



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/>

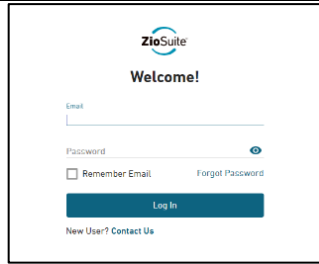
ZIOSUITE APPLICATIONS

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 blue "Log In" button is positioned below the input fields. At the bottom of the form, there is a link for "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

The screenshot shows the Allied Health Professionals dashboard. It features a navigation bar at the top with 'Home', 'Patients', 'Reports', 'Interpretation', and 'Tools'. Below this, there are three main sections:

- Posted Final Reports:** A table with columns for Patient ID, Patient Name, Report ID, Report Date, and Report Status. It includes a 'Download' button for each row.
- Reports Pending Interpretation:** A table with columns for Patient ID, Patient Name, Report ID, Report Date, and Report Status. It includes 'Print' and 'Download' buttons for each row.
- Unregistered Monitors:** A table with columns for Patient ID, Patient Name, Monitor ID, and Monitor Status. It includes a 'Register' button for each row.

The screenshot shows the Physicians dashboard. It features a navigation bar at the top with 'Home', 'Patients', 'Reports', 'Interpretation', and 'Tools'. Below this, there are four main sections:

- Reports Pending Interpretation:** A table with columns for Patient ID, Patient Name, Report ID, Report Date, and Report Status. It includes 'Assign', 'Print', and 'Download' buttons for each row.
- Posted Final Reports:** A table with columns for Patient ID, Patient Name, Report ID, Report Date, and Report Status. It includes 'Download', 'Print', and 'Archive' buttons for each row.
- My Interpretation History:** A table with columns for Patient ID, Patient Name, Report ID, Report Date, and Report Status. It includes 'Print' and 'Download' buttons for each row.
- Active Patients:** A table with columns for Patient ID, Patient Name, and Patient Status. It includes a 'View' button for each row.

ENROLMENT

ZioSuite Website

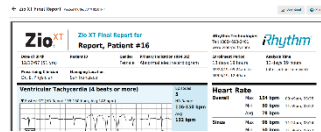
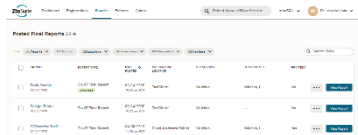
1. Enrol a patient and create a registration for the Zio Service by clicking “Register Patient” button on the Dashboard (or select Registrations->New Registration menu item).
2. Select the account location and type of enrolment (In-Clinic or Zio Direct to Patient)
3. Provide the enrolment details. All 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 displays the 'Register Patient' interface. At the top, there is a prominent blue button labeled '+ Register Patient'. Below this, the 'Start Registration' section includes a 'Location' dropdown menu currently set to 'TestClinic1' and an 'Enrollment Type' section with radio buttons for 'In-Clinic' (selected) and 'Home'. The main form area is titled 'New Registration' and is divided into several sections: 'PATIENT INFORMATION' (Name, DOB, Gender, Race, Ethnicity, Address, City, State, Zip, Phone, Email, SSN, Mailing Address), 'PHYSICIAN INFORMATION' (Physician Name, Address, City, State, Zip, Phone, Email), 'REGISTRATION INFORMATION' (Registration Type, Start Date, End Date, Renewal Date, Renewal Frequency, Renewal Day, Renewal Time, Renewal Location, Renewal Notes), and 'PATIENT INFORMATION' (Patient Name, Address, City, State, Zip, Phone, Email, SSN, Mailing Address). At the bottom of the form, there are three buttons: 'Cancel', 'Save As Draft', and 'Complete Registration'.

REPORT ACCESS

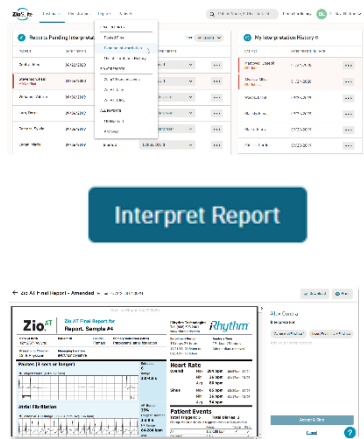
ZioSuite Website

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.

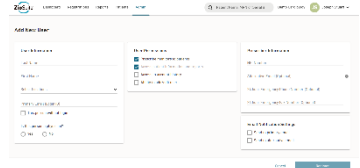


USER MANAGEMENT

ZioSuite Website

Add User


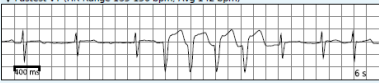
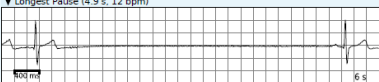
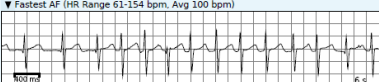
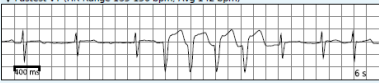
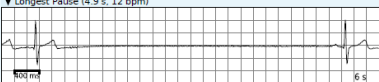
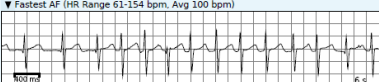
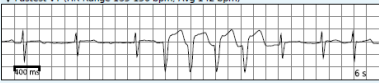
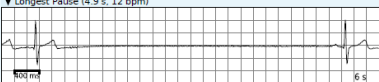
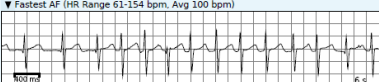
1. To add a user select the Admin->Add New User menu option.
2. Fill-in the user registration details and select the 'Register' option.



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;">  Zio XT Final Report for Report, Patient #16 </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="font-size: small;">Date of Birth 12/12/67 (51 yrs)</td> <td style="font-size: small;">Patient ID</td> <td style="font-size: small;">Gender Female</td> <td style="font-size: small;">Primary Indication (R94.31) Abnormal electrocardiogram</td> </tr> <tr> <td style="font-size: small;">Prescribing Clinician Dr. E. Physician</td> <td colspan="3" style="font-size: small;">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 style="width: 100%;"> <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 style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 80%;">Ventricular Tachycardia (4 beats or more)</td> <td style="width: 20%; font-size: small;">Episodes 5</td> </tr> <tr> <td style="font-size: x-small;">▼ Fastest VT (HR Range 135-150 bpm, Avg 142 bpm)</td> <td style="font-size: small;">HR Range 116-150 bpm</td> </tr> <tr> <td></td> <td style="font-size: small;">Avg 132 bpm</td> </tr> <tr> <td>Pauses (3 secs or longer)</td> <td style="font-size: small;">Episodes 3</td> </tr> <tr> <td style="font-size: x-small;">▼ Longest Pause (4.9 s, 12 bpm)</td> <td style="font-size: small;">Range 3.9-4.9 s</td> </tr> <tr> <td></td> <td></td> </tr> <tr> <td>Atrial Fibrillation</td> <td style="font-size: small;">AF Burden 37%</td> </tr> <tr> <td style="font-size: x-small;">▼ Fastest AF (HR Range 61-154 bpm, Avg 100 bpm)</td> <td style="font-size: small;">Longest Duration 1 d 19 h</td> </tr> <tr> <td></td> <td style="font-size: small;">HR Range 50-154 bpm</td> </tr> <tr> <td></td> <td style="font-size: small;">Avg 97 bpm</td> </tr> <tr> <td>AV Block (2nd° Mobitz II, 3rd°)</td> <td></td> </tr> <tr> <td style="border: 1px solid black; height: 40px; text-align: center;">None found</td> <td></td> </tr> <tr> <td>Supraventricular Tachycardia (4 beats or more)</td> <td style="font-size: small;">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	 Do not use if package is damaged

TROUBLESHOOTING

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

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