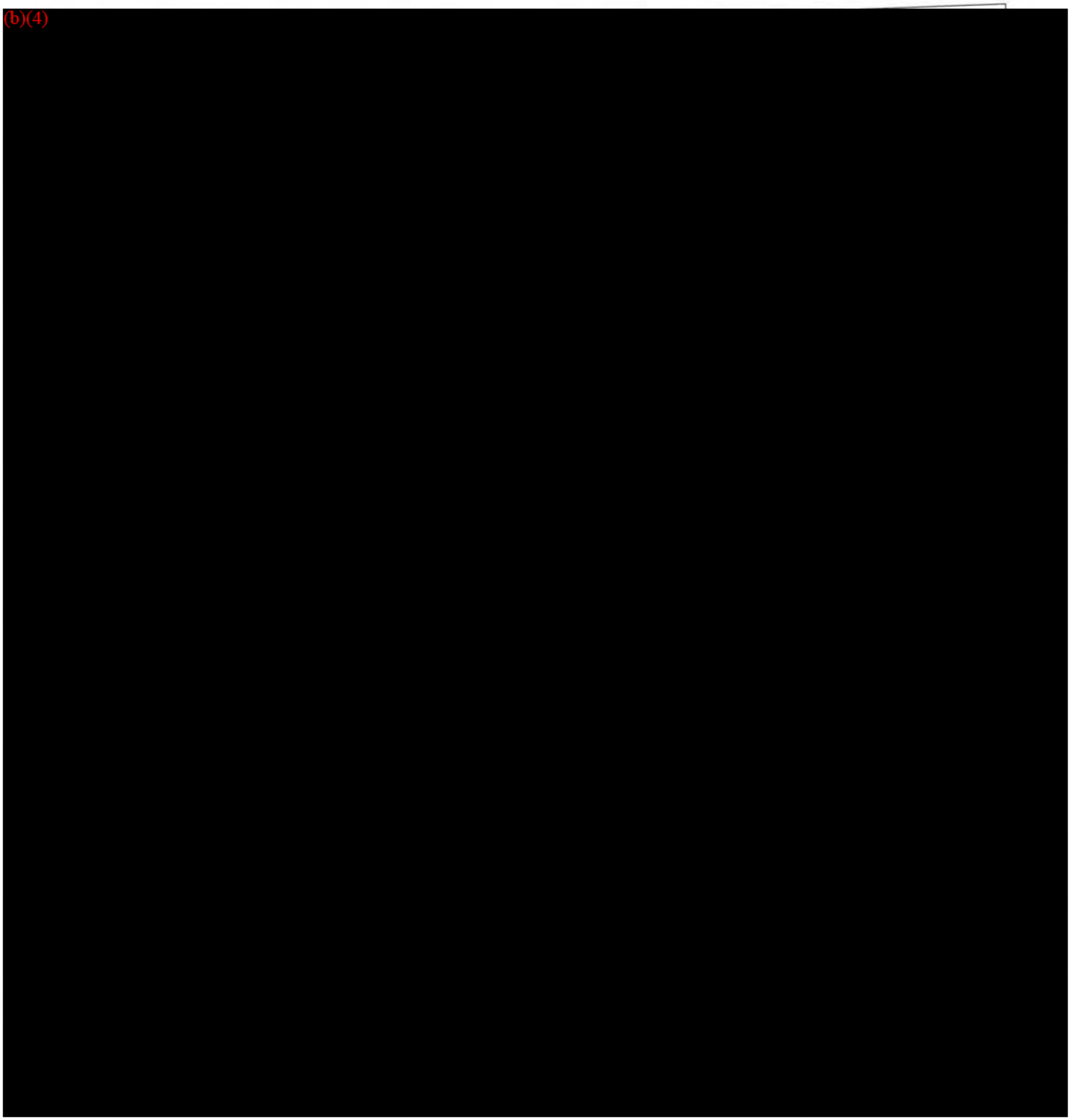
(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4)



(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4) Requirements Specification

(b)(4)

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

iRhythm	Document #: (b)(4)	Effective: On Approval	Rev: (b)(4)	Page: 1 of 26
	TITLE: SkyRunner Gateway Firmware Design Description			

(b)(4)

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4)

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

(b)(4) Design Description

iRhythm

February 19, 2015

K143513/S001

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type:	Traditional 510(k)
Holder Name:	iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 San Francisco, CA. 94103
Registration No.	3007208829

Reference: **K143513** – Acceptance Review Notification - Refuse To Accept (RTA) received December 22, 2014

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this response to the RTA received on December 22, 2014 from Konstantinos Makrodimitris, Lead Reviewer for 510(k) K143513 ZIO® SKYRUNNER (SR) ELECTROCARDIOGRAM (ECG) MONITORING SERVICE.

Enclosed are two copies of the RTA response for the ZIO SR ECG Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is otherwise an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

Rich Laguna
Director of Quality & Regulatory Affairs

CONFIDENTIAL

iRhythm

February 19, 2015

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type:	Traditional 510(k)
Holder Name:	iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 San Francisco, CA. 94103
Registration No.	3007208829

Reference: **K143513** – Acceptance Review Notification - Refuse To Accept (RTA) received December 22, 2014

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this response to the RTA received on December 22, 2014 from Konstantinos Makrodimitris, Lead Reviewer for 510(k) K143513 ZIO® SKYRUNNER (SR) ELECTROCARDIOGRAM (ECG) MONITORING SERVICE.

Enclosed are two copies of the RTA response for the ZIO SR ECG Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is otherwise an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

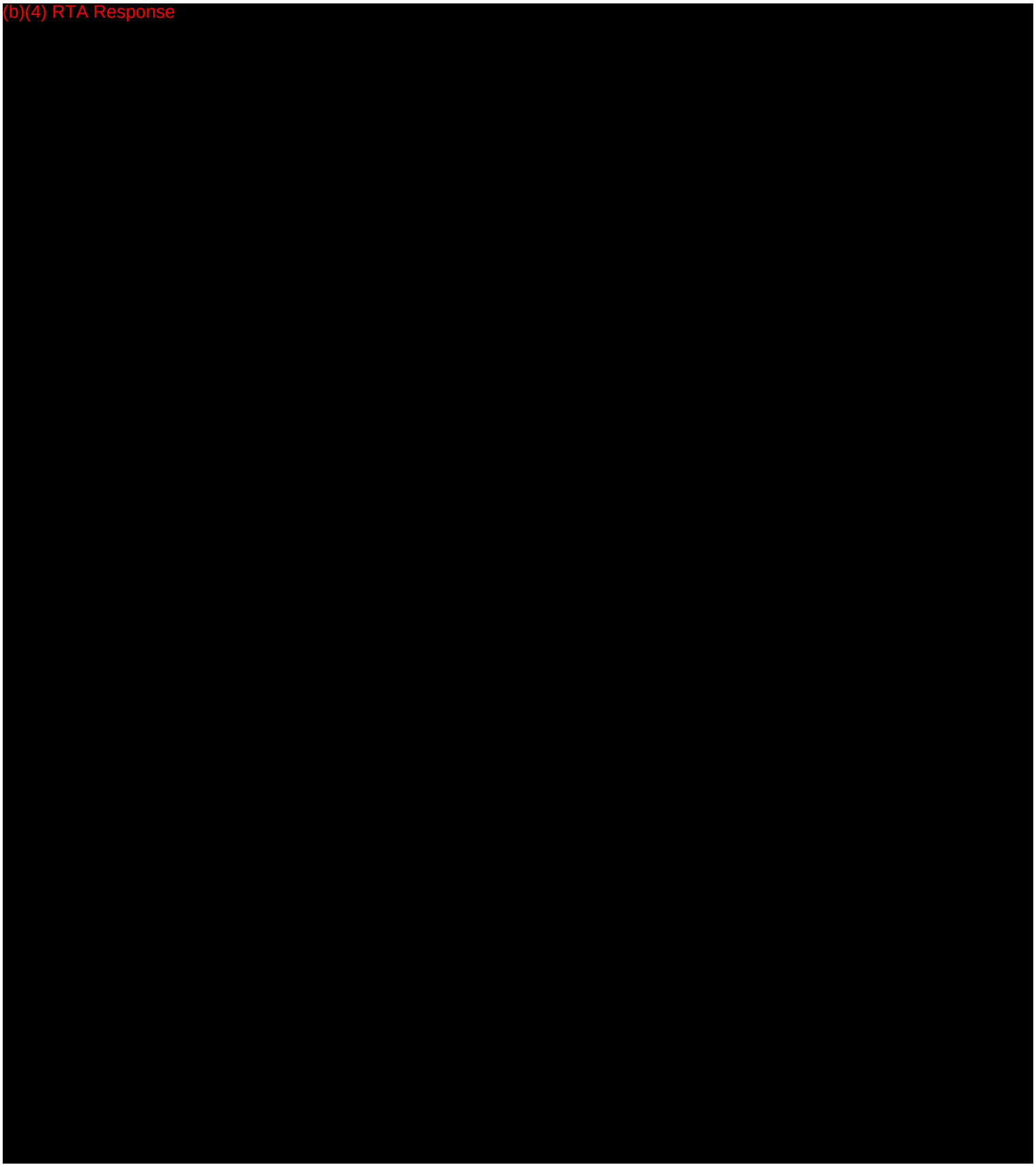
Rich Laguna
Director of Quality & Regulatory Affairs

CONFIDENTIAL

iRhythm

RTA RESPONSE

(b)(4) RTA Response



iRhythm

(b)(4) RTA Response

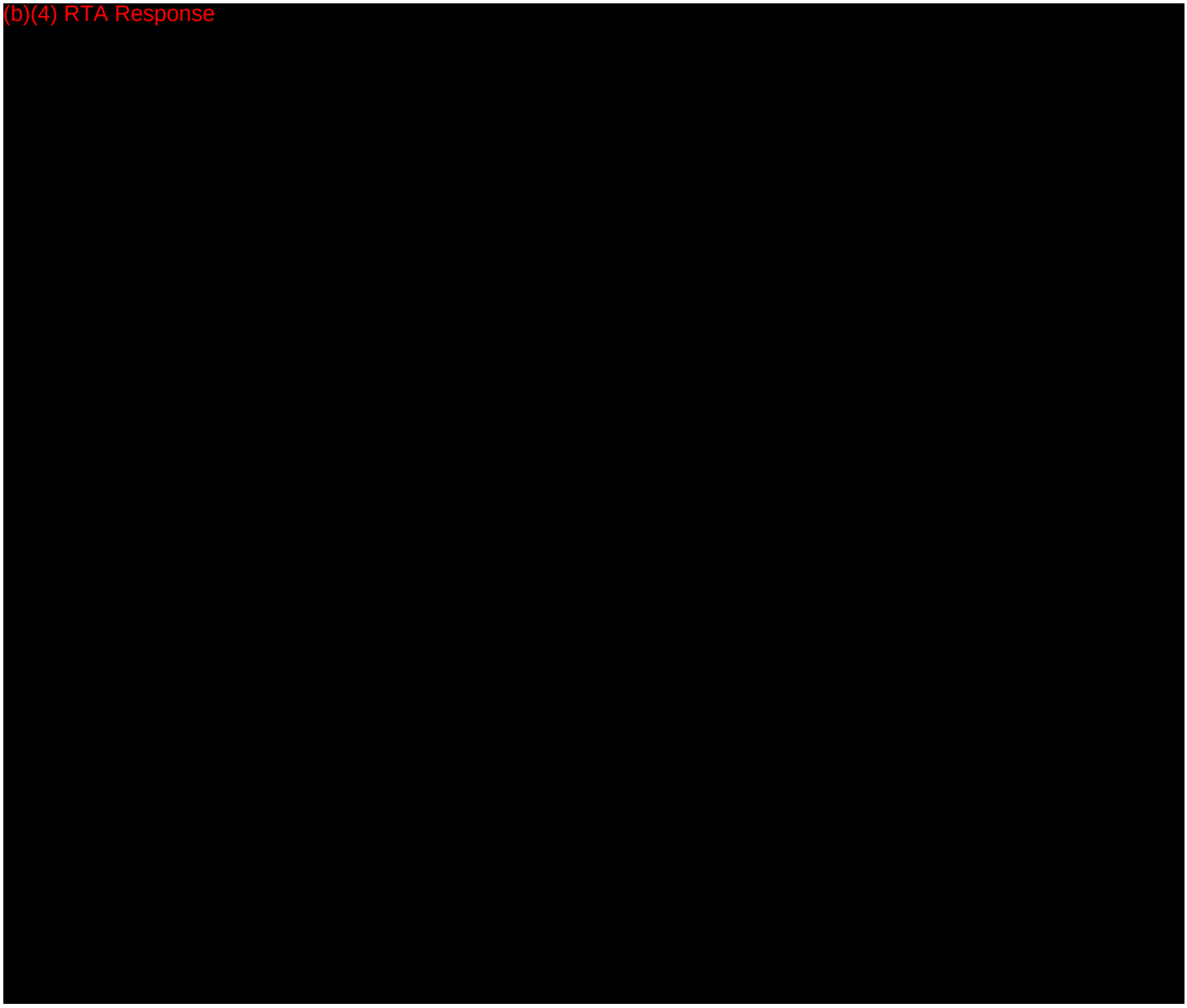


TABLE OF CONTENTS

iRhythm	Technical Report Number: (b)(4)	Rev: (b)(4)	Page: 1 of 8
	Project Name: (b)(4)	Report Date: January 22, 2015	
	TITLE: (b)(4)	Biocompatibility Report	

(b)(4)

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Biocompatibility Report

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

iRhythm

K143513/S2

May 15, 2015

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type:	Traditional 510(k)
Holder Name:	iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 San Francisco, CA. 94103
Registration No.	3007208829
Reference:	**K143513/S001** – ZIO® SKYRUNNER (SR) ELECTROCARDIOGRAM (ECG) MONITORING SERVICE, ADDITIONAL INFORMATION (AI) REQUEST (April 21, 2015)

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this in response to the request for additional information received on April 21, 2015 from Konstantinos Makrodimitris, Lead Reviewer for 510(k) **K143513** Traditional ZIO SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service.

Enclosed are two copies of the additional information response for the ZIO SR ECG Monitoring Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is otherwise an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

Rich Laguna
Director of Quality & Regulatory Affairs

14

PREMARKET NOTIFICATION

TRADITIONAL 510(K)

ZIO® SKYRUNNER (SR)
ELECTROCARDIOGRAM (ECG) MONITORING SERVICE

K143513/S001

ADDITIONAL INFORMATION (AI) RESPONSE

RESPONSE DATE
MAY 15, 2015

BINDER

1 OF 1

IRHYTHM TECHNOLOGIES, INC.
650 TOWNSEND STREET, SUITE 380
SAN FRANCISCO, CA 94103

iRhythm

K143513/S001 – ZIO® SKYRUNNER (SR) ELECTROCARDIOGRAM (ECG) MONITORING SERVICE, ADDITIONAL INFORMATION (AI) REQUEST (April 21, 2015)

Table of Contents

iRhythm

May 15, 2015

U.S. Food and Drug Administration
Center of Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Springs, MD 20993-0002

Application type:	Traditional 510(k)
Holder Name:	iRhythm Technologies, Inc. 650 Townsend Street, Suite 380 San Francisco, CA. 94103
Registration No.	3007208829
Reference:	**K143513/S001** – ZIO® SKYRUNNER (SR) ELECTROCARDIOGRAM (ECG) MONITORING SERVICE, ADDITIONAL INFORMATION (AI) REQUEST (April 21, 2015)

Dear Madam/Sir:

iRhythm Technologies, Inc. ("iRhythm Technologies") submits this in response to the request for additional information received on April 21, 2015 from Konstantinos Makrodimitris, Lead Reviewer for 510(k) **K143513** Traditional ZIO SkyRunner (SR) Electrocardiogram (ECG) Monitoring Service.

Enclosed are two copies of the additional information response for the ZIO SR ECG Monitoring Service. iRhythm Technologies is enclosing an electronic copy of this submission on a portable flash drive for the reviewer's convenience as the second copy. The electronic copy is otherwise an exact duplicate of the paper copy; however, minor formatting changes may have been introduced as a result of PDF conversions.

This submission contains technical, commercial and confidential trade secret information and iRhythm Technologies, Inc. requests the maximum protection provided by law in accordance with 21 CFR §807.95.

If there are any questions, contact me by phone at 415-632-5749 or by fax at 415-632-5701 or by email at rlaguna@irhythmtech.com.

Sincerely,

Rich Laguna
Director of Quality & Regulatory Affairs

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Information

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Software Verification Report

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

PATIENT INSTRUCTIONS & BUTTON PRESS LOG

NAME:

PHYSICIAN:

START DATE: / /

TO BE COMPLETED BY PATIENT:

DATE REMOVED: / /

The ZIO SR patch records every heartbeat and the ZIO SR gateway sends a section of data for analysis each time the patch button is pressed.

☺ IT IS OKAY IF …

- The patch peels or lifts at the edges.
- You experience some itching.
- There are no lights on your patch and gateway.

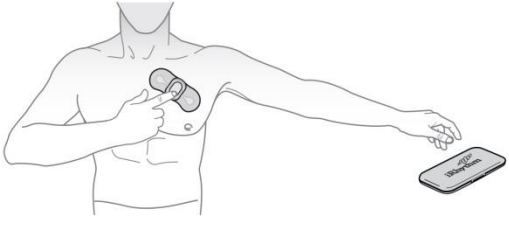
CALL 1.888.693.2401 IF …

- The patch falls off.
- You feel severe itching or irritation.
- Patch or gateway lights are flashing.
  - ➔ This does not mean there is a problem with your heart
  - ➔ Turn to p.7 and p.8 to troubleshoot

PATIENT INSTRUCTIONS

During Recording:

Wear the patch during your normal daily activities, even while showering and sleeping. Keep the gateway in arm's reach and in view to stay connected.



Each time you feel a symptom, press the patch button and then record your symptom in a *Button Press Log* in this booklet or online at www.myzio.com.

When you are done wearing the patch:

Turn to the end of this booklet for removal and return instructions.

ZIO DO's

DO your normal activities while wearing the patch	**BUT...**
DO shower with your patch on	**BUT...**
DO try to keep your gateway with you, in arm's reach and in view	**BUT...**
DO try to keep the gateway in a place with cellular signal	**BUT...**
DO carry the gateway with you when you can	**BUT...**
DO travel with your patch and gateway	**BUT...**
DO put your patch inside the gateway and send it to iRhythm for analysis	**BUT...**

ZIO DON'Ts

DON'T do activities that cause heavy sweating

DON'T put your patch under water or let the gateway get wet

DON'T worry if it is out of range for a while

DON'T worry if it is out of range for a while

DON'T leave the gateway within 6 feet of 2.4 GHz devices like wireless routers, baby monitors and TV senders

DON'T forget to turn off airplane mode (p. 10)

DON'T put other objects in the gateway

WARNING

If at any time you feel the need for immediate medical care, call 911. The ZIO® SR device will not provide any medical assistance and cannot contact medical personnel for you.

PATCH TROUBLESHOOTING GUIDE

If the patch light is flashing orange slowly (once every 3 seconds):

→ Your patch is not making good contact. Press evenly on the patch for 3 to 5 minutes. If flashing continues, call 1-888-693-2401.

If the patch light is flashing orange fast (three times per second):

→ Your patch is not recording. Call 1-888-693-2401.

GATEWAY TROUBLESHOOTING GUIDE

Open your gateway and look inside...

If the gateway light is flashing orange slowly (once every 3 seconds):

→ The gateway lost connection to your patch. Keep the gateway near to the patch for at least 10 minutes. If flashing continues, call Customer Support at 1-888-693-2401.

If any gateway light is flashing orange fast (three times per second):

→ Your gateway is not working. Call Customer Support at 1-888-693-2401.

GATEWAY TROUBLESHOOTING GUIDE

Open your gateway and look inside...

SLOW

If the gateway light is flashing orange slowly (once every 3 seconds):

→ The gateway does not have cell signal. Move the gateway to a place with good cell signal, near a window or outside and hold the button for 3 seconds until the light flashes green.

- Keep the gateway there until green flashing stops.
- If it does not flash green, move the gateway to a new place and try again.

If orange flashing continues, call Customer Support at 1-888-693-2401.

TRAVELING WITH YOUR ZIO® SR

The patch can be worn through security screenings. A security statement is provided on the opposite page.

Airplane Mode ON (to turn off the cell radio):

1) Open the gateway
2) Press and hold the  button for 3 seconds until the inside lights flash orange quickly. The outside airplane light will flash as long as the gateway is in “Airplane Mode.”

Airplane Mode OFF (to turn on the cell radio):

1) Open the gateway
2) Press and hold the  button for 3 seconds until the inside lights flash green quickly. The outside airplane light will flash stop flashing.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

How long am I supposed to wear the patch?

Wear the patch for as long as your doctor prescribed but no longer than 14 days. NOTE: Each person's wear experience is different and actual wear time may be shorter than prescribed.

What is the patch doing?

The patch is recording every heartbeat. Your doctor will use the data from the patch to look at your heart rhythm and determine the right course of action.

What is the gateway doing?

The gateway is wirelessly sending a section of heart rhythm data from the patch each time the patch button is pressed. The data is received at iRhythm for analysis and a report is provided to your doctor.

What should I do if I feel a symptom?

Press the button and fill out a page of the *Button Press Log* in this booklet or on www.myzio.com. Make sure to keep the gateway in arm's reach and in view

What if I forget to press the button when I feel a symptom?

While pressing the button is important to "tag" and wirelessly send an event, the patch is recording every heartbeat.

What if I press the button but forget to write down the information in this booklet?

While the *Button Press Log* information is useful, pressing the button indicates that you felt your symptoms at that time.

What if I don't have symptoms?

That's okay. The patch records every heartbeat.

Do I need to do anything with the gateway to send heart rhythm data wirelessly?

No, you only need to keep the gateway in arm's reach and in view to stay connected wirelessly after you press the patch button. The gateway should also be kept in a place with good cell signal.

How do I know the patch and the gateway are working?

When they were turned on, the staff at your doctor's office made sure that the patch and gateway were working. When they are working with no problems, the patch and gateway will not flash or make noise.

Will the gateway show any lights or make any sounds?

No. As long as it is able to send data, the gateway will not flash or make noise.

What if I press the patch button while the gateway is not in range?

The patch will store the data until the gateway is in range, then the data will be sent.

What happens if I press the patch button while the gateway doesn't have cell signal?

The gateway will store the data until it has cell signal, then the data will be sent.

What kinds of devices can affect wireless connection with the gateway?

Other wireless devices that use 2.4 GHz signals such as baby monitors, TV senders, and wireless routers can interrupt communication between patch and gateway if used within 6 feet.

What should I do if the patch falls off?

Call Customer Support at 1-888-693-2401.

What should I do if the patch peels or lifts at the edges?

Press and hold along the edges to re-stick.

Can I exercise while wearing the patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the patch on?

Yes, but showers should be short. Keep soaps and lotions away from the patch. When towel-drying, hold the patch down with one hand. Press the patch against your skin to secure it.

Can I take a bath?

Yes, but keep the patch above water.

Can I go swimming or in a hot tub?

No. The patch should not be put under water and heavy sweating will reduce shorten wear time.

Is it normal for the ZIO® SR Patch wings to become cloudy?

Yes, the wings of the patch may become cloudy after a few days of wear.

Is it normal for the patch to move slightly from its original position?

Yes. The patch may move slightly from its original position. A blue gel may be seen under the wings of the patch.

Is it normal to experience skin irritation or itchiness in the area of the patch?

Most patients do not experience skin irritation or itchiness. However, some patients have reported minor skin irritation and/or itching while wearing the patch. If the irritation or itching is severe or hives or blisters develop please call Customer Support at 1-888-693-2401.

What activities should I avoid?

Activities that cause heavy sweating should be avoided. Sweat can cause the patch to slide, become loose, fall off, and shorten wear time.

I think I see blood under my patch. What should I do?

Call Customer Support at 1-888-693-2401. It is probably due to a small shaving cut when the patch was applied to your chest.

What if the patch flashes orange while I am wearing it?

If you see the patch flashing orange, this does not mean there is a problem with your heart; it just means that the patch is not well attached. Press evenly on the patch for 3 to 5 minutes. If the flashing continues or comes back, call Customer Support at 1-888-693-2401.

What should I do if my gateway is flashing orange?

If you see the gateway flashing orange, this does not mean there is a problem with your heart; it just means that the patch cannot send information wirelessly. Turn to page 8 to troubleshoot or call Customer Support at 1-888-693-2401.

Can I travel with the patch on?

Yes. If questioned during security screening, show the statement on page 11.

Can I fly with the gateway?

Yes. The gateway cellular radio can be turned off by pressing the airplane button inside the gateway for 3 seconds. The gateway cellular radio can be turned back on by pressing the airplane button for 3 seconds. While in "airplane

mode" the airplane light on the outside face of the gateway will flash. See page 10.

How do I return the patch and gateway?

You can drop off the sealed envelope at the Post Office, in a USPS (blue) mailbox or give it to your mail carrier. Turn to the end of this booklet for removal and return instructions.

I have removed the patch and it is flashing orange. Is this okay?

The patch may flash orange after removal. It is okay to mail the device while it is flashing. Turn to the end of this booklet for return instructions.

Who should I call if I have questions about the patch or gateway?

Call Customer Support at 1-888-693-2401.

BUTTON PRESS LOG

I pressed the button on...

mm/dd/yy hh:mm

05/29/13 07:45 [X] AM [ ] PM

...because I felt:

- [ ] anxious
- [ ] arm or neck pain/tingling
- [ ] chest pain or pressure
- [X] dizziness
- [ ] fainted
- [X] light headed
- [ ] pounding
- [X] fluttering or racing
- [ ] short of breath
- [ ] skipped beat(s), irregular beats
- [ ] other (describe):

...for this duration:

- [X] 1 min or less
- [ ] 10 mins or less
- [ ] 1 hour or less
- [ ] More than 1 hour

...while I was

describe activity: getting out of bed

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m ☐ AM ☐ PM

...because I felt:

- ☐ anxious
- ☐ arm or neck pain/tingling
- ☐ chest pain or pressure
- ☐ dizziness
- ☐ fainted
- ☐ light headed
- ☐ pounding
- ☐ fluttering or racing
- ☐ short of breath
- ☐ skipped beat(s), irregular beats
- ☐ other (describe):

...for this duration:

- ☐ 1 min or less
- ☐ 10 mins or less
- ☐ 1 hour or less
- ☐ More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

m m / d d / y y h h : m m AM PM

...because I felt:

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- fainted
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped beat(s), irregular beats
- other (describe):

...for this duration:

- 1 min or less
- 10 mins or less
- 1 hour or less
- More than 1 hour

...while I was

describe activity

ZIO® SR DATA ANALYSIS

Your ZIO® SR data is analyzed at the iRhythm Clinical Centers. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R. section 410.33) can be found at the iRhythm website www.irhythmtech.com.

PATIENT IDENTIFICATION

Before placing your device in the prepaid envelope, please write your name on the line above the return address. By writing your name on the envelope you are providing another method of identification for the patch and gateway and are consenting to the potential viewing of your name on the envelope. You may choose to not write your name on the envelope.

NOTICE OF PRIVACY PRACTICES

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your

Protected Health Information (PHI). Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

INDICATIONS FOR USE

The ZIO SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the inteded user to render a dianosis based on clinical judgment and experience.

CONTRAINDICATIONS

- Do not use the ZIO® SR for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient.
- Do not use the ZIO® SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO® SR in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.

- Do not use the ZIO® SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

WARNINGS

- Do not use the ZIO® SR patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO® SR. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO® SR on patients residing in areas with limited to no cellular reception.

⚠ If skin irritation such as severe redness, itching or allergic symptoms develop, remove the patch.

CAUTION: Federal (USA) law restricts the sale of this device to or on the order of a physician

Prescription-use only

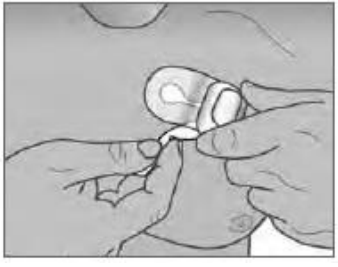

RF Transmitter


Keep Dry

PRECAUTIONS

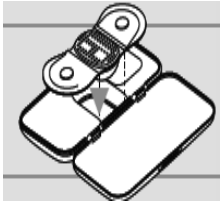
- The ZIO® SR includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the ZIO® SR on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

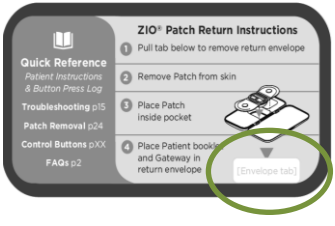
REMOVING AND RETURNING THE PATCH



1) Use the adhesive remover to the right. Tilt the center of the patch up and sweep between your skin and the patch while lifting one side from the center out. Repeat for the other side, lifting from the center out. Wash skin with mild soap, rinse with water, and pat dry.

2) Place the patch inside the gateway as shown





3) Pull tab in the gateway to remove envelope. Place the patch, gateway and this booklet inside the envelope and seal. Mail to iRhythm.

iRhythm Technologies, Inc.
Clinical Centers
650 Townsend St., Suite 380
San Francisco, CA 94103

2 Marriott Drive
Lincolnshire, IL 60069
363 N. Sam Houston Parkway East, Suite 125
Houston, TX 77060

1.888.693.2401 | irhythmtech.com | @iRhythmTech

FOR SUPPORT, CALL **1.888.693.2401**

PROPOSED

Clinical Reference Manual

TABLE OF CONTENTS

DESCRIPTION

The ZIO® SR ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system consisting of four components: (1) ZIO SR Patch ECG Recorder, (2) ZIO SR Patient Gateway, (3) Proprietary algorithm software and (4) ZIO SR Report.

The ZIO® SR Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic data transmission for up to 14 days. The ZIO® SR Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of an ECG strip. The wireless transfer of data is enabled by the ZIO® SR Gateway, which requires proximity and reception but no patient interaction. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom-rhythm correlation in the ZIO SR Report. Alternatively, the patient can go to www.myzio.com to enter symptom logs and view received transmissions online.

At the conclusion of the wear period (up to 14 days), the patient removes the ZIO® SR Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of symptomatic or continuous ECG data at iRhythm's Clinical Center (iCC) the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report.

Upon explicit request from a clinician responsible for the patient's healthcare, segments of ECG data from the continuous recording on the Patch can also be wirelessly retrieved during the wear period.

INDICATIONS FOR USE

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

CONTRAINDICATIONS

- Do not use the ZIO® SR for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use the ZIO® SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO® SR in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use the ZIO® SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
Tel. +1.888.693.2401 (USA Only)
Fax. +888.693.2402

SYMBOLS

Consult instructions for use

Caution

Prescription use only

Manufacturer

Date of manufacture

Serial Number

Use by

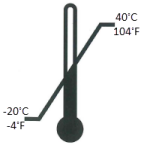
Do Not Reuse

IPx4 ZIO Patch

Splash-proof equipment

IPx2 Gateway

Drip-proof equipment



Temperature limitations

Humidity limitations

Separate collection

Do not use if package is damaged

Type BF applied part

RF Transmitter

Keep Dry

QTY:

Net quantity of contents

WARNINGS

- Do not use the ZIO® SR Patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO® SR Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO® SR on patients residing in areas with limited to no cellular reception.

⚠If skin irritation such as severe redness, itching or allergic symptoms develop, remove the ZIO® SR Patch from the patient's chest. Call iRhythm Customer Support at **1-888-693-2401**

Rx ONLY **CAUTION:** Federal (USA) law restricts the sale of this device to or on the order of a physician.

PRECAUTIONS

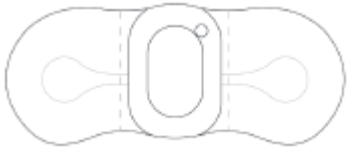
- The ZIO® SR Patch includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR Patch has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR Patch if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR Patch on pediatric patients (younger than 18 years old) has not been established.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe

tissue injury if ingested.

- Safety and effectiveness of the ZIO® SR Patch on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

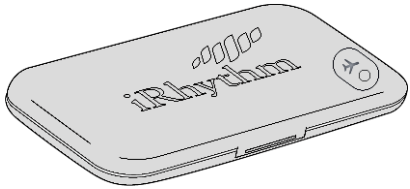
PACKAGE CONTENTS

1 ZIO® SR Patch



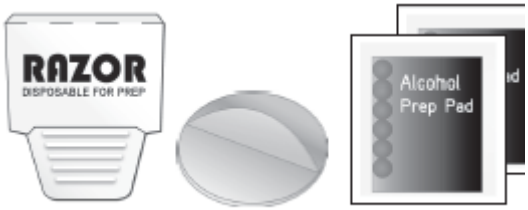
1 ZIO® SR Gateway, containing:

- 1 postage-paid return envelope



1 Skin Prep & Placement Kit containing:

- 1 disposable razor
- 1 abrader disc
- 4 alcohol pads



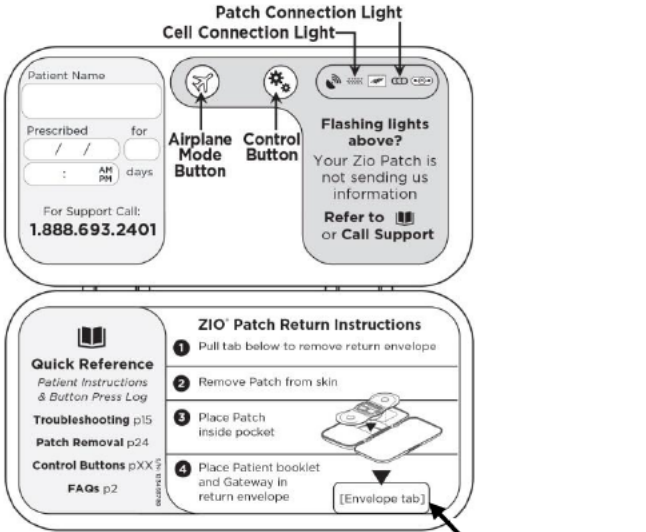
1 Patient Instructions & Button Press Log containing:

- 1 adhesive remover wipe

DEVICE DIAGRAMS

ZIO® Patch

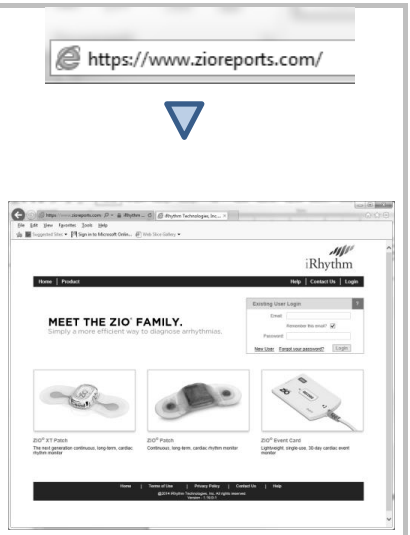
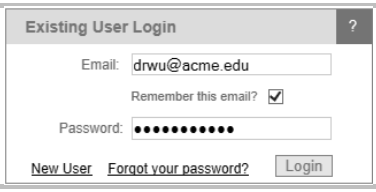
ZIO® Gateway Exterior



ZIO® Gateway Interior

ACCOUNT SETUP

To allow effective use of the ZIO service, an account on iRhythm's Patient Management system (www.zioreports.com) has been assigned to the clinic. The following steps should be performed to verify account access .

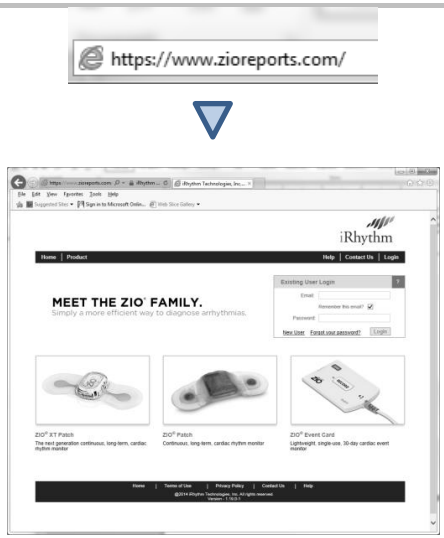
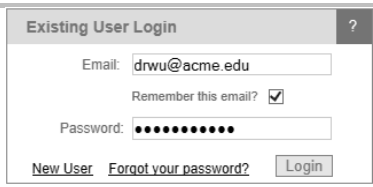
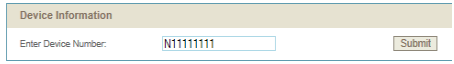
1. Open up Internet Explorer and go to www.zioreports.com	
2. Enter your email address and password to securely login into zioreports.com	

Ensure you can access iRhythm Patient Management system via provided username and password. If you are unable to access zioreports.com please contact iRhythm Customer Support at **1-888-693-2401**

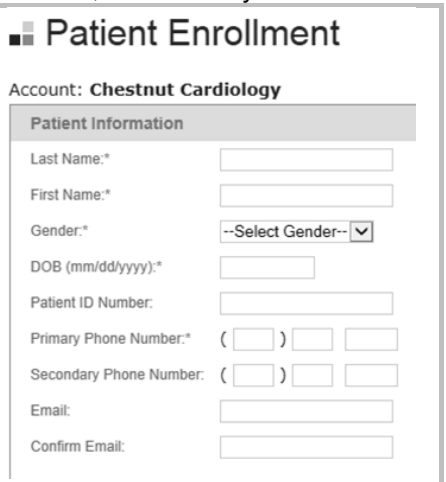
DURING PATIENT VISIT

REGISTRATION

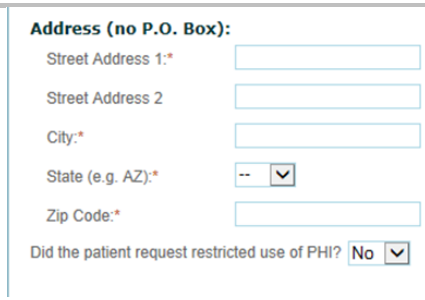
1) Register patient online at www.zioreports.com.

a) Open up Internet Explorer and go to www.zioreports.com	
b) Enter your email address and password to securely login into zioreports.com	
c) Select Register New Patient Option (Patient->Register New Patient)	
d) Enter in the Serial # and the Submit button	

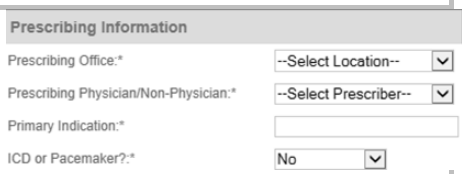
e) Enter the following Patient Information
   i. Last Name (Required)
   ii. First Name (Required)
   iii. Gender (Required)
   iv. DOB (Required)
   v. Patient ID Number
   vi. Primary Phone Number (Required)
   vii. Secondary Phone Number
   viii. Email
   ix. Confirm Email (Required if Email provided)

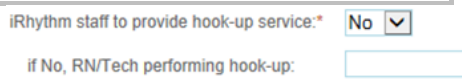
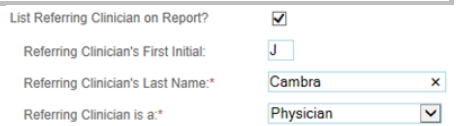


f) Enter the Patient Address
   i. Street Address 1 (Required)
   ii. Street Address 2
   iii. City (Required)
   iv. State (Required)
   v. Zip Code (Required)
   vi. Patient PHI restricted use indicator



g) Enter the following Prescribing Information
   i. Physician Office (Required)
   ii. Prescribing Physician/Non-Physician (Required)
   iii. Primary Indication

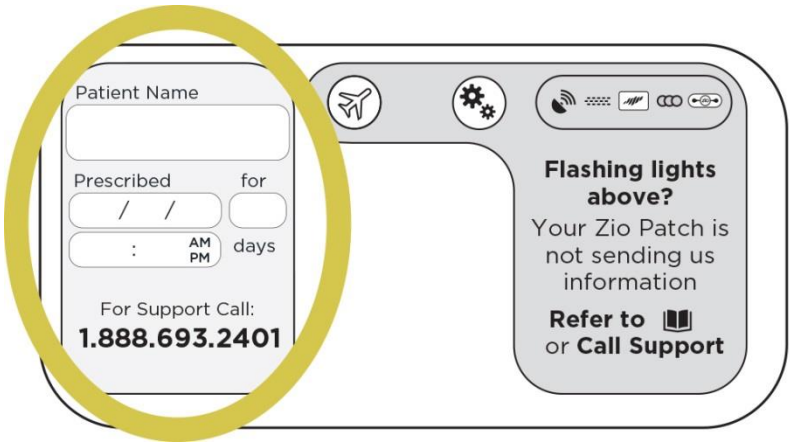


(Required) – Enter associated ICD 9 code. iv. ICD or Pacemaker? [Yes/No] (Required)	
h) Enter Patch Hookup Information – iRhythm Staff performing hook-up? i. If Yes – then select 'Yes' ii. If No – then select 'No' and enter Rn/Tech name	
i) If it is desired to include the Referring Physician on the Zio® SR Patch Report enter a check next to "List Referring Clinician on Report" and enter the following information: i. Referring Clinician's First Name ii. Referring Clinician Last Name (Required) iii. Referring Clinician is a (Required)	
j) Enter the following Patch Wear information i. Patch Start Date (Required) ii. Prescribed Wear Duration (Required)	

k) Complete the patient registration by clicking 'Submit' button	

2) Remove the ZIO® SR Patch and ZIO Gateway from the packaging.

3) Inside the ZIO Gateway on the label, write the patient's name, start date, time and prescription duration using Pen or Marker. Instruct the patient to write the date when they remove the ZIO® SR Patch for return.



APPLICATION INSTRUCTIONS

1. Have the patient **stand** with their arms resting at their sides during the ZIO® Patch application.
   - If the patient cannot stand, have them sit up straight with their arms relaxed at their side.
2. Determine placement area without removing the backing.
   - You may hold the ZIO® Patch up to the patient's **left** chest and use it as a guide to determine the placement area *(Fig. A)*.
     - Place on flattest part of the left chest
     - About 1 finger width below the collar bone, centered over left pectoral muscle
     - Edge of the ZIO® Patch next to the sternum
     - Avoid armpit and breast tissue
   - Angle so the arrow on the top label points upwards *(Fig C)*

Alternative placement may be necessary depending on the patient's anatomy. It is acceptable to modify the placement, but quality of ECG and record duration may be affected.

3. Prepare the patient's skin using the materials from the *Skin Prep & Placement Kit*.

   ***Note** that the preparation area will need to extend larger than where the ZIO® Patch will be applied.*

   a. Remove the razor by holding the cover on the sides and pulling down on the handle *(Fig. D)*.

   b. **Shave** the placement area if hair is present. DO NOT add pressure to the razor; shave across the skin lightly.

      - ***NOTE:** If a cut should occur, treat the site and only continue once bleeding has stopped. After it has stopped, do not place electrode over cut.*
      - ***NOTE:** Dispose of razor in proper sharps container.*

   c. Applying pressure, **abrade** the entire area using 40 broad strokes ***NOTE:** This is essential for skin-patch adhesion and high ECG signal quality.*

   d. **Clean** the area thoroughly with four alcohol pads, using both sides of pads as needed. Allow skin to dry for 1 minute.

      - Be sure to clean off any perspiration, lotion or

sunscreen.

- Let dry for 1 minute.
- Skin must be completely dry before applying the ZIO SR Patch

The order of steps c and d are important! All skin cells / debris from the abrader must be removed for the ZIO SR patch to stick.

The steps above are critical to achieve good signal quality and adhesion.

---

4. Hold device in the center and remove clear backings. Keep top label on. Do not touch adhesive.
5. Apply the ZIO® SR Patch to the patient's chest, making sure to place it in the prepared area *(Fig. F)*.

6. Press firmly across the wings of the device for approximately 2 minutes *(Fig. G)*.
   This helps skin-patch bonding because the adhesive is pressure-sensitive.

7. Remove the top label *(Fig. H)*:
   - Peel off the 2 parts of the top label, one at a time. As you peel, use your other hand to press down on the patch to keep it in place.

   a) **Press firmly for 2 minutes** across the entire device, working adhesive into the skin, which helps skin-patch bonding.

   b) Firmly press the 'ZIO' button and release *(F ig. I)*. The green light will flash 5 times indicating that the monitoring has started.

Pr

8. Open the gateway clasp and press the "Control" button *(Fig. J)* to power on the gateway. Watch for orange flashing light (this will take about 5 seconds) that changes to 5 green flashes. Green flashes indicate that the gateway and patch have connected and the wireless connection is good.

Press button to turn on

9. After you have seen green lights on both patch and gateway:
   - Help the patient practice pressing the patch button. This will familiarize the patient with the action of pressing the button when symptoms are felt. *Button presses within the first five minutes of activation will not be captured, however the device will continue to record.*

REVIEW WITH YOUR PATIENT

Using the ZIO® SR Patch and Gateway

1. The ZIO® Patch is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient). The gateway should be kept within arm's reach and in view to maintain a wireless connection. Ensure the patient understands the purpose and importance of each device.
2. The ZIO® Patch should not be removed before the end of the prescribed period unless skin irritation or itching is severe or hives or blisters develop (see Removal Instructions on page 12). If this occurs, the patient should call Customer Support at 1-888-693-2401.
3. If symptoms are felt the patient should press the 'ZIO' button on the device *(Fig. K).*
   - This will mark the ECG recording, indicating that the patient felt a symptom.
   - The ZIO® Patch will **not** show a light when the patient presses the button.
   - A click should be felt and/or heard, indicating that the button has been pressed and a symptom has been marked.
4. Each time the patient presses the 'ZIO' button to mark a symptom an entry should be made in the Patient Instructions & Button Press Log *(Fig. L)* or at myzio.irhythmtech.com.

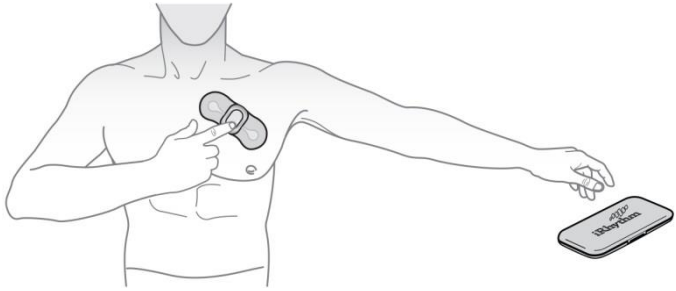
K

Pre

L

Bu

5. The gateway device sends heart rhythm data wirelessly when the patient presses the 'ZIO' button on the patch. In order for the gateway device to function properly:
   - The patient should keep the gateway within arm's length and line of sight as long as they are wearing the ZIO SR patch.



   - The patient may carry the device in a purse or coat pocket in order to maintain proximity while they are out of the home.
   - The patient should ensure that the gateway is located in an area with adequate cellular reception. (Note: the ZIO® SR device is not suitable for patients who live in rural areas with no cellular coverage.)

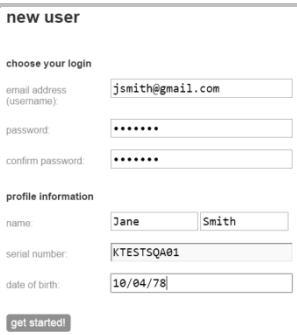
Note: Both Patch and Gateway device do not show lights when functioning properly

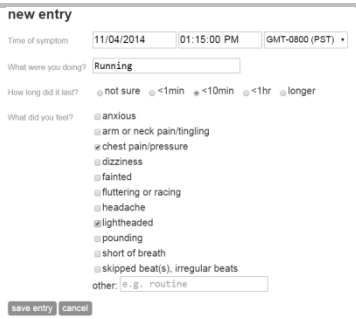
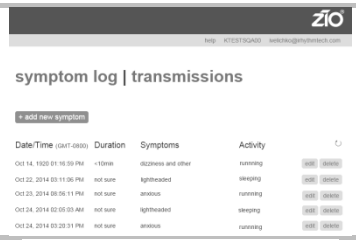
---

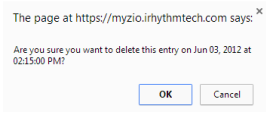
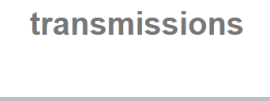
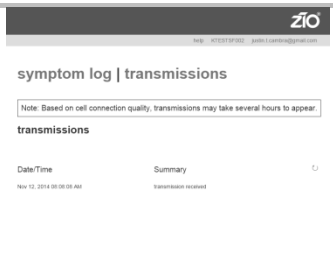
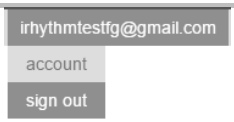
Transmission times may vary depending on the patient maintaining proximity to gateway and ensuring cellular reception.

Proximity to gateway should be maintained at the end of the 14-day monitoring period to ensure complete transmission of events from patch to gateway. Transmissions to gateway will not continue after the 14-day monitoring period is complete.

---

1. Open up Internet Explorer and go to myzio.irhythmtech.com	
2. To register select “new user”	
3. Enter the following Registration Information: i. Patient Email Address (Required) ii. Password (Required) iii. Confirm Password (Required) iv. Last Name (Required) v. First Name (Required) vi. Patch Serial Number (Required)	
4. Complete the myzio.irhythmtech.com registration by clicking ‘get started!’ button	
5. To enter Symptoms login to myzio.irhythmtech.com by providing your email address and password used during	

registration and click the 'sign in' button	
6. To enter a symptom select the "+ add new symptom" button.	
7. Enter the following Symptom Information: i. Date & Time of the Symptom (Required) ii. What were you doing? (i.e. Running, Walking,…) iii. How long did it last? (Required) iv. What did you feel? – Enter as many that apply. Use other if the symptom is not listed.	
8. Complete the Symptom Journal entry by clicking 'save entry' button.	
9. To edit a symptom, locate the symptom of interest from the Main page, and click the 'edit' button.	
10. Make the desired changes to the Symptom journal entry and click 'save entry' to save edits made.	
11. To delete a symptom, locate	

the symptom of interest from the Main page, and click the 'delete' button.	
12. To confirm the deletion, click the 'OK' button.	
13.To view list of Transmissions received, select the 'transmissions' tab.	
14. From the transmissions page the list of transmissions received are listed by date/time. *Note Based on cell connection quality and proximity to the gateway, transmissions may take several hours to appear.*	
15. To logout, select the tab with your email address and select 'sign out'	

Traveling with the ZIO® SR System

1. The ZIO® Patch can be worn through security screenings. A security statement, as shown below, is provided in the Patient Instructions & Button Press Log.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

2. The ZIO® SR system allows the patient to power the cellular radio on and off with an Airplane Mode:
   a. To turn on Airplane Mode (when the cellular radio needs to be shut off), the patient should open the gateway and press and hold the "Airplane Mode" button for 3 seconds until the inside status lights flash orange momentarily. The outside airplane light will flash continuously while in Airplane Mode.
   b. To exit Airplane Mode (and turn the cellular radio back on), the same "Airplane Mode" button should be held for 3 seconds until the inside status lights flash green momentarily to show success. The outside airplane light will stop flashing and the cellular radio is turned on.

Removal of the ZIO SR Patch & Return of the ZIO® System

1. At the end of the wear period, detach the adhesive remover wipe from the back page of the *Patient Instructions & Button Press Log*.
2. Gently tilt the center of the ZIO® Patch up. Using the adhesive remover, sweep the wipe between the skin and the Patch while peeling the right side from the center out. Repeat for the other side, peeling from the center out *(Fig. M)*.

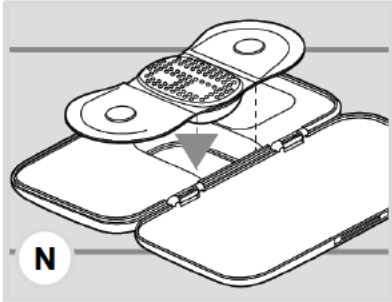
Ac

3. Wash skin with mild soap, rinse with water, and pat dry.

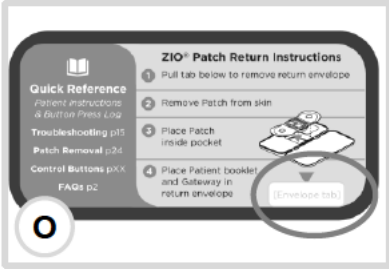
If patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, have them use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

---

4. Place the ZIO® Patch in the gateway and close the gateway such that the clasp clicks. *(Fig.N)*



5. Pull tab in the gateway to remove return envelope. *(Fig.O)*



6. Place Patient booklet and gateway in return envelope. Seal the envelope and mail it back via the U.S. postal service as soon as possible.

Analysis of the full continuous record cannot be performed until receipt of the patch. Encourage the patient to mail back the patch, gateway and patient booklet on the day of patch removal.

DURING MONITORING

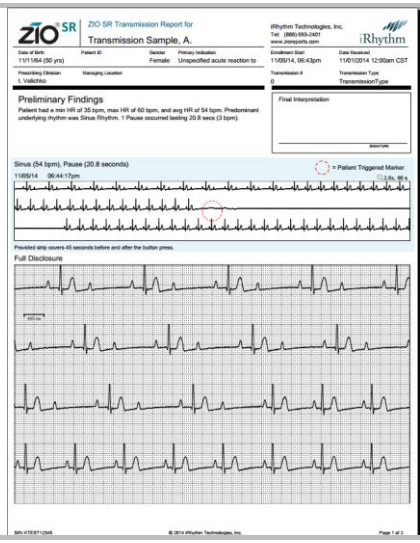
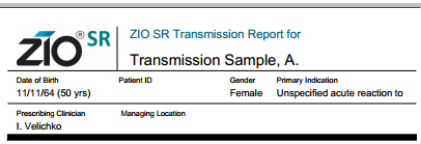
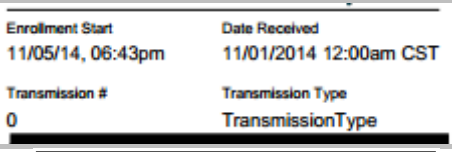
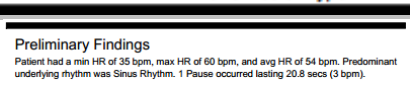
During monitoring the ZIO® device will record continuous beat to beat ECG information and transmit patient triggered ECG to provide accurate arrhythmia detection. Note that expected event transmission delays may vary significantly depending on how effectively the patient maintains patch-gateway proximity and gateway cellular reception. Transmission reports will be provided after receipt and analysis of patient triggered ECG strips.

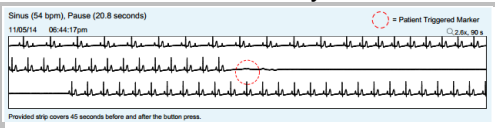
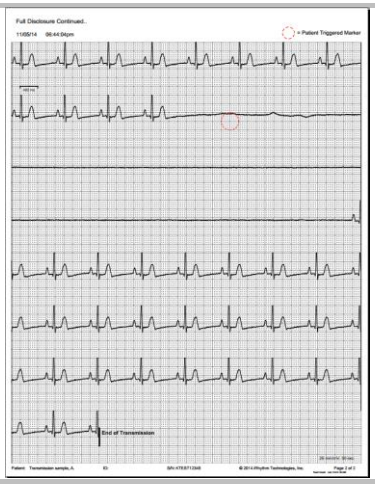
In special circumstances, when patient data needs to be accessed by the Physician during the wear period an Urgent Data Request can be made. In order to make an Urgent Data Request, the clinician should call iRhythm at 1-888-693-2401.

REPORTS

ZIO® SR TRANSMISSION REPORT

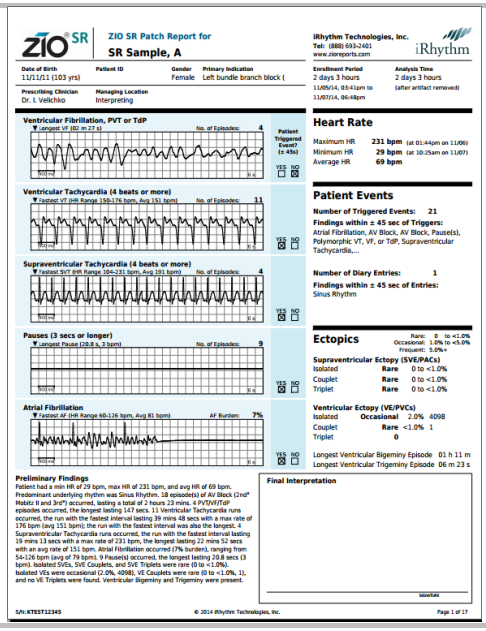
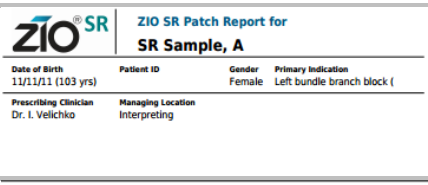
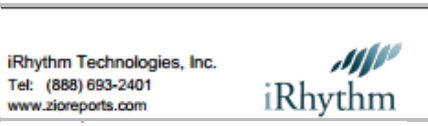
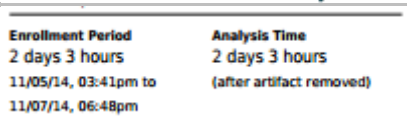
The transmission report is a snapshot of cardiac data during monitoring period.

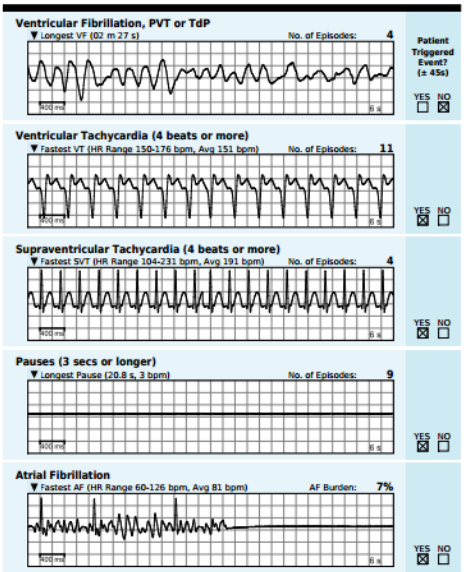
Each transmission report contains a 90 second ECG record centered on the Patient's button press time.	
It contains:	
"ZIO SR Transmission Report for" label followed by the Patient Demographics and prescription information:	 ZIO® SR ZIO SR Transmission Report for Transmission Sample, A. Date of Birth: 11/11/64 (50 yrs) Patient ID: Gender: Female Primary Indication: Unspecified acute reaction to Prescribing Clinician: I. Velichko Managing Location:
iRhythm contact information:	 iRhythm Technologies, Inc. Tel: (888) 693-2401 www.zioreports.com iRhythm
Enrollment and Event Transmission information:	 Enrollment Start: 11/05/14, 06:43pm Date Received: 11/01/2014 12:00am CST Transmission #: 0 Transmission Type: TransmissionType
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm)	 Preliminary Findings Patient had a min HR of 35 bpm, max HR of 60 bpm, and avg HR of 54 bpm. Predominant underlying rhythm was Sinus Rhythm. 1 Pause occurred lasting 20.8 secs (3 bpm).

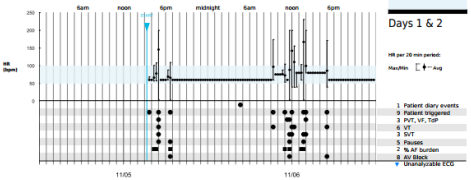
A 200 mm/30 seconds resolution of the 90 second Event Transmission with a marker indicating the button press:	
A 25mm/sec resolution of the 90 seconds Event Transmission with a marker indicating the button press:	

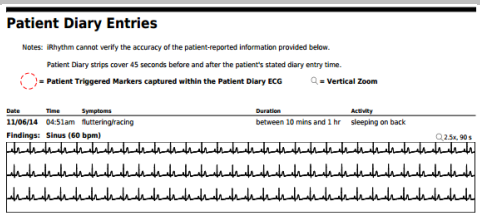
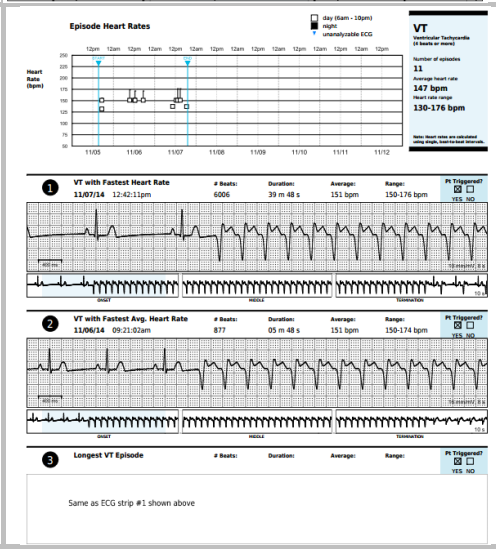
ZIO® SR PATCH CONTINUOUS REPORT

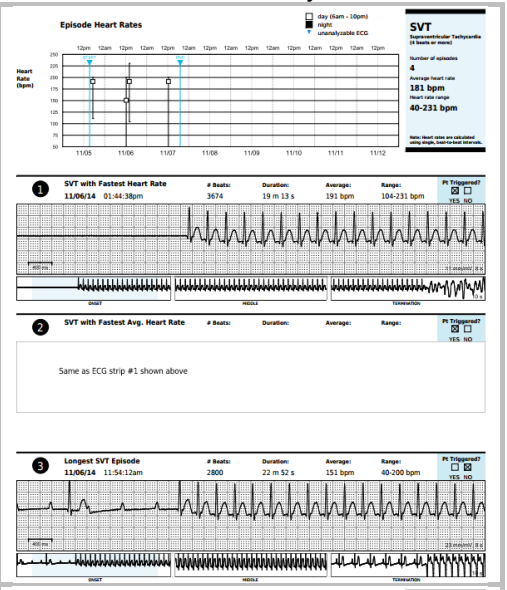
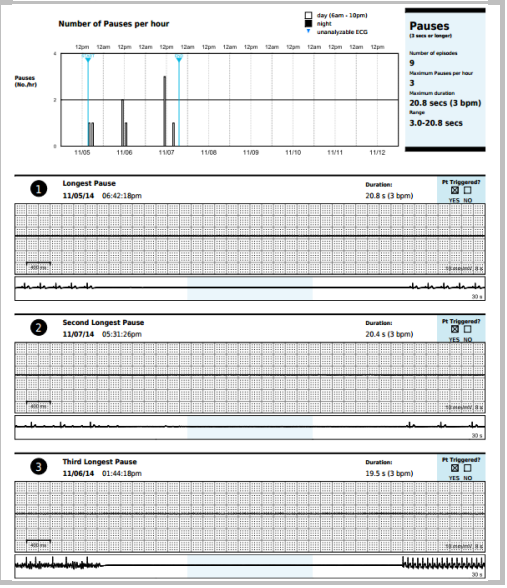
The ZIO® SR patch report is a comprehensive summary of symptomatic and asymptomatic arrhythmia findings that includes pertinent statistics, wear and analysis time, patient triggered and diary events.

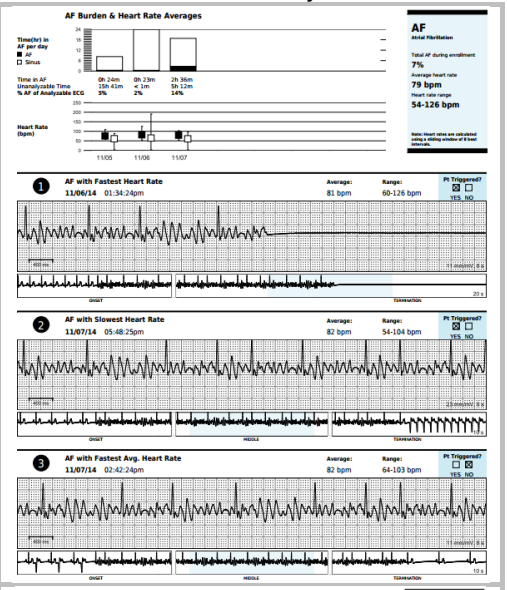
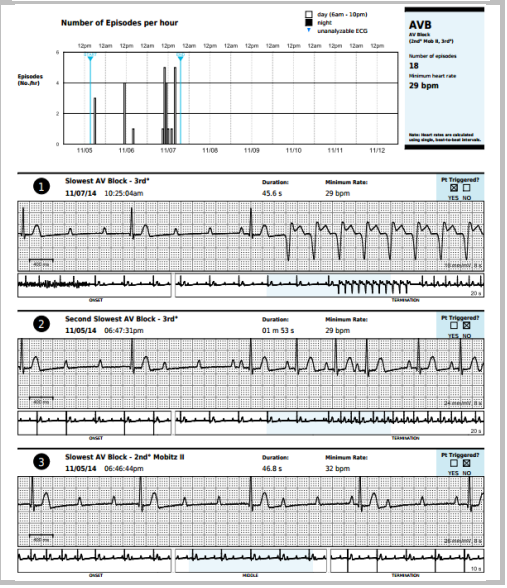
The front page includes a summary of all the finding:	
It contains:	
"ZIO SR Patch Report for" label followed by the Patient Demographics and prescription information:	
iRhythm contact information:	
Enrollment and Analysis information:	

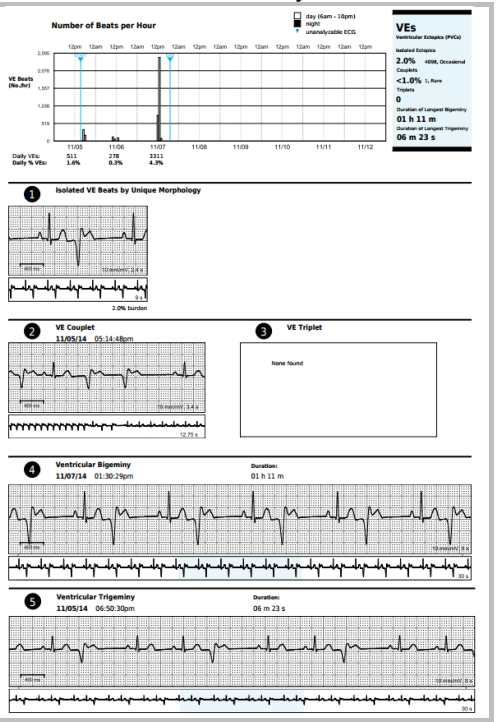
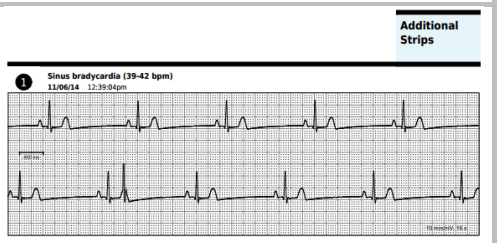
Arrhythmia Summary section:	
Heart Rate Summary section:	**Heart Rate** Maximum HR **231 bpm** (at 01:44pm on 11/06) Minimum HR **29 bpm** (at 10:25am on 11/07) Average HR **69 bpm**
Events (Patient Triggered and Diary Entry) summary:	**Patient Events** **Number of Triggered Events: 21** **Findings within ± 45 sec of Triggers:** Atrial Fibrillation, AV Block, AV Block, Pause(s), Polymorphic VT, VF, or TdP, Supraventricular Tachycardia,... **Number of Diary Entries: 1** **Findings within ± 45 sec of Entries:** Sinus Rhythm

Ectopics Summary section (including VEs, SVEs, Ventricular Bigeminy and Trigeminy):	**Ectopics** Rare: 0 to <1.0% Occasional: 1.0% to <5.0% Frequent: 5.0%+ **Supraventricular Ectopy (SVE/PACs)** Isolated **Rare** 0 to <1.0% Couplet **Rare** 0 to <1.0% Triplet **Rare** 0 to <1.0% **Ventricular Ectopy (VE/PVCs)** Isolated **Occasional** 2.0% 4098 Couplet **Rare** <1.0% 1 Triplet **0** Longest Ventricular Bigeminy Episode 01 h 11 m Longest Ventricular Trigeminy Episode 06 m 23 s
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm):	**Preliminary Findings** Patient had a min HR of 29 bpm, max HR of 231 bpm, and avg HR of 69 bpm. Predominant underlying rhythm was Sinus Rhythm. 18 episode(s) of AV Block (2nd° Mobitz II and 3rd°) occurred, lasting a total of 2 hours 23 mins. 4 PVT/VF/TdP episodes occurred, the longest lasting 147 secs. 11 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 39 mins 48 secs with a max rate of 176 bpm (avg 151 bpm); the run with the fastest interval was also the longest. 4 Supraventricular Tachycardia runs occurred, the run with the fastest interval lasting 19 mins 13 secs with a max rate of 231 bpm, the longest lasting 22 mins 52 secs with an avg rate of 151 bpm. Atrial Fibrillation occurred (7% burden), ranging from 54-126 bpm (avg of 79 bpm). 9 Pause(s) occurred, the longest lasting 20.8 secs (3 bpm). Isolated SVEs, SVE Couplets, and SVE Triplets were rare (0 to <1.0%). Isolated VEs were occasional (2.0%, 4098), VE Couplets were rare (0 to <1.0%, 1), and no VE Triplets were found. Ventricular Bigeminy and Trigeminy were present.
An area to include clinician's interpretation (when configured):	**Final Interpretation** SIGNATURE
Events Chart with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each 20 minutes segment:	**Events** Days 1 & 2 
90 seconds (-/+ 45 secs.) 200 mm/30 seconds resolution ECG strips around patient button presses with a marker indicating the button press:	**Patient Events** **Patient Triggered Events** Note: Triggered Event strips cover 45 seconds before and after the button press. = Patient Triggered Marker = Vertical Zoom * = No heart rate will be displayed if insufficient beats of the rhythm are included in the strip. 11/05/14 03:51:50pm Sinus (60 bpm) 2.5x, 90 s

90 seconds (-/+ 45 secs.) 30 seconds resolution ECG strips around patient diary entries and a button press marker whenever it occurred during a diary entry:	
Chapter with details of Ventricular Fibrillation, Polymorphic Ventricular Tachycardia & Torsade de Points (VF/PVT/ TdP):	
Chapter with details of Ventricular Tachycardia (VT):	

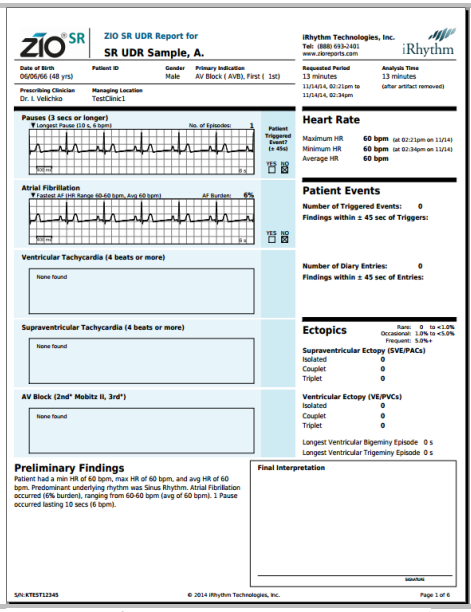
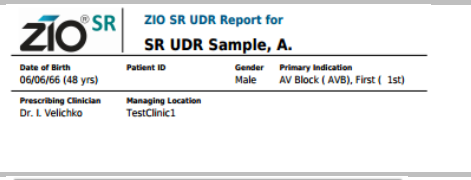
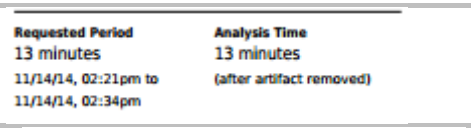
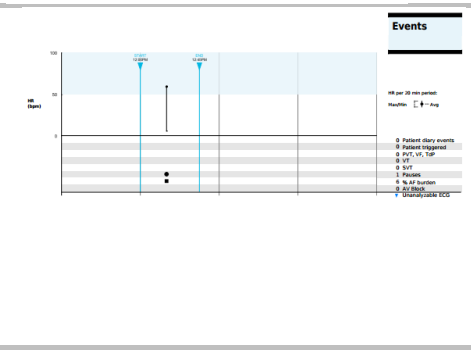
Chapter with details of Supraventricular Tachycardia (SVT):	
Chapter with details of Pause(s):	

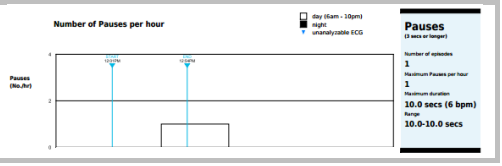
Chapter with details of Atrial Fibrillation/Flutter (AF/AFL):	
Chapter with details of AV Block (AVB):	

Chapters with details of Ectopics (VEs and SVEs):	
Chapters for any additional ECG strips, which are either not included in the arrhythmia chapters or shown in different resolution:	

ZIO® SR URGENT DATA REQUEST (UDR) REPORT

The UDR report is an abbreviated version of the ZIO® report for a specific time period during the patient wear period requested by the clinician.

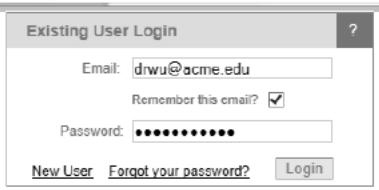
Each Urgent Data Request Report contains summary of all the findings within the requested data period. This report is very similar to the final summary report with differences mentioned below:	
"ZIO SR UDR Report for" label on the top of the Patient Demographics and prescription information:	
Requested Duration and Analysis information:	
Higher time resolution Events charts with indications for Start and End times of the data requests with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each	

20 minutes segment :	
Higher resolution arrhythmia chapter charts:	

ACCESSING REPORTS

1) Open up Internet Explorer and go to www.zioreports.com

2) Enter your email address and password to securely login into zioreports.com



3) Select Register New Patient Option (Patient->Register New Patient)

4) From the Pending Reports list select the Timeline icon for the patient of interest

5) Within the Timeline, click the link to the appropriate report to open the attached report.

TROUBLESHOOTING

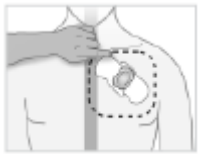
FOR CUSTOMER SUPPORT, CALL **1-888-693-2401**

FREQUENTLY ASKED QUESTIONS

Application

1. **The chest area was prepped and the device was applied. When the 'ZIO' button was pressed, it flashed orange (rather than green) five times.**
   Press down on the adhesive wings for a moment, so the device makes better contact with the skin. Then, press the 'ZIO' button again to attempt activation.
   If the devices does not activate (flash green) on the second attempt, please contact Customer Support at 1-888-693-2401.

2. **I think I placed the ZIO® SR Patch in the wrong position. Can I remove it and reposition it?**
   No. If the ZIO® SR Patch is over the heart in a slight diagonal as shown,
   the positioning should be acceptable.
   DO NOT attempt to reapply the ZIO® SR Patch.



3. **The top label was peeled off, but there still seems to be a white label stuck to the wings of the ZIO® SR Patch.**
   The top label may have separated. Peel the remaining white labels from the center of the ZIO® SR Patch outward.

4. **Are there tests or treatments that are not compatible with the ZIO® SR Patch?**
   Yes. The following are not recommended during wear of the ZIO® SR Patch:
   a. Magnetic Field(s): Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field

b. Neuromuscular Stimulators: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit
c. External Cardioversion/Defibrillation

NOTE: Data may not be interpretable during the time the stimulators are being used. Usage is at physician's discretion.

5. **Can the ZIO® SR Patch be left on a patient during Cardioversion/Defibrillation?**
   No, the ZIO® SR Patch should be removed if the patient requires Cardioversion or Defibrillation.

7. **I turned the gateway on but it is flashing orange?**
   Ensure that the patch has been turned on and is located within 10 feet of the gateway. If the gateway continues to flash orange for more than 2 minutes, please contact Customer Support at 1-888-693-2401.

Patient Questions

1. **How long is the patient supposed to wear the ZIO® SR Patch?**
   A patient can wear the ZIO® SR Patch for up to 14 days or as prescribed. Note: The ZIO® SR Patch will not record ECG data after 14 days.
   Based on individual wear experiences the patient's actual wear time may be shorter than prescribed.

2. **What is the ZIO® SR Patch doing?**
   The ZIO® SR Patch is recording every heartbeat. Pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

3. **What is the ZIO SR Gateway doing?**
   The ZIO SR Gateway is sending heart rhythm data wirelessly when the ZIO button on the patch is pressed. The data is received at iRhythm and a report is provided to the patient's doctor while the patient may still be wearing the patch.

4. **Who should the patient call if they have questions about the ZIO SR Patch or Gateway?**
   The patient can read the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

5. **Who should the patient call if they have questions about the ZIO® SR Patch or if it falls off?**
   The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

6. **What should the patient do if they feel a symptom?**
   Press the 'ZIO' button and fill out a page of the *Patient Instructions & Button Press Log*.

7. **What if the patient forgets to press the 'ZIO' button when they feel a symptom?**
   While pressing the 'ZIO' button is important, the ZIO® SR Patch is recording every heartbeat.

8. **What if the patient presses the 'ZIO' button but forgets to write down the information on a Button Press Log page?**
   While the *Button Press Log* information is useful, pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

9. **What if the patient does not have symptoms?**
   That's okay. The ZIO® SR Patch records every heartbeat.

10. **What activities should the patient avoid while wearing the ZIO® SR Patch?**
    Activities that cause excessive sweating. This could cause the ZIO® SR Patch to slide, become loose, fall off, and shorten wear time.

11. **Can the patient exercise while wearing the ZIO® SR Patch?**
    Yes, but excessive sweating may shorten wear time.

12. **Can the patient shower with the ZIO® SR Patch on?**

Yes, but showers should be brief. Keep soaps and lotions away from the ZIO® SR Patch. If possible, face away from the water when showering. When towel-drying, the patient should hold the ZIO® SR Patch down with one hand so that it is not accidently knocked off. Instruct the patient to press the ZIO® SR Patch against their skin to secure it.

13. **Can the patient take a bath?**
    Yes, but the patient should keep the ZIO® SR Patch above water.

14. **Can the patient go swimming or in a hot tub?**
    No. The ZIO® SR Patch and ZIO® Gateway should not be submerged in water.

15. **Is it normal for the ZIO® SR Patch to move slightly from its original position?**
    Yes. The ZIO® SR Patch may move slightly from its original position. A blue gel may become visible under the wings of the ZIO® SR Patch.

16. **Is it normal to experience skin irritation or itchiness in the area of the ZIO® SR Patch?**
    Minor skin irritation and/or itching while wearing the ZIO® SR Patch may occur. If the irritation or itching is severe instruct the patient to remove the ZIO® SR Patch and call Customer Support at 1-888-693-2401.

17. **Is it normal for the ZIO® SR Patch wings to become cloudy in appearance?**
    Yes, the wings of the ZIO® SR Patch may become cloudy after a few days of wear.

18. **What should the patient do if they think they see blood under the ZIO® SR Patch?**
    Instruct the patient to call Customer Support at 1-888-693-2401. It is likely due to a small shaving cut when the device was applied to the chest.

19. **How will the patient know the ZIO® SR Patch is working?**

Once the ZIO® SR Patch is applied to the body, and the 'ZIO' button is pressed, a green light should flash, indicating that it was turned on. Afterwards, it will not flash or make noise when it is working properly.

20. **Will the ZIO® SR Patch flash while the patient is wearing it?**
No.If it is working properly, the ZIO® SR Patch will not flash or make noise. If the patient sees the ZIO® SR Patch flashing orange, this does not mean there is a problem with the patient's heart; it just means that the ZIO® SR Patch is not well attached. Instruct the patient to press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call Customer Support at 1-888-693-2401.

21. **Can a patient travel with the ZIO® SR Patch on?**
Yes. Please take the Patient Instruction and Button Press Log with you when traveling. If questioned during security screening there is a statement included in the *Patient Instruction & Button Press Log* for them to reference.

22. **When the patient removes the ZIO® SR Patch, it is flashing orange. Is this okay?**
The ZIO® SR Patch may blink orange after removal. It is okay to mail the device while it is blinking.

23. **Will the ZIO Gateway show any lights or make any sounds during normal use?**
No. If it is able to send data, the ZIO Gateway will not flash or make noise. If the patient sees the gateway flashing orange, this means there is a problem sending data wirelessly to the patch or to iRhythm.

24. **Does the patient need to do anything with the ZIO Gateway to send heart rhythm data wirelessly?**
The patient only needs to keep the Gateway within 6 feet of the patch and within range of good cellular reception. No action is

required for the Gateway to send symptomatic heart rhythm data other than pressing the ZIO button on the patch.

25. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway is not within 10 feet?**
    The patch will store the data until the Gateway is within range, then the data will be sent.

26. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway doesn't have cellular reception?**
    The gateway will store the data until it has cellular reception, then the data will be sent.

27. **What should the patient do if the ZIO Gateway is flashing orange?**
    Gateway flashing orange means that the patch cannot send us information wirelessly. The patient can attempt troubleshooting using the "Gateway Troubleshooting Guide" in the *Patient Instructions and Button Press Log* (see page 35 of this manual) or call Customer Support at 1-888-693-2401.

28. **Can the patient fly with the ZIO Gateway?**
    Yes. The gateway cellular radio can be turned off by pressing the airplane button inside the gateway for 3 seconds. The gateway cellular radio can be turned back on by pressing the airplane button for 3 seconds. While in "Airplane Mode" the airplane light on the outside face of the gateway will flash.

PATCH FLASHING LIGHTS KEY

If the light on the patch is flashing orange, pick the troubleshooting action based on the following:

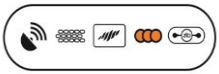
- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

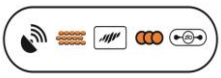
Flashing light location	Light flashing speed	Recommended action
	SLOW	Press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, call Customer Support at 1-888-693-2401.
	FAST	Call Customer Support at 1-888-693-2401.

GATEWAY FLASHING LIGHTS KEY

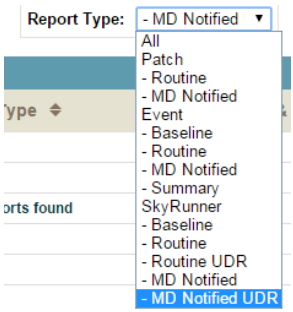
If the outside status light on the gateway is flashing orange, open the gateway and pick the troubleshooting action based on the following:

- Which inside lights are flashing orange?
- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

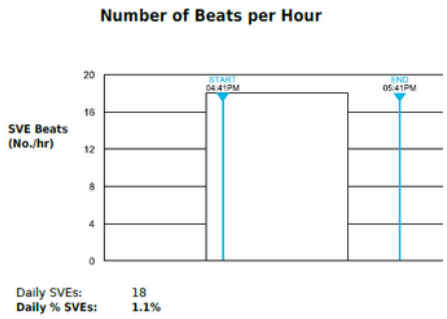
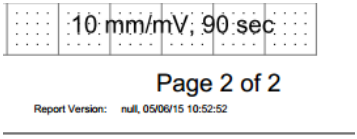
Flashing light location	Light flashing speed	Recommended action
	SLOW	Keep the gateway near to the patch for at least 10 minutes. If the light continues to flash, call Customer Support at 1-888-693-2401.
	SLOW	Move the gateway to an area with cellular reception and press the “Control” button for 3 seconds. If the gateway is able to connect and send the information, the light will flash green until it is done sending. Keep the gateway in the same location until the green flashing stops. If orange flashing does not stop even in an area with good cellular reception, call Customer Support at 1-888-693-2401.

	FAST	Call Customer Support at 1-888-693-2401.

ZIO SR SERVICE ERRATA

Errata	Workaround
myZIO Registration – Patient Enrollment	In order for a patient to register with myZIO they must first be enrolled in www.zioreports.com. In the event that the patient attempts to register prior to completion of enrollment they will receive a notification indicating "Unknown device", until enrollment has been completed. (SYS-2281)
ZIO SR Transmission Report – Duplicate transmissions	It is possible to receive duplicate transmissions for the same button press event. Both of these reports contain the same ECG recording. Occurrence of duplicate reports can be identified by two transmissions having the same date. If this scenario occurs, the duplicate copy can be ignored. (SYS-2351)
ZIO SR Transmission Report Type Filter	To view only transmission specific reports in the Report Inbox, select Baseline, Routine, MD Notified under the SkyRunner section.  (SYS-2323)
ZIO SR Urgent Data Report – Button Press Events	Patient button press events are not provided in the ZIO SR Urgent Data Report.

	This report is limited to present only findings identified within the ~20 minutes of ECG recording captured. A Full Disclosure version of the UDR report containing the entire ECG recording can be provided on request. (SYS-2337)
ZIO SR Urgent Data Report – ECG strip scaling .	For 8s ECG strips provided in the ZIO SR Urgent Data Report, the scale is fixed to 10 mm/mV resolution. (SYS-2339)
Patient Timeline – Paper Booklet Diary Entries	For patients with the ZIO SR Patch, ZIOReports provides a timeline screen that displays along with ZIO Transmission, UDR, and Final patch reports, patient provided diary entries. For each diary entry the date and time of the symptom reported is displayed. In the event that a patient does not provide the date/time for a symptom on the paper booklet, the timeline will display a date with a year starting in 3000. Dates that have a year of 3000 or greater indicate that the patient did not provide the timestamp of the symptom experienced. (SYS-2315)
ZIO SR Urgent Data Report – Overview Chart	For the VE/SVE overview charts in the ZIO SR Urgent Data Report, the width of the number of beats bar in the overview chart extends outside the start/end time indicators. This is a display issue, the number of beats observed is for the period between the start and end markers.

	 (SYS-2328)
ZIO SR Transmission Report – Report Version	The version of the ZIO SR Transmission Report is not provided.  (SYS-2237)

IRHYTHM CLINICAL FACILITY CERTIFICATION

The ZIO® SR Patch heart monitor is analyzed at the iRhythm Clinical Center. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R.section 410.33) can be found at the iRhythm website www.irhythmtech.com.

NOTICE OF PRIVACY PRACTICES (NOPP)

iRhythm is committed to protecting the privacy of your personal information. We are required by the U.S. - EU Safe Harbor Framework to maintain the privacy of your personal information, and to notify you of our privacy practices, our legal duties, and your rights concerning your personal information.

Why?	As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information ("PHI"). This notice describes our privacy practices, our legal duties, and your rights concerning your PHI. We will follow the privacy practices described in this notice while it is in effect. We reserve the right to revise this notice and to make the new notice provisions effective for all PHI we maintain. If we revise this notice, we will post the revised notice on this page.
What?	In providing diagnostic services, the types of information we collect may include: - Name - Gender - Date of Birth - Medicare and Secondary Insurance Information - Address and Phone Number - Prescribing Physician and Office - Primary Indication - ECG Recording - Symptoms and Activities You Report, by Time and Date - Activity Level During Monitoring - Patient Identification Number - Clinical Information and Diagnostic Results
How?	By providing diagnostic services to our patients, we regularly collect information through: - Phone conversations - Patient submitted documents - Prescribing physician submitted documents - ZIO® Event card transmissions - Return of ZIO® XT Patches

How We May Use Your Information			
We have the right to use and disclose health information for your treatment, to secure payment for your health care, and to operate our business.			
Without Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
To You	We must disclose your PHI to you, as described in the "Your Rights" section of this notice.	Yes	Yes
For Payment	We may use and disclose PHI to obtain payment for services provided to you. We may also disclose your PHI to a health care provider or health plan so that the provider or plan may obtain payment of a claim or engage in other payment activities.	Yes	Yes
For Treatment	We may use and disclose PHI to provide and manage your diagnostic services. That may include consulting with other health care providers about your diagnostic services. For example, we will release the results of your diagnostic services to your prescribing physician, to the physician treating you, or in a medical emergency, if applicable.	Yes	No
For Health Care Operations	We may use or disclose PHI to conduct quality assessment and improvement activities, to conduct fraud and abuse investigations, to engage in care coordination or case management, or to communicate with you about health related benefits and services or treatment alternatives that may be of interest to you. We may also disclose PHI to a health care provider or health plan	Yes	No

	subject to federal privacy laws, as long as the provider or plan has or had a relationship with you and the PHI is disclosed only for certain health care operations of that provider or plan. We may also disclose PHI to other entities with which we have contracted to perform or provide certain services on our behalf (e.g., business associates).		
For Business Operations	We may use both De-Identified and Limited Data Sets (a data set that, per the Health Insurance Portability and Accountability Act of 1996 regulations, has had patient-identifiable data removed except for dates of service) for development of future products, devices or services. Once information is De-Identified through an approved method, the data is stripped of individual identifiers, at which point iRhythm may share this information without restriction externally to support research, market development, trend analysis, etc. Information containing Limited Data Sets may be provided externally to support market and product development. However, iRhythm will obtain the required data use agreements when transferring Limited Data Sets to external parties.	Yes	Yes
For Public Health And Safety	We may use or disclose PHI to the extent necessary to avert a serious and imminent threat to the health or safety of you or others. We may also disclose PHI for public health and government health care oversight activities and to report suspected abuse, neglect or domestic violence to government authorities	Yes	No
As Required By Law	We may use or disclose PHI when we are required to do so by law.	Yes	No

For Process And Proceedings	We may disclose PHI in response to a court or administrative order, subpoena, discovery request, or other lawful process.	Yes	No
For Law Enforcement	We may disclose PHI to a law enforcement official with regard to crime victims and criminal activities.	Yes	No
Special Government Functions	We may disclose the PHI of military personnel or inmates or other persons in lawful custody under certain circumstances. We may disclose PHI to authorized federal officials for lawful national security activities.	Yes	No
For Research, Death, And Organ Donation	We may use or disclose PHI in certain circumstances related to research, death or organ donation.	Yes	No
For Workers' Compensation	We may disclose PHI as permitted by workers' compensation and similar laws.	Yes	No
With Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
You may give us written authorization to use your PHI or disclose it to anyone for any purpose not otherwise permitted or required by law. If you give us such authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosure permitted by your authorization while it was in effect.		Yes	Yes
While the law permits us in certain circumstances to disclose your PHI to family, friends and others, we will do so only with your authorization. In the event you are unable to authorize		Yes	Yes

such disclosure, but emergency or similar circumstances indicate that disclosure would be in your best interest, we may disclose your PHI to family, friends or others to the extent necessary to help with your health care coverage arrangements.		

Your Rights	
Access	With limited exceptions, you have the right to review in person, or obtain copies of, your PHI. We may charge you a reasonable fee as allowed by law to obtain this information.
Amendment	With limited exceptions, you have the right to request that we amend your PHI.
Disclosure Accounting	You have the right to request and receive a list of certain disclosures made of your PHI. If you request this list more than once in a 12-month period, we may charge you a reasonable fee as allowed by law to respond to any additional request.
Use/Disclosure Restriction	You have the right to request that we restrict our use or disclosure of your PHI for certain purposes. We are not required to agree to a requested restriction. We will agree to restrict use or disclosure of your PHI provided that the law allows and we determine the restriction does not impact our ability to operate our business, provide diagnostic services, and comply with the law. Even when we agree to a restriction request, we may still disclose your PHI in a medical emergency and use or disclose your PHI for public health and safety and other similar public benefit purposes permitted or required by law.
Confidential Communication	You have the right to request that we communicate with you in confidence about your PHI at an alternative address.
Privacy Notice	You have the right to request and receive a copy of this notice at any time. For more information or if you have questions

	about this notice, please contact us using the information listed at the end of this notice.
Complaints / Violations	
If you are concerned that we may have violated your privacy rights, you may inquire with us using the contact information listed at the end of this notice. You may also submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address for the U.S. Department of Health and Human Services upon request. We support your right to protect the privacy of your PHI. We will not retaliate in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.	
To Limit Our Sharing Or Submit Complaints	Call 1-888-693-2401 - our Customer Service staff will assist you
Questions?	Call 1-888-693-2401
Who We Are	
Who Is Providing This Notice?	This privacy notice is being provided by iRhythm Technologies, Inc., and applies to the diagnostic services offered in connection with prescribed health care.
What We Do	
How Does iRhythm Protect My PHI?	To protect your PHI from unauthorized access and use, iRhythm has implemented security safeguards that comply with federal law to secure physical and electronic information.
Company Contact Details	
Address:	iRhythm Technologies, Inc. 650 Townsend Street Suite 380

	San Francisco, CA 94103 Attn: Privacy Official www.irhythmtech.com
Phone:	415.632.5700
Fax:	415.632.5701

DEVICE SPECIFICATIONS

PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	1 day

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Cellular RF Transmit/Receive	800 / 1900 MHz CDMA Effective Radiated Power ≤ 300mW

POWER CHARACTERISTICS

Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.0 x 0.5 inches
Patch Weight	24.7 g

Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g

ENVIRONMENTAL CHARACTERISTICS

Operational Temperature	36 to 104 degrees
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IPX4
Gateway IP Classification	IPX2

ESSENTIAL PERFORMANCE

The ZIO SR device records and transmits ECG for analysis after receipt of data. In the event it cannot record or transmit in a timely fashion, the ZIO SR alerts the patient that functionality is impaired.

HEART RATE CALCULATIONS

Episode Heart Rates	Max	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (i.e., minimum of all instantaneous heart rates within the episode)
	Avg	The average episode heart rate (i.e., average of all instantaneous heart rates within the episode)
Overall Rhythm Heart Rates	Max	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (i.e., minimum of all rhythm episode minimum heart rates exclusive of Pause heart rates within the record)
	Avg	The average overall heart rate (i.e., duration-weighted average of all rhythm episode heart rates within the record)

PAUSE DETERMINATION

Pause is defined as an RR interval greater than 3 seconds.

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The ZIO SR needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The ZIO SR should not be used adjacent to or stacked with other equipment.
- WARNING: The ZIO SR may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.

Table 1: Guidance and manufacturer's declaration— electromagnetic emissions

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ZIO® SR device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ZIO® SR device is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZIO® SR device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$80 MHz to 800 MHz $d = 2.3\sqrt{P}$800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 3, Continued

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZIO® SR is used exceeds the applicable RF compliance level above, the ZIO® SR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZIO® SR Patch.

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

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the ZIO® SR

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**80 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

(b)(4) Third Party Testing

iRhythm	Document #: (b)(4)	Effective: On Approval	Rev: (b)(4)	Date: November 21, 2014
	Title: SkyRunner Product Hazard Analysis			

(b)(4)

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4) Hazard Analysis

(b)(4)

[redacted]

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

(b)(4) Risk Management Report

PROPOSED

Clinical Reference Manual

TABLE OF CONTENTS

DESCRIPTION

The ZIO® SR ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system consisting of four components: (1) ZIO SR Patch ECG Recorder, (2) ZIO SR Patient Gateway, (3) Proprietary algorithm software and (4) ZIO SR Report.

The ZIO® SR Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording in addition to symptomatic data transmission for up to 14 days. The ZIO® SR Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger button which marks the continuous record and initiates a wireless transfer of an ECG strip. The wireless transfer of data is enabled by the ZIO® SR Gateway, which requires proximity and reception but no patient interaction. The patient is encouraged to fill out a log to document symptomatic events, which will support symptom-rhythm correlation in the ZIO SR Report. Alternatively, the patient can go to www.myzio.com to enter symptom logs and view received transmissions online.

At the conclusion of the wear period (up to 14 days), the patient removes the ZIO® SR Patch and returns it by mail to an iRhythm data processing center.

Upon receipt of symptomatic or continuous ECG data at iRhythm's Clinical Center (iCC) the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report.

Upon explicit request from a clinician responsible for the patient's healthcare, segments of ECG data from the continuous recording on the Patch can also be wirelessly retrieved during the wear period.

INDICATIONS FOR USE

The ZIO® SR ECG Monitoring Service is intended to capture, analyze, and report symptomatic and/or continuous electrocardiogram (ECG) information for long-term monitoring (up to 14 days). It is indicated for use on adult patients 18 years or older who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reported ECG metrics include single-lead analysis on a beat by beat basis, heart rate measurement and rhythm analysis. The report does not contain diagnostic interpretation; the reported analysis is provided for review by the intended user to render a diagnosis based on clinical judgment and experience.

CONTRAINDICATIONS

- Do not use the ZIO® SR for patients with symptomatic episodes where variations in cardiac performance could result in immediate danger to the patient or when real-time or in-patient monitoring should be prescribed.
- Do not use the ZIO® SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO® SR in combination with external cardiac defibrillators or high frequency surgical equipment near strong magnetic fields or devices such as MRI.
- Do not use the ZIO® SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO® SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

iRhythm Technologies, Inc.
650 Townsend Street, Suite 380
San Francisco, CA 94103
Tel. +1.888.693.2401 (USA Only)
Fax. +888.693.2402

SYMBOLS

Consult instructions for use

Caution

Prescription use only

Manufacturer

Date of manufacture

Serial Number

Use by

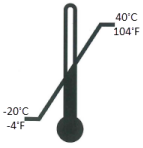
Do Not Reuse

IPx4 ZIO Patch

Splash-proof equipment

IPx2 Gateway

Drip-proof equipment



Temperature limitations

Humidity limitations

Separate collection

Do not use if package is damaged

Type BF applied part

RF Transmitter

Keep Dry

QTY:

Net quantity of contents

WARNINGS

- Do not use the ZIO® SR Patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO® SR Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO® SR on patients residing in areas with limited to no cellular reception.

⚠If skin irritation such as severe redness, itching or allergic symptoms develop, remove the ZIO® SR Patch from the patient's chest. Call iRhythm Customer Support at **1-888-693-2401**

Rx ONLY **CAUTION:** Federal (USA) law restricts the sale of this device to or on the order of a physician.

PRECAUTIONS

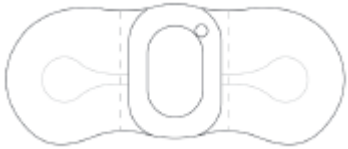
- The ZIO® SR Patch includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR Patch has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR Patch if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR Patch on pediatric patients (younger than 18 years old) has not been established.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe

tissue injury if ingested.

- Safety and effectiveness of the ZIO® SR Patch on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

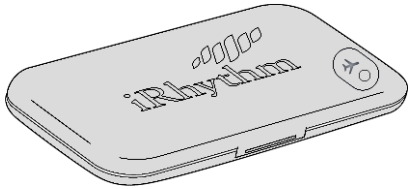
PACKAGE CONTENTS

1 ZIO® SR Patch



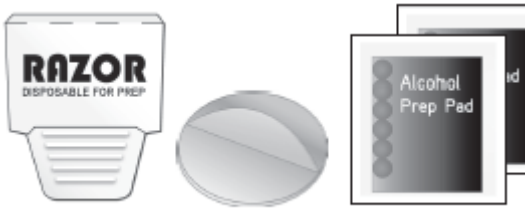
1 ZIO® SR Gateway, containing:

- 1 postage-paid return envelope



1 Skin Prep & Placement Kit containing:

- 1 disposable razor
- 1 abrader disc
- 4 alcohol pads



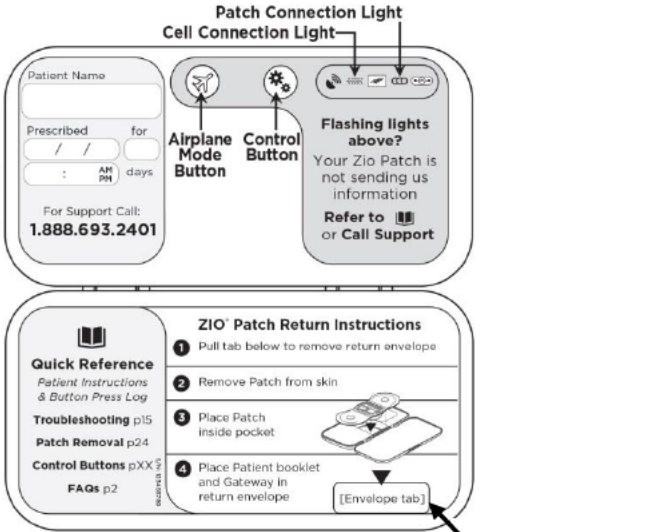
1 Patient Instructions & Button Press Log containing:

- 1 adhesive remover wipe

DEVICE DIAGRAMS

ZIO® Patch

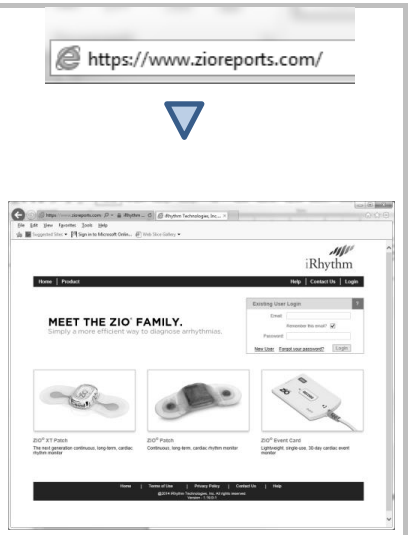
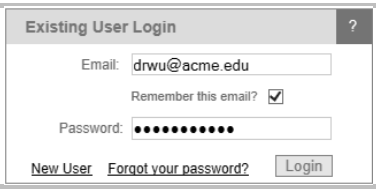
ZIO® Gateway Exterior



ZIO® Gateway Interior

ACCOUNT SETUP

To allow effective use of the ZIO service, an account on iRhythm's Patient Management system (www.zioreports.com) has been assigned to the clinic. The following steps should be performed to verify account access .

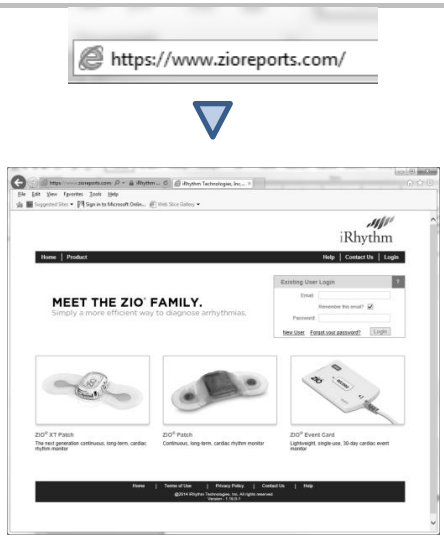
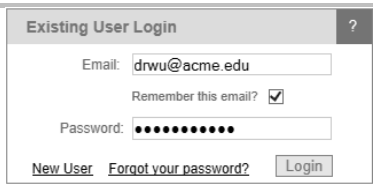
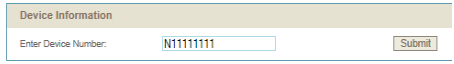
1. Open up Internet Explorer and go to www.zioreports.com	
2. Enter your email address and password to securely login into zioreports.com	

Ensure you can access iRhythm Patient Management system via provided username and password. If you are unable to access zioreports.com please contact iRhythm Customer Support at **1-888-693-2401**

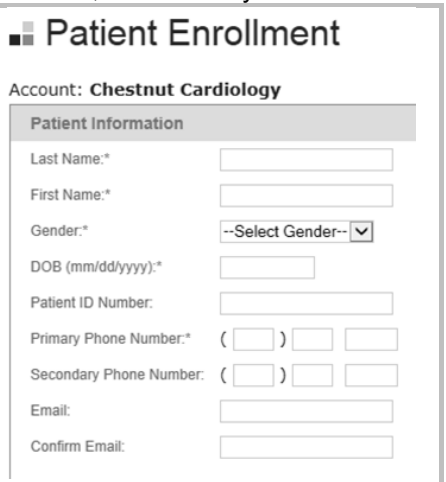
DURING PATIENT VISIT

REGISTRATION

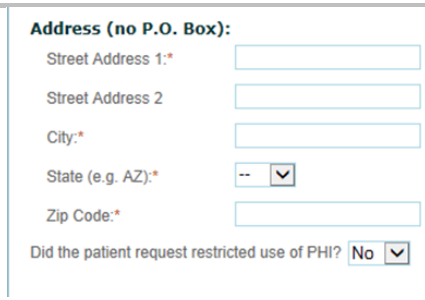
1) Register patient online at www.zioreports.com.

a) Open up Internet Explorer and go to www.zioreports.com	
b) Enter your email address and password to securely login into zioreports.com	
c) Select Register New Patient Option (Patient->Register New Patient)	
d) Enter in the Serial # and the Submit button	

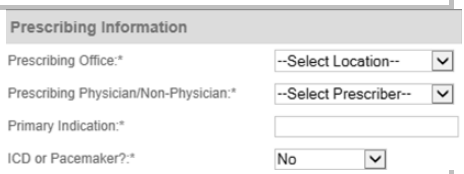
e) Enter the following Patient Information
   i. Last Name (Required)
   ii. First Name (Required)
   iii. Gender (Required)
   iv. DOB (Required)
   v. Patient ID Number
   vi. Primary Phone Number (Required)
   vii. Secondary Phone Number
   viii. Email
   ix. Confirm Email (Required if Email provided)

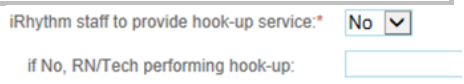
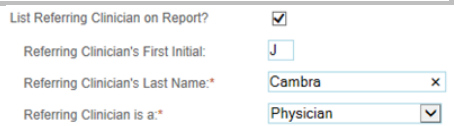


f) Enter the Patient Address
   i. Street Address 1 (Required)
   ii. Street Address 2
   iii. City (Required)
   iv. State (Required)
   v. Zip Code (Required)
   vi. Patient PHI restricted use indicator



g) Enter the following Prescribing Information
   i. Physician Office (Required)
   ii. Prescribing Physician/Non-Physician (Required)
   iii. Primary Indication

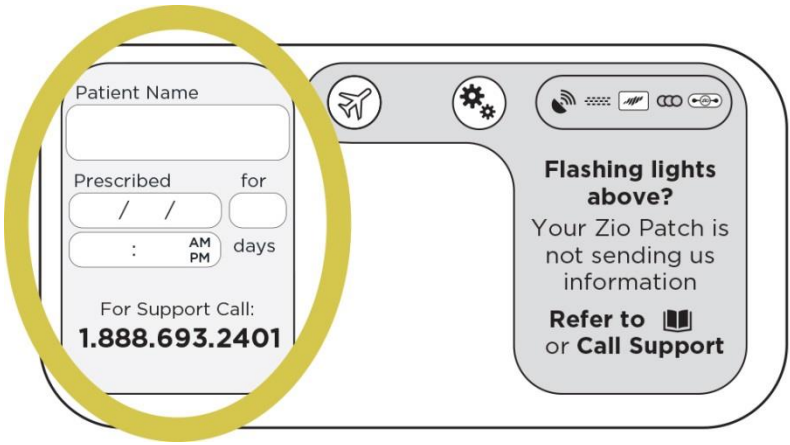


(Required) – Enter associated ICD 9 code. iv. ICD or Pacemaker? [Yes/No] (Required)	
h) Enter Patch Hookup Information – iRhythm Staff performing hook-up? i. If Yes – then select 'Yes' ii. If No – then select 'No' and enter Rn/Tech name	
i) If it is desired to include the Referring Physician on the Zio® SR Patch Report enter a check next to "List Referring Clinician on Report" and enter the following information: i. Referring Clinician's First Name ii. Referring Clinician Last Name (Required) iii. Referring Clinician is a (Required)	
j) Enter the following Patch Wear information i. Patch Start Date (Required) ii. Prescribed Wear Duration (Required)	

k) Complete the patient registration by clicking 'Submit' button	

2) Remove the ZIO® SR Patch and ZIO Gateway from the packaging.

3) Inside the ZIO Gateway on the label, write the patient's name, start date, time and prescription duration using Pen or Marker. Instruct the patient to write the date when they remove the ZIO® SR Patch for return.



APPLICATION INSTRUCTIONS

1. Have the patient **stand** with their arms resting at their sides during the ZIO® Patch application.
   - If the patient cannot stand, have them sit up straight with their arms relaxed at their side.
2. Determine placement area without removing the backing.
   - You may hold the ZIO® Patch up to the patient's **left** chest and use it as a guide to determine the placement area *(Fig. A)*.
     - Place on flattest part of the left chest
     - About 1 finger width below the collar bone, centered over left pectoral muscle
     - Edge of the ZIO® Patch next to the sternum
     - Avoid armpit and breast tissue
   - Angle so the arrow on the top label points upwards *(Fig C)*

Alternative placement may be necessary depending on the patient's anatomy. It is acceptable to modify the placement, but quality of ECG and record duration may be affected.

3. Prepare the patient's skin using the materials from the *Skin Prep & Placement Kit*.

   ***Note** that the preparation area will need to extend larger than where the ZIO® Patch will be applied.*

   a. Remove the razor by holding the cover on the sides and pulling down on the handle *(Fig. D)*.

   b. **Shave** the placement area if hair is present. DO NOT add pressure to the razor; shave across the skin lightly.

      - ***NOTE:** If a cut should occur, treat the site and only continue once bleeding has stopped. After it has stopped, do not place electrode over cut.*
      - ***NOTE:** Dispose of razor in proper sharps container.*

   c. Applying pressure, **abrade** the entire area using 40 broad strokes ***NOTE:** This is essential for skin-patch adhesion and high ECG signal quality.*

   d. **Clean** the area thoroughly with four alcohol pads, using both sides of pads as needed. Allow skin to dry for 1 minute.

      - Be sure to clean off any perspiration, lotion or

sunscreen.

- Let dry for 1 minute.
- Skin must be completely dry before applying the ZIO SR Patch

The order of steps c and d are important! All skin cells / debris from the abrader must be removed for the ZIO SR patch to stick.

The steps above are critical to achieve good signal quality and adhesion.

---

4. Hold device in the center and remove clear backings. Keep top label on. Do not touch adhesive.
5. Apply the ZIO® SR Patch to the patient's chest, making sure to place it in the prepared area *(Fig. F)*.

6. Press firmly across the wings of the device for approximately 2 minutes *(Fig. G)*.
   This helps skin-patch bonding because the adhesive is pressure-sensitive.

7. Remove the top label *(Fig. H)*:
   - Peel off the 2 parts of the top label, one at a time. As you peel, use your other hand to press down on the patch to keep it in place.

   a) **Press firmly for 2 minutes** across the entire device, working adhesive into the skin, which helps skin-patch bonding.

   b) Firmly press the 'ZIO' button and release *(F ig. I)*. The green light will flash 5 times indicating that the monitoring has started.

Pr

8. Open the gateway clasp and press the "Control" button *(Fig. J)* to power on the gateway. Watch for orange flashing light (this will take about 5 seconds) that changes to 5 green flashes. Green flashes indicate that the gateway and patch have connected and the wireless connection is good.

Press button to turn on

9. After you have seen green lights on both patch and gateway:
   - Help the patient practice pressing the patch button. This will familiarize the patient with the action of pressing the button when symptoms are felt. *Button presses within the first five minutes of activation will not be captured, however the device will continue to record.*

REVIEW WITH YOUR PATIENT

Using the ZIO® SR Patch and Gateway

1. The ZIO® Patch is intended to be worn continuously for up to 14 days, through sleep and showering. (Actual wear time may vary by patient). The gateway should be kept within arm's reach and in view to maintain a wireless connection. Ensure the patient understands the purpose and importance of each device.
2. The ZIO® Patch should not be removed before the end of the prescribed period unless skin irritation or itching is severe or hives or blisters develop (see Removal Instructions on page 12). If this occurs, the patient should call Customer Support at 1-888-693-2401.
3. If symptoms are felt the patient should press the 'ZIO' button on the device *(Fig. K).*
   - This will mark the ECG recording, indicating that the patient felt a symptom.
   - The ZIO® Patch will **not** show a light when the patient presses the button.
   - A click should be felt and/or heard, indicating that the button has been pressed and a symptom has been marked.
4. Each time the patient presses the 'ZIO' button to mark a symptom an entry should be made in the Patient Instructions & Button Press Log *(Fig. L)* or at myzio.irhythmtech.com.

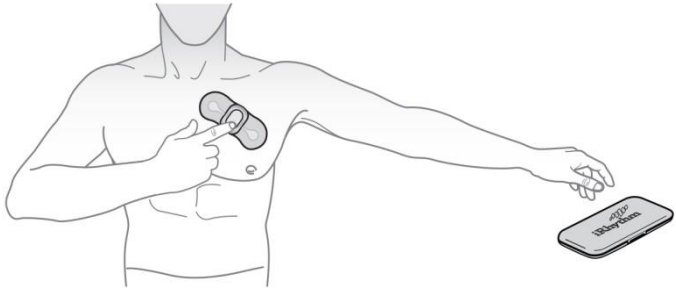
K

Pre

L

Bu

5. The gateway device sends heart rhythm data wirelessly when the patient presses the 'ZIO' button on the patch. In order for the gateway device to function properly:
   - The patient should keep the gateway within arm's length and line of sight as long as they are wearing the ZIO SR patch.



   - The patient may carry the device in a purse or coat pocket in order to maintain proximity while they are out of the home.
   - The patient should ensure that the gateway is located in an area with adequate cellular reception. (Note: the ZIO® SR device is not suitable for patients who live in rural areas with no cellular coverage.)

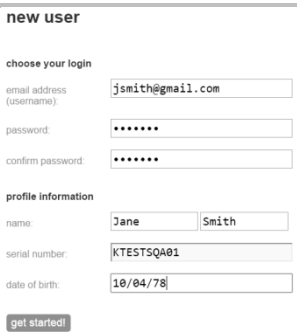
Note: Both Patch and Gateway device do not show lights when functioning properly

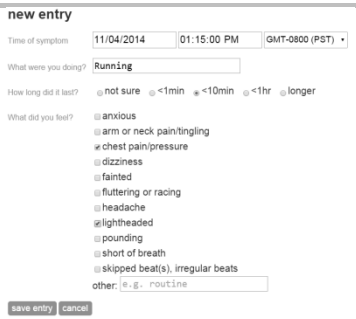
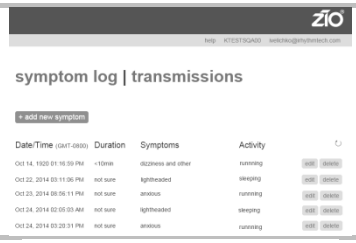
---

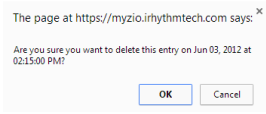
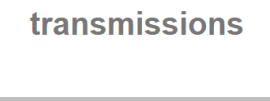
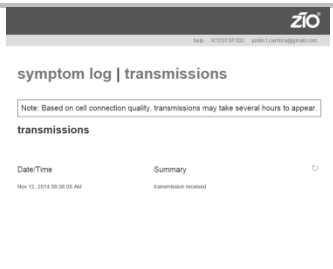
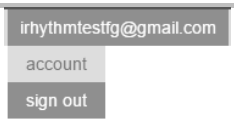
Transmission times may vary depending on the patient maintaining proximity to gateway and ensuring cellular reception.

Proximity to gateway should be maintained at the end of the 14-day monitoring period to ensure complete transmission of events from patch to gateway. Transmissions to gateway will not continue after the 14-day monitoring period is complete.

---

1. Open up Internet Explorer and go to myzio.irhythmtech.com	
2. To register select “new user”	
3. Enter the following Registration Information: i. Patient Email Address (Required) ii. Password (Required) iii. Confirm Password (Required) iv. Last Name (Required) v. First Name (Required) vi. Patch Serial Number (Required)	
4. Complete the myzio.irhythmtech.com registration by clicking ‘get started!’ button	
5. To enter Symptoms login to myzio.irhythmtech.com by providing your email address and password used during	

registration and click the 'sign in' button	
6. To enter a symptom select the "+ add new symptom" button.	
7. Enter the following Symptom Information: i. Date & Time of the Symptom (Required) ii. What were you doing? (i.e. Running, Walking,…) iii. How long did it last? (Required) iv. What did you feel? – Enter as many that apply. Use other if the symptom is not listed.	
8. Complete the Symptom Journal entry by clicking 'save entry' button.	
9. To edit a symptom, locate the symptom of interest from the Main page, and click the 'edit' button.	
10. Make the desired changes to the Symptom journal entry and click 'save entry' to save edits made.	
11. To delete a symptom, locate	

the symptom of interest from the Main page, and click the 'delete' button.	
12. To confirm the deletion, click the 'OK' button.	
13.To view list of Transmissions received, select the 'transmissions' tab.	
14. From the transmissions page the list of transmissions received are listed by date/time. *Note Based on cell connection quality and proximity to the gateway, transmissions may take several hours to appear.*	
15. To logout, select the tab with your email address and select 'sign out'	

Traveling with the ZIO® SR System

1. The ZIO® Patch can be worn through security screenings. A security statement, as shown below, is provided in the Patient Instructions & Button Press Log.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm Zio® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at

1.888.693.2401

24 hours/day, 7 days/week.

2. The ZIO® SR system allows the patient to power the cellular radio on and off with an Airplane Mode:
   a. To turn on Airplane Mode (when the cellular radio needs to be shut off), the patient should open the gateway and press and hold the "Airplane Mode" button for 3 seconds until the inside status lights flash orange momentarily. The outside airplane light will flash continuously while in Airplane Mode.
   b. To exit Airplane Mode (and turn the cellular radio back on), the same "Airplane Mode" button should be held for 3 seconds until the inside status lights flash green momentarily to show success. The outside airplane light will stop flashing and the cellular radio is turned on.

Removal of the ZIO SR Patch & Return of the ZIO® System

1. At the end of the wear period, detach the adhesive remover wipe from the back page of the *Patient Instructions & Button Press Log*.
2. Gently tilt the center of the ZIO® Patch up. Using the adhesive remover, sweep the wipe between the skin and the Patch while peeling the right side from the center out. Repeat for the other side, peeling from the center out *(Fig. M)*.

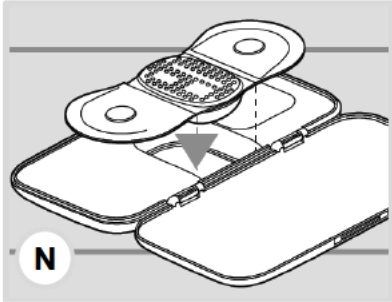
Ac

3. Wash skin with mild soap, rinse with water, and pat dry.

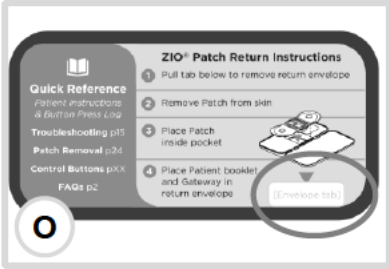
If patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, have them use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

---

4. Place the ZIO® Patch in the gateway and close the gateway such that the clasp clicks. *(Fig.N)*



5. Pull tab in the gateway to remove return envelope. *(Fig.O)*



6. Place Patient booklet and gateway in return envelope. Seal the envelope and mail it back via the U.S. postal service as soon as possible.

Analysis of the full continuous record cannot be performed until receipt of the patch. Encourage the patient to mail back the patch, gateway and patient booklet on the day of patch removal.

DURING MONITORING

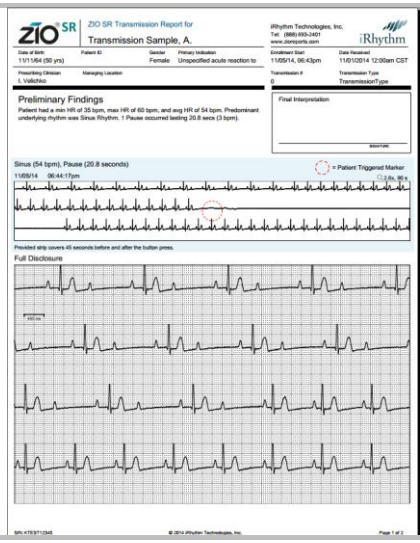
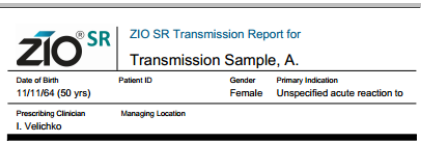
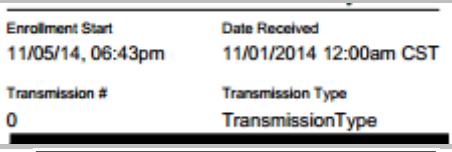
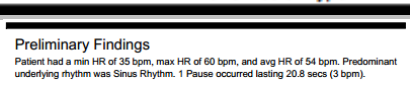
During monitoring the ZIO® device will record continuous beat to beat ECG information and transmit patient triggered ECG to provide accurate arrhythmia detection. Note that expected event transmission delays may vary significantly depending on how effectively the patient maintains patch-gateway proximity and gateway cellular reception. Transmission reports will be provided after receipt and analysis of patient triggered ECG strips.

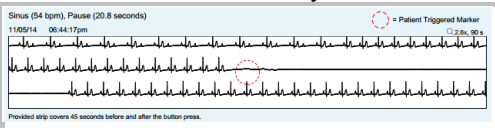
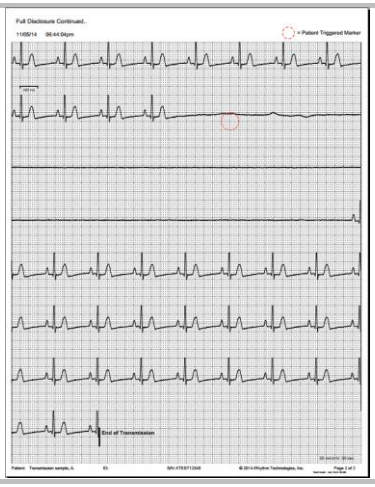
In special circumstances, when patient data needs to be accessed by the Physician during the wear period an Urgent Data Request can be made. In order to make an Urgent Data Request, the clinician should call iRhythm at 1-888-693-2401.

REPORTS

ZIO® SR TRANSMISSION REPORT

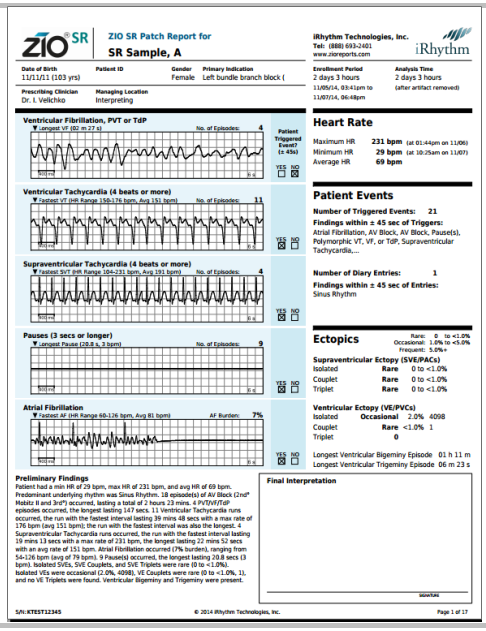
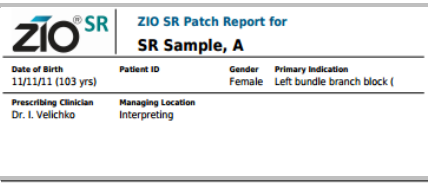
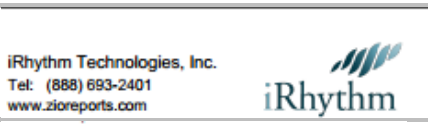
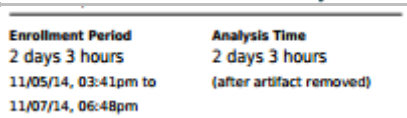
The transmission report is a snapshot of cardiac data during monitoring period.

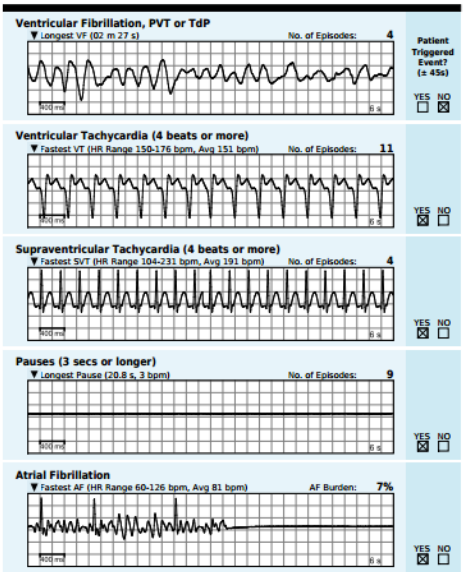
Each transmission report contains a 90 second ECG record centered on the Patient's button press time.	
It contains:	
"ZIO SR Transmission Report for" label followed by the Patient Demographics and prescription information:	 ZIO® SR ZIO SR Transmission Report for Transmission Sample, A. Date of Birth: 11/11/64 (50 yrs) Patient ID: Gender: Female Primary Indication: Unspecified acute reaction to Prescribing Clinician: I. Velichko Managing Location:
iRhythm contact information:	 iRhythm Technologies, Inc. Tel: (888) 693-2401 www.zioreports.com iRhythm
Enrollment and Event Transmission information:	 Enrollment Start: 11/05/14, 06:43pm Date Received: 11/01/2014 12:00am CST Transmission #: 0 Transmission Type: TransmissionType
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm)	 Preliminary Findings Patient had a min HR of 35 bpm, max HR of 60 bpm, and avg HR of 54 bpm. Predominant underlying rhythm was Sinus Rhythm. 1 Pause occurred lasting 20.8 secs (3 bpm).

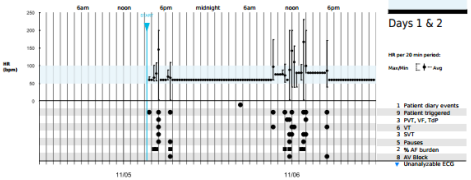
A 200 mm/30 seconds resolution of the 90 second Event Transmission with a marker indicating the button press:	
A 25mm/sec resolution of the 90 seconds Event Transmission with a marker indicating the button press:	

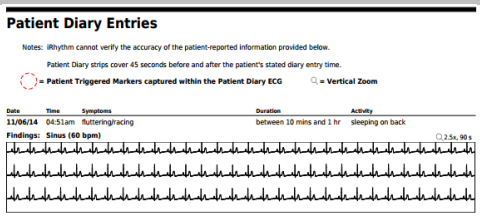
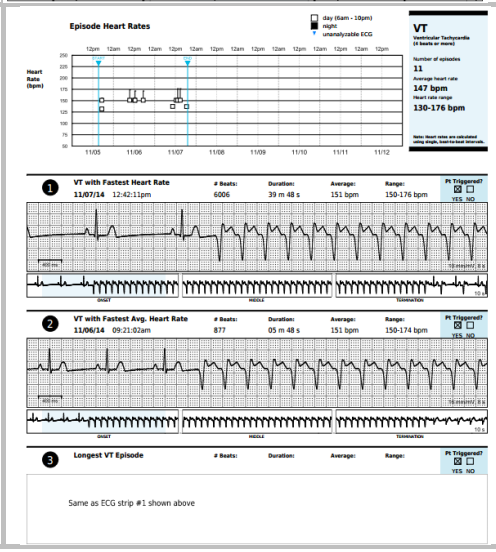
ZIO® SR PATCH CONTINUOUS REPORT

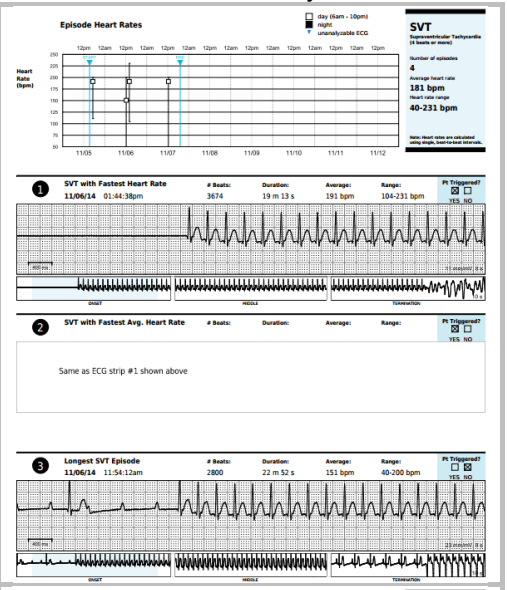
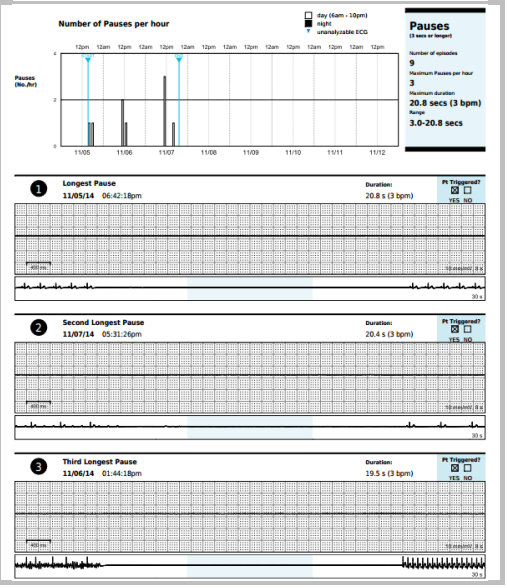
The ZIO® SR patch report is a comprehensive summary of symptomatic and asymptomatic arrhythmia findings that includes pertinent statistics, wear and analysis time, patient triggered and diary events.

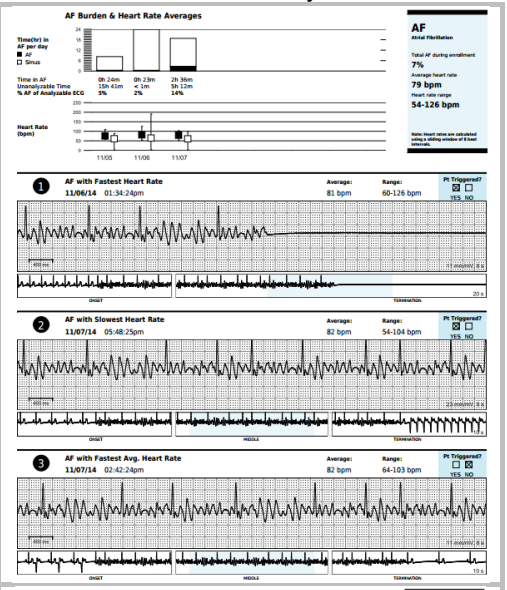
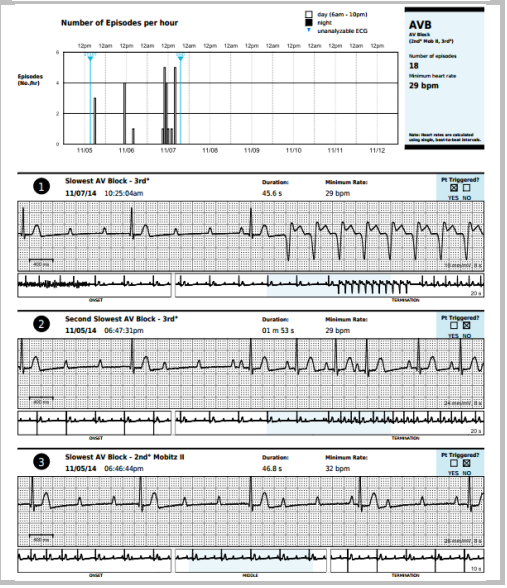
The front page includes a summary of all the finding:	
It contains:	
"ZIO SR Patch Report for" label followed by the Patient Demographics and prescription information:	
iRhythm contact information:	
Enrollment and Analysis information:	

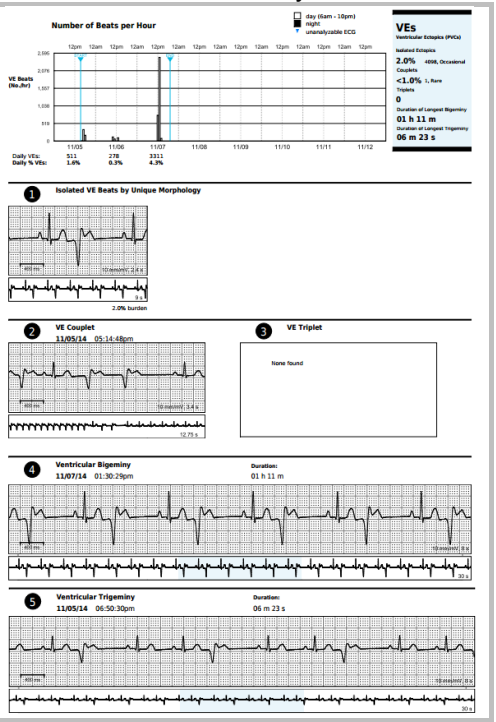
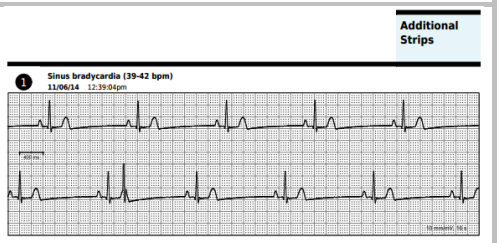
Arrhythmia Summary section:	
Heart Rate Summary section:	**Heart Rate** Maximum HR **231 bpm** (at 01:44pm on 11/06) Minimum HR **29 bpm** (at 10:25am on 11/07) Average HR **69 bpm**
Events (Patient Triggered and Diary Entry) summary:	**Patient Events** **Number of Triggered Events: 21** **Findings within ± 45 sec of Triggers:** Atrial Fibrillation, AV Block, AV Block, Pause(s), Polymorphic VT, VF, or TdP, Supraventricular Tachycardia,... **Number of Diary Entries: 1** **Findings within ± 45 sec of Entries:** Sinus Rhythm

Ectopics Summary section (including VEs, SVEs, Ventricular Bigeminy and Trigeminy):	**Ectopics** Rare: 0 to <1.0% Occasional: 1.0% to <5.0% Frequent: 5.0%+ **Supraventricular Ectopy (SVE/PACs)** Isolated **Rare** 0 to <1.0% Couplet **Rare** 0 to <1.0% Triplet **Rare** 0 to <1.0% **Ventricular Ectopy (VE/PVCs)** Isolated **Occasional** 2.0% 4098 Couplet **Rare** <1.0% 1 Triplet **0** Longest Ventricular Bigeminy Episode 01 h 11 m Longest Ventricular Trigeminy Episode 06 m 23 s
Preliminary ECG rhythm findings (reviewed and edited by CCTs at iRhythm):	**Preliminary Findings** Patient had a min HR of 29 bpm, max HR of 231 bpm, and avg HR of 69 bpm. Predominant underlying rhythm was Sinus Rhythm. 18 episode(s) of AV Block (2nd° Mobitz II and 3rd°) occurred, lasting a total of 2 hours 23 mins. 4 PVT/VF/TdP episodes occurred, the longest lasting 147 secs. 11 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 39 mins 48 secs with a max rate of 176 bpm (avg 151 bpm); the run with the fastest interval was also the longest. 4 Supraventricular Tachycardia runs occurred, the run with the fastest interval lasting 19 mins 13 secs with a max rate of 231 bpm, the longest lasting 22 mins 52 secs with an avg rate of 151 bpm. Atrial Fibrillation occurred (7% burden), ranging from 54-126 bpm (avg of 79 bpm). 9 Pause(s) occurred, the longest lasting 20.8 secs (3 bpm). Isolated SVEs, SVE Couplets, and SVE Triplets were rare (0 to <1.0%). Isolated VEs were occasional (2.0%, 4098), VE Couplets were rare (0 to <1.0%, 1), and no VE Triplets were found. Ventricular Bigeminy and Trigeminy were present.
An area to include clinician's interpretation (when configured):	**Final Interpretation** SIGNATURE
Events Chart with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each 20 minutes segment:	**Events** Days 1 & 2 
90 seconds (-/+ 45 secs.) 200 mm/30 seconds resolution ECG strips around patient button presses with a marker indicating the button press:	**Patient Events** **Patient Triggered Events** Note: Triggered Event strips cover 45 seconds before and after the button press. = Patient Triggered Marker = Vertical Zoom * = No heart rate will be displayed if insufficient beats of the rhythm are included in the strip. 11/05/14 03:51:50pm Sinus (60 bpm) 2.5x, 90 s

90 seconds (-/+ 45 secs.) 30 seconds resolution ECG strips around patient diary entries and a button press marker whenever it occurred during a diary entry:	
Chapter with details of Ventricular Fibrillation, Polymorphic Ventricular Tachycardia & Torsade de Points (VF/PVT/ TdP):	
Chapter with details of Ventricular Tachycardia (VT):	

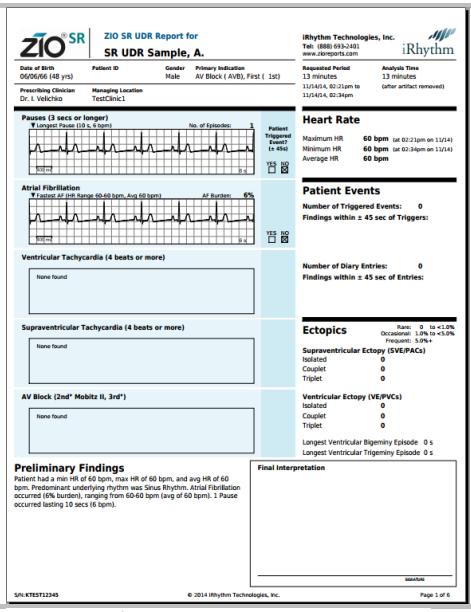
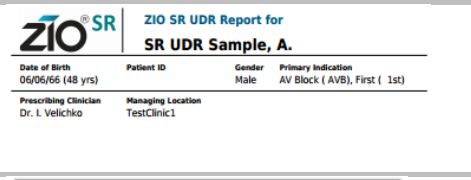
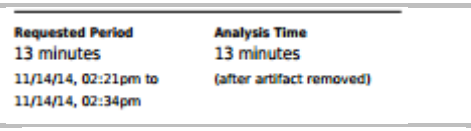
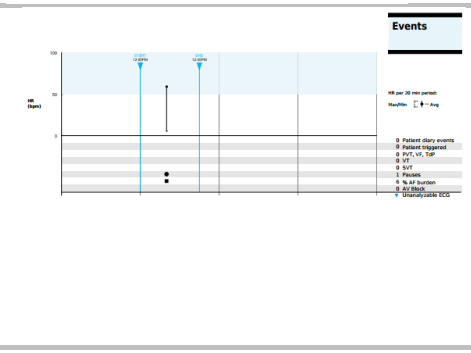
Chapter with details of Supraventricular Tachycardia (SVT):	
Chapter with details of Pause(s):	

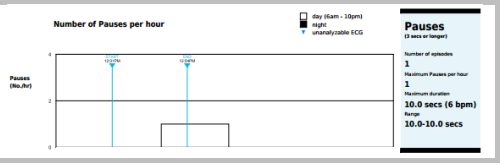
Chapter with details of Atrial Fibrillation/Flutter (AF/AFL):	
Chapter with details of AV Block (AVB):	

Chapters with details of Ectopics (VEs and SVEs):	
Chapters for any additional ECG strips, which are either not included in the arrhythmia chapters or shown in different resolution:	

ZIO® SR URGENT DATA REQUEST (UDR) REPORT

The UDR report is an abbreviated version of the ZIO® report for a specific time period during the patient wear period requested by the clinician.

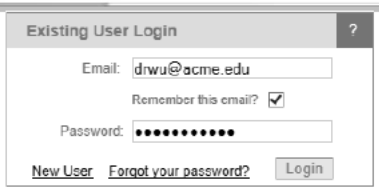
Each Urgent Data Request Report contains summary of all the findings within the requested data period. This report is very similar to the final summary report with differences mentioned below:	
"ZIO SR UDR Report for" label on the top of the Patient Demographics and prescription information:	
Requested Duration and Analysis information:	
Higher time resolution Events charts with indications for Start and End times of the data requests with min/max/avg. heart rates for 20 minutes increments and type of arrhythmias present in each	

20 minutes segment :	
Higher resolution arrhythmia chapter charts:	

ACCESSING REPORTS

1) Open up Internet Explorer and go to www.zioreports.com

2) Enter your email address and password to securely login into zioreports.com



3) Select Register New Patient Option (Patient->Register New Patient)

4) From the Pending Reports list select the Timeline icon for the patient of interest

5) Within the Timeline, click the link to the appropriate report to open the attached report.

TROUBLESHOOTING

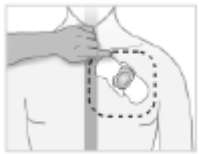
FOR CUSTOMER SUPPORT, CALL **1-888-693-2401**

FREQUENTLY ASKED QUESTIONS

Application

1. **The chest area was prepped and the device was applied. When the 'ZIO' button was pressed, it flashed orange (rather than green) five times.**
   Press down on the adhesive wings for a moment, so the device makes better contact with the skin. Then, press the 'ZIO' button again to attempt activation.
   If the devices does not activate (flash green) on the second attempt, please contact Customer Support at 1-888-693-2401.

2. **I think I placed the ZIO® SR Patch in the wrong position. Can I remove it and reposition it?**
   No. If the ZIO® SR Patch is over the heart in a slight diagonal as shown,
   the positioning should be acceptable.
   DO NOT attempt to reapply the ZIO® SR Patch.



3. **The top label was peeled off, but there still seems to be a white label stuck to the wings of the ZIO® SR Patch.**
   The top label may have separated. Peel the remaining white labels from the center of the ZIO® SR Patch outward.

4. **Are there tests or treatments that are not compatible with the ZIO® SR Patch?**
   Yes. The following are not recommended during wear of the ZIO® SR Patch:
   a. Magnetic Field(s): Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field

b. Neuromuscular Stimulators: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit
c. External Cardioversion/Defibrillation

NOTE: Data may not be interpretable during the time the stimulators are being used. Usage is at physician's discretion.

5. **Can the ZIO® SR Patch be left on a patient during Cardioversion/Defibrillation?**
   No, the ZIO® SR Patch should be removed if the patient requires Cardioversion or Defibrillation.

7. **I turned the gateway on but it is flashing orange?**
   Ensure that the patch has been turned on and is located within 10 feet of the gateway. If the gateway continues to flash orange for more than 2 minutes, please contact Customer Support at 1-888-693-2401.

Patient Questions

1. **How long is the patient supposed to wear the ZIO® SR Patch?**
   A patient can wear the ZIO® SR Patch for up to 14 days or as prescribed. Note: The ZIO® SR Patch will not record ECG data after 14 days.
   Based on individual wear experiences the patient's actual wear time may be shorter than prescribed.

2. **What is the ZIO® SR Patch doing?**
   The ZIO® SR Patch is recording every heartbeat. Pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

3. **What is the ZIO SR Gateway doing?**
   The ZIO SR Gateway is sending heart rhythm data wirelessly when the ZIO button on the patch is pressed. The data is received at iRhythm and a report is provided to the patient's doctor while the patient may still be wearing the patch.

4. **Who should the patient call if they have questions about the ZIO SR Patch or Gateway?**
   The patient can read the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

5. **Who should the patient call if they have questions about the ZIO® SR Patch or if it falls off?**
   The patient can refer to FAQs in the *Patient Instructions & Button Press Log* or call Customer Support at 1-888-693-2401.

6. **What should the patient do if they feel a symptom?**
   Press the 'ZIO' button and fill out a page of the *Patient Instructions & Button Press Log*.

7. **What if the patient forgets to press the 'ZIO' button when they feel a symptom?**
   While pressing the 'ZIO' button is important, the ZIO® SR Patch is recording every heartbeat.

8. **What if the patient presses the 'ZIO' button but forgets to write down the information on a Button Press Log page?**
   While the *Button Press Log* information is useful, pressing the 'ZIO' button indicates that the patient felt a symptom at that time.

9. **What if the patient does not have symptoms?**
   That's okay. The ZIO® SR Patch records every heartbeat.

10. **What activities should the patient avoid while wearing the ZIO® SR Patch?**
    Activities that cause excessive sweating. This could cause the ZIO® SR Patch to slide, become loose, fall off, and shorten wear time.

11. **Can the patient exercise while wearing the ZIO® SR Patch?**
    Yes, but excessive sweating may shorten wear time.

12. **Can the patient shower with the ZIO® SR Patch on?**

Yes, but showers should be brief. Keep soaps and lotions away from the ZIO® SR Patch. If possible, face away from the water when showering. When towel-drying, the patient should hold the ZIO® SR Patch down with one hand so that it is not accidently knocked off. Instruct the patient to press the ZIO® SR Patch against their skin to secure it.

13. **Can the patient take a bath?**
    Yes, but the patient should keep the ZIO® SR Patch above water.

14. **Can the patient go swimming or in a hot tub?**
    No. The ZIO® SR Patch and ZIO® Gateway should not be submerged in water.

15. **Is it normal for the ZIO® SR Patch to move slightly from its original position?**
    Yes. The ZIO® SR Patch may move slightly from its original position. A blue gel may become visible under the wings of the ZIO® SR Patch.

16. **Is it normal to experience skin irritation or itchiness in the area of the ZIO® SR Patch?**
    Minor skin irritation and/or itching while wearing the ZIO® SR Patch may occur. If the irritation or itching is severe instruct the patient to remove the ZIO® SR Patch and call Customer Support at 1-888-693-2401.

17. **Is it normal for the ZIO® SR Patch wings to become cloudy in appearance?**
    Yes, the wings of the ZIO® SR Patch may become cloudy after a few days of wear.

18. **What should the patient do if they think they see blood under the ZIO® SR Patch?**
    Instruct the patient to call Customer Support at 1-888-693-2401. It is likely due to a small shaving cut when the device was applied to the chest.

19. **How will the patient know the ZIO® SR Patch is working?**

Once the ZIO® SR Patch is applied to the body, and the 'ZIO' button is pressed, a green light should flash, indicating that it was turned on. Afterwards, it will not flash or make noise when it is working properly.

20. **Will the ZIO® SR Patch flash while the patient is wearing it?**
No.If it is working properly, the ZIO® SR Patch will not flash or make noise. If the patient sees the ZIO® SR Patch flashing orange, this does not mean there is a problem with the patient's heart; it just means that the ZIO® SR Patch is not well attached. Instruct the patient to press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, have the patient call Customer Support at 1-888-693-2401.

21. **Can a patient travel with the ZIO® SR Patch on?**
Yes. Please take the Patient Instruction and Button Press Log with you when traveling. If questioned during security screening there is a statement included in the *Patient Instruction & Button Press Log* for them to reference.

22. **When the patient removes the ZIO® SR Patch, it is flashing orange. Is this okay?**
The ZIO® SR Patch may blink orange after removal. It is okay to mail the device while it is blinking.

23. **Will the ZIO Gateway show any lights or make any sounds during normal use?**
No. If it is able to send data, the ZIO Gateway will not flash or make noise. If the patient sees the gateway flashing orange, this means there is a problem sending data wirelessly to the patch or to iRhythm.

24. **Does the patient need to do anything with the ZIO Gateway to send heart rhythm data wirelessly?**
The patient only needs to keep the Gateway within 6 feet of the patch and within range of good cellular reception. No action is

required for the Gateway to send symptomatic heart rhythm data other than pressing the ZIO button on the patch.

25. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway is not within 10 feet?**
    The patch will store the data until the Gateway is within range, then the data will be sent.

26. **What happens if the patient presses the ZIO button on the patch while the ZIO Gateway doesn't have cellular reception?**
    The gateway will store the data until it has cellular reception, then the data will be sent.

27. **What should the patient do if the ZIO Gateway is flashing orange?**
    Gateway flashing orange means that the patch cannot send us information wirelessly. The patient can attempt troubleshooting using the "Gateway Troubleshooting Guide" in the *Patient Instructions and Button Press Log* (see page 35 of this manual) or call Customer Support at 1-888-693-2401.

28. **Can the patient fly with the ZIO Gateway?**
    Yes. The gateway cellular radio can be turned off by pressing the airplane button inside the gateway for 3 seconds. The gateway cellular radio can be turned back on by pressing the airplane button for 3 seconds. While in "Airplane Mode" the airplane light on the outside face of the gateway will flash.

PATCH FLASHING LIGHTS KEY

If the light on the patch is flashing orange, pick the troubleshooting action based on the following:

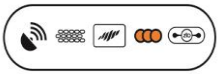
- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

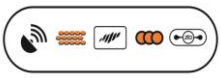
Flashing light location	Light flashing speed	Recommended action
	SLOW	Press evenly on the ZIO® SR Patch for 3 to 5 minutes. If flashing persists or reoccurs, call Customer Support at 1-888-693-2401.
	FAST	Call Customer Support at 1-888-693-2401.

GATEWAY FLASHING LIGHTS KEY

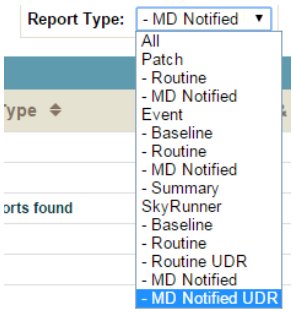
If the outside status light on the gateway is flashing orange, open the gateway and pick the troubleshooting action based on the following:

- Which inside lights are flashing orange?
- Is the flashing slow (once every 3 seconds) or fast (3 times per second)?

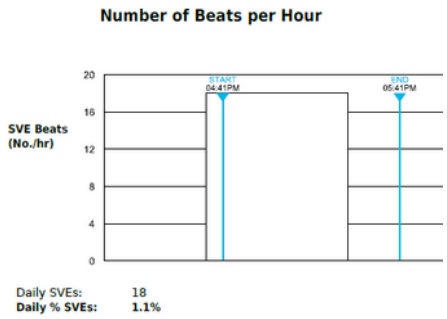
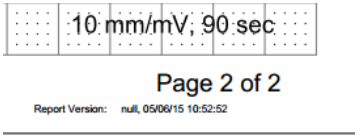
Flashing light location	Light flashing speed	Recommended action
	SLOW	Keep the gateway near to the patch for at least 10 minutes. If the light continues to flash, call Customer Support at 1-888-693-2401.
	SLOW	Move the gateway to an area with cellular reception and press the “Control” button for 3 seconds. If the gateway is able to connect and send the information, the light will flash green until it is done sending. Keep the gateway in the same location until the green flashing stops. If orange flashing does not stop even in an area with good cellular reception, call Customer Support at 1-888-693-2401.

	FAST	Call Customer Support at 1-888-693-2401.

ZIO SR SERVICE ERRATA

Errata	Workaround
myZIO Registration – Patient Enrollment	In order for a patient to register with myZIO they must first be enrolled in www.zioreports.com. In the event that the patient attempts to register prior to completion of enrollment they will receive a notification indicating "Unknown device", until enrollment has been completed. (SYS-2281)
ZIO SR Transmission Report – Duplicate transmissions	It is possible to receive duplicate transmissions for the same button press event. Both of these reports contain the same ECG recording. Occurrence of duplicate reports can be identified by two transmissions having the same date. If this scenario occurs, the duplicate copy can be ignored. (SYS-2351)
ZIO SR Transmission Report Type Filter	To view only transmission specific reports in the Report Inbox, select Baseline, Routine, MD Notified under the SkyRunner section.  (SYS-2323)
ZIO SR Urgent Data Report – Button Press Events	Patient button press events are not provided in the ZIO SR Urgent Data Report.

	This report is limited to present only findings identified within the ~20 minutes of ECG recording captured. A Full Disclosure version of the UDR report containing the entire ECG recording can be provided on request. (SYS-2337)
ZIO SR Urgent Data Report – ECG strip scaling .	For 8s ECG strips provided in the ZIO SR Urgent Data Report, the scale is fixed to 10 mm/mV resolution. (SYS-2339)
Patient Timeline – Paper Booklet Diary Entries	For patients with the ZIO SR Patch, ZIOReports provides a timeline screen that displays along with ZIO Transmission, UDR, and Final patch reports, patient provided diary entries. For each diary entry the date and time of the symptom reported is displayed. In the event that a patient does not provide the date/time for a symptom on the paper booklet, the timeline will display a date with a year starting in 3000. Dates that have a year of 3000 or greater indicate that the patient did not provide the timestamp of the symptom experienced. (SYS-2315)
ZIO SR Urgent Data Report – Overview Chart	For the VE/SVE overview charts in the ZIO SR Urgent Data Report, the width of the number of beats bar in the overview chart extends outside the start/end time indicators. This is a display issue, the number of beats observed is for the period between the start and end markers.

	 (SYS-2328)
ZIO SR Transmission Report – Report Version	The version of the ZIO SR Transmission Report is not provided.  (SYS-2237)

IRHYTHM CLINICAL FACILITY CERTIFICATION

The ZIO® SR Patch heart monitor is analyzed at the iRhythm Clinical Center. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards. A link to these standards (42 C.F.R.section 410.33) can be found at the iRhythm website www.irhythmtech.com.

NOTICE OF PRIVACY PRACTICES (NOPP)

iRhythm is committed to protecting the privacy of your personal information. We are required by the U.S. - EU Safe Harbor Framework to maintain the privacy of your personal information, and to notify you of our privacy practices, our legal duties, and your rights concerning your personal information.

Why?	As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information ("PHI"). This notice describes our privacy practices, our legal duties, and your rights concerning your PHI. We will follow the privacy practices described in this notice while it is in effect. We reserve the right to revise this notice and to make the new notice provisions effective for all PHI we maintain. If we revise this notice, we will post the revised notice on this page.
What?	In providing diagnostic services, the types of information we collect may include: - Name - Gender - Date of Birth - Medicare and Secondary Insurance Information - Address and Phone Number - Prescribing Physician and Office - Primary Indication - ECG Recording - Symptoms and Activities You Report, by Time and Date - Activity Level During Monitoring - Patient Identification Number - Clinical Information and Diagnostic Results
How?	By providing diagnostic services to our patients, we regularly collect information through: - Phone conversations - Patient submitted documents - Prescribing physician submitted documents - ZIO® Event card transmissions - Return of ZIO® XT Patches

How We May Use Your Information			
We have the right to use and disclose health information for your treatment, to secure payment for your health care, and to operate our business.			
Without Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
To You	We must disclose your PHI to you, as described in the "Your Rights" section of this notice.	Yes	Yes
For Payment	We may use and disclose PHI to obtain payment for services provided to you. We may also disclose your PHI to a health care provider or health plan so that the provider or plan may obtain payment of a claim or engage in other payment activities.	Yes	Yes
For Treatment	We may use and disclose PHI to provide and manage your diagnostic services. That may include consulting with other health care providers about your diagnostic services. For example, we will release the results of your diagnostic services to your prescribing physician, to the physician treating you, or in a medical emergency, if applicable.	Yes	No
For Health Care Operations	We may use or disclose PHI to conduct quality assessment and improvement activities, to conduct fraud and abuse investigations, to engage in care coordination or case management, or to communicate with you about health related benefits and services or treatment alternatives that may be of interest to you. We may also disclose PHI to a health care provider or health plan	Yes	No

	subject to federal privacy laws, as long as the provider or plan has or had a relationship with you and the PHI is disclosed only for certain health care operations of that provider or plan. We may also disclose PHI to other entities with which we have contracted to perform or provide certain services on our behalf (e.g., business associates).		
For Business Operations	We may use both De-Identified and Limited Data Sets (a data set that, per the Health Insurance Portability and Accountability Act of 1996 regulations, has had patient-identifiable data removed except for dates of service) for development of future products, devices or services. Once information is De-Identified through an approved method, the data is stripped of individual identifiers, at which point iRhythm may share this information without restriction externally to support research, market development, trend analysis, etc. Information containing Limited Data Sets may be provided externally to support market and product development. However, iRhythm will obtain the required data use agreements when transferring Limited Data Sets to external parties.	Yes	Yes
For Public Health And Safety	We may use or disclose PHI to the extent necessary to avert a serious and imminent threat to the health or safety of you or others. We may also disclose PHI for public health and government health care oversight activities and to report suspected abuse, neglect or domestic violence to government authorities	Yes	No
As Required By Law	We may use or disclose PHI when we are required to do so by law.	Yes	No

For Process And Proceedings	We may disclose PHI in response to a court or administrative order, subpoena, discovery request, or other lawful process.	Yes	No
For Law Enforcement	We may disclose PHI to a law enforcement official with regard to crime victims and criminal activities.	Yes	No
Special Government Functions	We may disclose the PHI of military personnel or inmates or other persons in lawful custody under certain circumstances. We may disclose PHI to authorized federal officials for lawful national security activities.	Yes	No
For Research, Death, And Organ Donation	We may use or disclose PHI in certain circumstances related to research, death or organ donation.	Yes	No
For Workers' Compensation	We may disclose PHI as permitted by workers' compensation and similar laws.	Yes	No
With Specific Authorization		**Does iRhythm Share?**	**Can You Limit This Sharing?**
You may give us written authorization to use your PHI or disclose it to anyone for any purpose not otherwise permitted or required by law. If you give us such authorization, you may revoke it in writing at any time. Your revocation will not affect any use or disclosure permitted by your authorization while it was in effect.		Yes	Yes
While the law permits us in certain circumstances to disclose your PHI to family, friends and others, we will do so only with your authorization. In the event you are unable to authorize		Yes	Yes

such disclosure, but emergency or similar circumstances indicate that disclosure would be in your best interest, we may disclose your PHI to family, friends or others to the extent necessary to help with your health care coverage arrangements.		

Your Rights	
Access	With limited exceptions, you have the right to review in person, or obtain copies of, your PHI. We may charge you a reasonable fee as allowed by law to obtain this information.
Amendment	With limited exceptions, you have the right to request that we amend your PHI.
Disclosure Accounting	You have the right to request and receive a list of certain disclosures made of your PHI. If you request this list more than once in a 12-month period, we may charge you a reasonable fee as allowed by law to respond to any additional request.
Use/Disclosure Restriction	You have the right to request that we restrict our use or disclosure of your PHI for certain purposes. We are not required to agree to a requested restriction. We will agree to restrict use or disclosure of your PHI provided that the law allows and we determine the restriction does not impact our ability to operate our business, provide diagnostic services, and comply with the law. Even when we agree to a restriction request, we may still disclose your PHI in a medical emergency and use or disclose your PHI for public health and safety and other similar public benefit purposes permitted or required by law.
Confidential Communication	You have the right to request that we communicate with you in confidence about your PHI at an alternative address.
Privacy Notice	You have the right to request and receive a copy of this notice at any time. For more information or if you have questions

	about this notice, please contact us using the information listed at the end of this notice.
Complaints / Violations	
If you are concerned that we may have violated your privacy rights, you may inquire with us using the contact information listed at the end of this notice. You may also submit a written complaint to the U.S. Department of Health and Human Services. We will provide you with the address for the U.S. Department of Health and Human Services upon request. We support your right to protect the privacy of your PHI. We will not retaliate in any way if you choose to file a complaint with us or with the U.S. Department of Health and Human Services.	
To Limit Our Sharing Or Submit Complaints	Call 1-888-693-2401 - our Customer Service staff will assist you
Questions?	Call 1-888-693-2401
Who We Are	
Who Is Providing This Notice?	This privacy notice is being provided by iRhythm Technologies, Inc., and applies to the diagnostic services offered in connection with prescribed health care.
What We Do	
How Does iRhythm Protect My PHI?	To protect your PHI from unauthorized access and use, iRhythm has implemented security safeguards that comply with federal law to secure physical and electronic information.
Company Contact Details	
Address:	iRhythm Technologies, Inc. 650 Townsend Street Suite 380

	San Francisco, CA 94103 Attn: Privacy Official www.irhythmtech.com
Phone:	415.632.5700
Fax:	415.632.5701

DEVICE SPECIFICATIONS

PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months
Out-of-Pouch Shelf Life	1 day

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Short-range RF Transmit/Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power < 1mW
Gateway Cellular RF Transmit/Receive	800 / 1900 MHz CDMA Effective Radiated Power ≤ 300mW

POWER CHARACTERISTICS

Patch Battery Type	2 Lithium Manganese Dioxide Coin Cells
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.0 x 0.5 inches
Patch Weight	24.7 g

Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g

ENVIRONMENTAL CHARACTERISTICS

Operational Temperature	36 to 104 degrees
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IPX4
Gateway IP Classification	IPX2

ESSENTIAL PERFORMANCE

The ZIO SR device records and transmits ECG for analysis after receipt of data. In the event it cannot record or transmit in a timely fashion, the ZIO SR alerts the patient that functionality is impaired.

HEART RATE CALCULATIONS

Episode Heart Rates	Max	The maximum episode heart rate (i.e., maximum of all instantaneous heart rates within the episode)
	Min	The minimum episode heart rate (i.e., minimum of all instantaneous heart rates within the episode)
	Avg	The average episode heart rate (i.e., average of all instantaneous heart rates within the episode)
Overall Rhythm Heart Rates	Max	The maximum overall heart rate (i.e., maximum of all rhythm episode maximum heart rates within the record)
	Min	The minimum overall heart rate (i.e., minimum of all rhythm episode minimum heart rates exclusive of Pause heart rates within the record)
	Avg	The average overall heart rate (i.e., duration-weighted average of all rhythm episode heart rates within the record)

PAUSE DETERMINATION

Pause is defined as an RR interval greater than 3 seconds.

ELECTRICAL SAFETY AND COMPATIBILITY

- CAUTION: The ZIO SR needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The ZIO SR should not be used adjacent to or stacked with other equipment.
- WARNING: The ZIO SR may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.

Table 1: Guidance and manufacturer's declaration— electromagnetic emissions

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The ZIO® SR device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ZIO® SR device is suitable for use in all establishments, including domestic establishments.
Harmonic emissions IEC 61000-3-2	Not applicable	Not applicable

Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	Not applicable

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

The ZIO® SR device is intended for use in the electromagnetic environment specified below. The customer or the user of the ZIO® SR device should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the ZIO® SR device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$80 MHz to 800 MHz $d = 2.3\sqrt{P}$800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Table 3, Continued

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

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ZIO® SR is used exceeds the applicable RF compliance level above, the ZIO® SR should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZIO® SR Patch.

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

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the ZIO® SR

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**80 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

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

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