



CLINICAL REFERENCE MANUAL

Rx
ONLY

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DESCRIPTION

ZioSuite is a web portal for healthcare professionals to manage/streamline clinical workflows associated with the Zio Service. The Zio Service consists of long-term cardiac recording using a prescribed Zio device in combination with the “ZEUS System” (Zio ECG Utilization Service), an iRhythm Technologies, Inc. software system utilizing proprietary deep-learned algorithms for data analysis. ZioSuite, a software module within the ZEUS System, offers capabilities to enrol patients into the Zio Service, access clinical reports, manage/perform clinical report interpretation, and administer user settings/access.

INTENDED USE

The device is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram information for long-term monitoring. After wear, ECG data from compatible monitoring devices is processed and analyzed by the ZEUS System. A final report is generated on the beat-to-beat information from the entire ECG recording. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

INDICATIONS FOR USE

The ZEUS System is indicated for use on patients 18 years or older who may be symptomatic and asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment and experience. It is not intended for use on critical care patients.

INTENDED PATIENT POPULATION

Adults 18 years and older. Patients who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety and patients who are asymptomatic.

USE ENVIROMENT

iRhythm Facility only for ZEUS

INTENDED USER

Physician, Healthcare Provider

CONTRAINDICATIONS

- Do not use the ZEUS System for critical care patients.
- Do not use ZEUS 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 ZEUS for patients with known history of life-threatening arrhythmias.

WARNINGS

- Registration errors may result in limited functionality or erroneous ECG reporting. Utmost caution should be taken to ensure that the patient registration is accurate and complete.

NOTICE OF PRIVACY PRACTICES

iRhythm Technologies is committed to upholding patient privacy and protecting the privacy of personal information, in particular health information collected and processed in conjunction with the Zio® Service. For detailed information on how iRhythm processes personal data and how to contact us to enforce your privacy rights please visit: <https://irhythmtech.co.uk/patient-notice/>

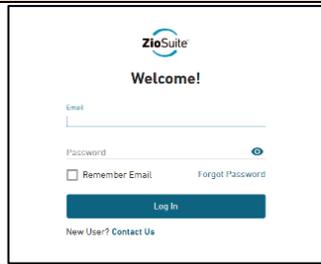
ZIOSUITE APPLICATIONS

Prior to accessing ZioSuite, a user account must be setup by your site administrator.

LOGIN

ZioSuite Website

1. Open a browser and go to www.ziosuite.co.uk
2. Enter email address and password, and then select “Log In”.



The screenshot shows the ZioSuite login interface. At the top, the ZioSuite logo is displayed above the text "Welcome!". Below this, there are two input fields: "Email" and "Password". The "Password" field includes a toggle icon for visibility. Under the "Password" field, there are two links: "Remember Email" (with an unchecked checkbox) and "Forgot Password". A dark blue "Log In" button is positioned below the input fields. At the bottom of the form, there is a link that reads "New User? Contact Us".

DASHBOARD

ZioSuite Website

Based on your user role, a targeted dashboard will be displayed. Below are the short list and actions available.

Allied Health Professionals

- Register Patient
- Posted Final Reports (Download, Print, or Archive Report)
- Unregistered Monitors
- Active Patients
- Reports Pending Interpretation (Print or Download)

Physicians

- Reports Pending Interpretation (Assign, Print, Download)
- Posted Final Reports (Download, Print, or Archive Report)
- My Interpretation History (Print or Download Report)
- Active Patients

ENROLMENT

ZioSuite Website

1. Enrol a patient and create a registration for the Zio Service by clicking “Register Patient” button on the Dashboard (or select Registrations->New Registration menu item).
2. Select the account location and type of enrolment (In-Clinic or Zio Direct to Patient)
3. Provide the enrolment details. All fields are required to be provided unless (Optional) indicated.
4. After providing all required fields, select ‘Complete Registration’ to finish enrolment. At any time the ‘Cancel’ option can be selected to exit out of an enrolment. Select ‘Save As Draft’ in the event you want to save fields entered but have not yet filled in all required fields.

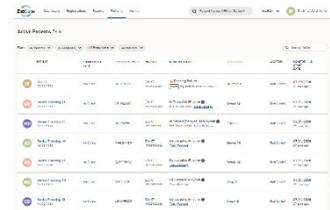
The screenshot shows the 'Register Patient' button at the top. Below it is the 'Start Registration' section with a 'Location' dropdown menu set to 'TestClinic1' and 'Enrolment Type' radio buttons for 'In-Clinic' (selected) and 'Home'. The main form area is titled 'New Registration' and contains several sections: 'PATIENT INFORMATION' with fields for Name, Date of Birth, and Gender; 'ADDRESS INFORMATION' with fields for Address, City, State, and Zip; 'CONTACT INFORMATION' with fields for Phone and Email; 'REGISTRATION INFORMATION' with fields for Registration Number, Start Date, and End Date; and 'ZIO INFORMATION' with fields for Zio Device, Zio Lead, and Zio Service. At the bottom, there are three buttons: 'Cancel', 'Save As Draft', and 'Complete Registration'.

PATIENT DETAIL

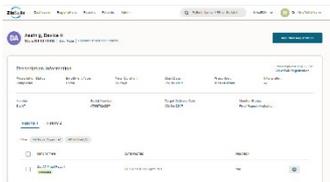
ZioSuite Website

1. To access the detailed view of a patient record select the Patients->Active Patient or Patients->All Patients menu option.
2. Scroll through the patient list and select the name of the patient record of interest. Note: If unable to locate the patient, type the name into the search window and select the name.
3. The following information is provided in the Patient Detail screen:
 - Patient Demographics
 - Prescriptions
 - Prescription Clinical Reports

Note: Clinical Report can be viewed by selecting the link.



The screenshot shows the ZioSuite website interface. At the top, there are navigation tabs: "Patients", "Prescriptions", "Reports", "Profile", and "Help". Below the navigation is a search bar and a "Log Out" button. The main content area displays a table of patient records. The table has columns for "Patient ID", "Patient Name", "DOB", "Gender", "Race", "Ethnicity", "Address", "City", "State", "Zip", "Phone", and "Email". The table contains several rows of patient data, including names like "John Doe" and "Jane Smith".

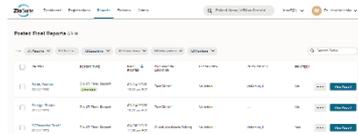


The screenshot shows the ZioSuite website interface for a patient detail view. At the top, there are navigation tabs: "Patients", "Prescriptions", "Reports", "Profile", and "Help". Below the navigation is a search bar and a "Log Out" button. The main content area displays the patient detail screen for "John Doe". The screen shows the patient's name, ID, and a "View Profile" button. Below this, there are sections for "Patient Demographics", "Prescriptions", and "Prescription Clinical Reports". The "Prescription Clinical Reports" section is currently selected and shows a list of reports with columns for "Report ID", "Report Name", "Report Date", and "Report Status".

REPORT ACCESS

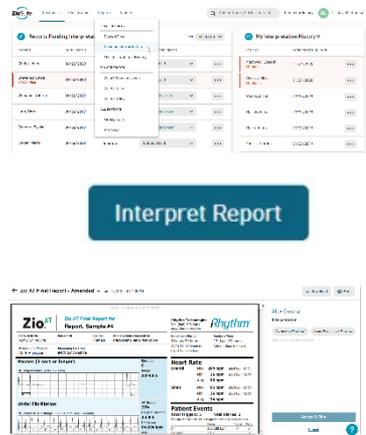
ZioSuite Website

1. To access a clinical report select the Reports->REPORT TYPE menu option.
2. Scroll through the report list and select "View Report" of the report of interest.
3. Upon selection the Clinical Report will be visible with options to download the Report.



REPORT INTERPRETATION

1. To interpret a clinical report select the Reports->Pending Interpretation menu option.
2. Scroll through the report list and select “Interpret Report” of the report of interest.
3. Upon selection the Clinical Report will be visible with options to indicate “Agree with Findings”, “Insert Preliminary Findings”, as well as to enter physician interpretation.
4. Select ‘Accept & Sign’ to incorporate an electronically signed interpretation into the report PDF.



USER MANAGEMENT

ZioSuite Website

Add User

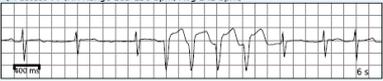
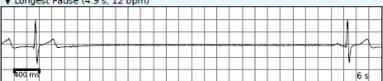
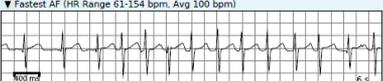
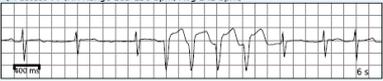
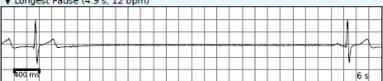
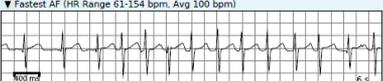
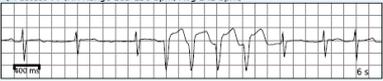
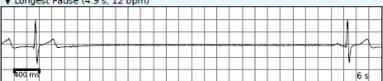
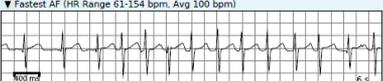
1. To add a user select the Admin->Add New User menu option.
2. Fill-in the user registration details and select the 'Register' option.



REPORT TYPES

Final Report

The Final Report is a comprehensive, end-of-wear PDF report showing the findings from the recording. Preliminary findings are provided for clinician review.

<p>Patient Demographics</p> <ul style="list-style-type: none"> • Patient Name • Date of Birth • Patient ID • Gender • Primary Indication • Prescribing Clinician <p>If applicable</p> <ul style="list-style-type: none"> • Managing Location • Referring Physician 	<div style="text-align: center;">  <p>Zio XT Final Report for Report, Patient #16</p> </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 25%;">Date of Birth 12/12/67 (51 yrs)</td> <td style="width: 25%;">Patient ID</td> <td style="width: 25%;">Gender Female</td> <td style="width: 25%;">Primary Indication (R94.31) Abnormal electrocardiogram</td> </tr> <tr> <td>Prescribing Clinician Dr. E. Physician</td> <td colspan="3">Managing Location San Francisco</td> </tr> </table>	Date of Birth 12/12/67 (51 yrs)	Patient ID	Gender Female	Primary Indication (R94.31) Abnormal electrocardiogram	Prescribing Clinician Dr. E. Physician	Managing Location San Francisco																				
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<p>Enrolment Details</p> <ul style="list-style-type: none"> • Enrolment Period • Analysis Time 	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Enrollment Period</td> <td style="width: 50%;">Analysis Time</td> </tr> <tr> <td>13 days 19 hours</td> <td>13 days 19 hours</td> </tr> <tr> <td>03/22/19, 05:24am to</td> <td>(after artifact removed)</td> </tr> <tr> <td>04/05/19, 12:40am</td> <td></td> </tr> </table>	Enrollment Period	Analysis Time	13 days 19 hours	13 days 19 hours	03/22/19, 05:24am to	(after artifact removed)	04/05/19, 12:40am																			
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<p>Arrhythmia Summary</p> <ul style="list-style-type: none"> • Ventricular Fibrillation/Torsades de Pointes/Polymorphic VT • Ventricular Tachycardia • Pauses • Atrial Fibrillation/Flutter • AV Block (2nd Mobitz II, 3rd) • Supraventricular Tachycardia 	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Ventricular Tachycardia (4 beats or more)</td> <td style="width: 20%;">Episodes 5</td> </tr> <tr> <td>▼ Fastest VT (HR Range 135-150 bpm, Avg 142 bpm)</td> <td>HR Range 116-150 bpm</td> </tr> <tr> <td></td> <td>Avg 132 bpm</td> </tr> <tr> <td>Pauses (3 secs or longer)</td> <td>Episodes 3</td> </tr> <tr> <td>▼ Longest Pause (4.9 s, 12 bpm)</td> <td>Range 3.9-4.9 s</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td>Atrial Fibrillation</td> <td>AF Burden 37%</td> </tr> <tr> <td>▼ Fastest AF (HR Range 61-154 bpm, Avg 100 bpm)</td> <td>Longest Duration 1 d 19 h</td> </tr> <tr> <td></td> <td>HR Range 50-154 bpm</td> </tr> <tr> <td></td> <td>Avg 97 bpm</td> </tr> <tr> <td>AV Block (2nd° Mobitz II, 3rd°)</td> <td></td> </tr> <tr> <td colspan="2" style="text-align: center;">None found</td> </tr> <tr> <td>Supraventricular Tachycardia (4 beats or more)</td> <td>None found</td> </tr> </table>	Ventricular Tachycardia (4 beats or more)	Episodes 5	▼ Fastest VT (HR Range 135-150 bpm, Avg 142 bpm)	HR Range 116-150 bpm		Avg 132 bpm	Pauses (3 secs or longer)	Episodes 3	▼ Longest Pause (4.9 s, 12 bpm)	Range 3.9-4.9 s			Atrial Fibrillation	AF Burden 37%	▼ Fastest AF (HR Range 61-154 bpm, Avg 100 bpm)	Longest Duration 1 d 19 h		HR Range 50-154 bpm		Avg 97 bpm	AV Block (2nd° Mobitz II, 3rd°)		None found		Supraventricular Tachycardia (4 beats or more)	None found
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<p>Heart Rate Summary</p> <ul style="list-style-type: none"> Overall maximum, minimum and average heart rate Sinus maximum, minimum and average heart rate 	<p>Heart Rate</p> <table border="1"> <tr> <td>Overall</td> <td>Max</td> <td>154 bpm</td> <td>09:49am, 03/25</td> </tr> <tr> <td></td> <td>Min</td> <td>50 bpm</td> <td>11:59pm, 03/22</td> </tr> <tr> <td></td> <td>Avg</td> <td>78 bpm</td> <td></td> </tr> <tr> <td>Sinus</td> <td>Max</td> <td>96 bpm</td> <td>11:14am, 03/24</td> </tr> <tr> <td></td> <td>Min</td> <td>50 bpm</td> <td>11:59pm, 03/22</td> </tr> <tr> <td></td> <td>Avg</td> <td>66 bpm</td> <td></td> </tr> </table>	Overall	Max	154 bpm	09:49am, 03/25		Min	50 bpm	11:59pm, 03/22		Avg	78 bpm		Sinus	Max	96 bpm	11:14am, 03/24		Min	50 bpm	11:59pm, 03/22		Avg	66 bpm																					
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<p>Patient Events Summary</p> <ul style="list-style-type: none"> Count of trigger events Count of diary events Range of findings for each event type 	<p>Patient Events</p> <p>Total Triggers: 2 Total Diaries: 1</p> <p>Findings within ± 45 sec of triggered events or diary entries:</p> <table border="1"> <thead> <tr> <th></th> <th>Range</th> <th>Trigger</th> <th>Diary</th> </tr> </thead> <tbody> <tr> <td>AF</td> <td>59-126 bpm</td> <td>✓</td> <td>✓</td> </tr> <tr> <td>Pause(s)</td> <td>3.9 s</td> <td>✓</td> <td></td> </tr> <tr> <td>Sinus</td> <td>56-73 bpm</td> <td>✓</td> <td></td> </tr> <tr> <td>SVE(s)</td> <td></td> <td>✓</td> <td></td> </tr> <tr> <td>VE(s)</td> <td></td> <td></td> <td>✓</td> </tr> </tbody> </table>		Range	Trigger	Diary	AF	59-126 bpm	✓	✓	Pause(s)	3.9 s	✓		Sinus	56-73 bpm	✓		SVE(s)		✓		VE(s)			✓																				
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<p>Ectopic Beats Summary</p> <ul style="list-style-type: none"> Supraventricular ectopy Ventricular Ectopy 	<p>Ectopics</p> <table border="1"> <thead> <tr> <th></th> <th>Rare <1%</th> <th>Occasional 1% to ≤5%</th> <th>Frequent >5%</th> </tr> </thead> <tbody> <tr> <td colspan="4">Supraventricular Ectopy (SVE/PACs)</td> </tr> <tr> <td>Isolated</td> <td>Rare</td> <td><1.0%</td> <td>6723</td> </tr> <tr> <td>Couplet</td> <td>Rare</td> <td><1.0%</td> <td>141</td> </tr> <tr> <td>Triplet</td> <td>Rare</td> <td><1.0%</td> <td>9</td> </tr> <tr> <td colspan="4">Ventricular Ectopy (VE/PVCs)</td> </tr> <tr> <td>Isolated</td> <td>Rare</td> <td><1.0%</td> <td>1716</td> </tr> <tr> <td>Couplet</td> <td>Rare</td> <td><1.0%</td> <td>192</td> </tr> <tr> <td>Triplet</td> <td>Rare</td> <td><1.0%</td> <td>26</td> </tr> <tr> <td>Longest Ventricular Bigeminy Episode</td> <td></td> <td></td> <td>0 s</td> </tr> <tr> <td>Longest Ventricular Trigeminy Episode</td> <td></td> <td></td> <td>0 s</td> </tr> </tbody> </table>		Rare <1%	Occasional 1% to ≤5%	Frequent >5%	Supraventricular Ectopy (SVE/PACs)				Isolated	Rare	<1.0%	6723	Couplet	Rare	<1.0%	141	Triplet	Rare	<1.0%	9	Ventricular Ectopy (VE/PVCs)				Isolated	Rare	<1.0%	1716	Couplet	Rare	<1.0%	192	Triplet	Rare	<1.0%	26	Longest Ventricular Bigeminy Episode			0 s	Longest Ventricular Trigeminy Episode			0 s
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<p>Preliminary Findings</p> <ul style="list-style-type: none"> Summary text of findings 	<p>Preliminary Findings</p> <p>Patient had a min HR of 50 bpm, max HR of 154 bpm, and avg HR of 78 bpm. Predominant underlying rhythm was Sinus Rhythm. 5 Ventricular Tachycardia runs occurred, the run with the fastest interval lasting 4 beats with a max rate of 150 bpm, the longest lasting 4 beats with an avg rate of 127 bpm. Episodes of Ventricular Tachycardia may be possible Atrial Fibrillation with aberrancy. Atrial Fibrillation occurred (37% burden), ranging from 50-154 bpm (avg of 97 bpm), the longest lasting 1 day 19 hours with an avg rate of 97 bpm. 3 Pauses occurred, the longest lasting 4.9 secs (12 bpm). Atrial Fibrillation and Pause were detected within +/- 45 seconds of symptomatic patient event(s). Isolated SVEs were rare (<1.0%, 6723), SVE Couplets were rare (<1.0%, 141), and SVE Triplets were rare (<1.0%, 9). Isolated VEs were rare (<1.0%, 1716), VE Couplets were rare (<1.0%, 192), and VE Triplets were rare (<1.0%, 26).</p>																																												
<p>Final Findings</p> <ul style="list-style-type: none"> Clinician interpretation 	<p>Final Interpretation</p> <ol style="list-style-type: none"> Agree with above interpretation Underlying Sinus rhythm with normal rates average =78/min 5 runs of VT some of which could be AF with aberrancy Atrial fibrillation with 37% burden and longest run of 42 hours Pauses of up to 4.9 seconds likely post conversion related Triggered events consistent with AF, Pauses <p>Electronically signed by Dr. Example Physician 04/12/19 06:18 PM (CT)</p> <p style="text-align: right;">SIGNATURE</p>																																												

RHYTHM DETECTION

The algorithm can analyse up to 14 days of data and detect the following rhythms:

- Ventricular fibrillation
- Atrial fibrillation/flutter
- Supraventricular tachycardia
- Ventricular tachycardia
- Idioventricular rhythm
- Pause ≥ 3 seconds
- Sinus rhythm (normal rhythm)
- Ectopic atrial rhythm
- Junctional rhythm
- Ventricular bigeminy
- Ventricular trigeminy
- Complete heart block
- Second degree AV block type II
- Second degree AV block type I (Wenckebach)

Arrhythmias noted in addition to this list and included in the end-of-wear report are observations from the Qualified ECG Specialist.

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)

UKCA MARK INFORMATION

COMPLIANCE



The Zio® ECG Monitoring System bears the UKCA marking UKCA-0086, indicating its conformity with the provisions in Part II of the UK MDR 2002 (as amended) concerning general medical devices and fulfills the essential requirements of Annex I of EU Council Directive 93/42/EEC.

The medical device has been assigned to Class IIa in accordance with the classification criteria set out in Annex IX of EU Council Directive 93/42/EEC.

SYMBOLS

 Serial Number	 Catalogue number	 Prescription use only
 Manufacturer	 Date of manufacture	 Net quantity of contents
 Consult instructions for use	 UK Responsible Person	

TROUBLESHOOTING

FOR CUSTOMER CARE, CALL **0808 189 3411**

iRhythm Technologies Ltd.

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56 London Road
Bagshot
Surrey
GU19 5HL
Tel: 0808 189 3411
Fax: 0808 189 3303
Email: supportuk@irhythmtech.com
irhythmtech.co.uk



iRhythm Technologies, Inc.

699 8th St., Suite 600
San Francisco, CA 94103 USA



Emergo Consulting (UK) Limited

c/o Cr360 - UL International
Compass House
Vision Park, Histon
Cambridge CB24 9BZ
United Kingdom



iRhythm™