ZIO® BY iRHYTHM

Zio® ECG Utilization Software (ZEUS) Instructions for Use

Rx ONLY

Depictions of screens or reports included in this manual are examples only.

Features available are dependent on your account settings.

Contents

DESCRIPTION

The ZioSuite® web portal and ZioSuite® mobile application are for healthcare professionals to manage and streamline clinical workflows associated with the Zio service. The Zio system consists of a long-term cardiac recording using a prescribed Zio device in combination with Zio ECG Utilization Software (ZEUS), a software system utilizing proprietary deep-learned algorithms for data analysis.

The ZioSuite software module within the ZEUS System offers capabilities to enroll patients into the Zio service, access clinical reports, manage/perform clinical report interpretation, and administer user settings/access.

INDICATIONS FOR 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. For the Zio AT service, the ZEUS System supports the capture and analysis of automatically-detected arrhythmia events, as well as the analysis of uploaded patient-triggered events.

The ZEUS System is indicated for use on 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 and patients who are asymptomatic. 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
18 years or older

Intended Use Environment
Professional use only

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.
- QT interval measurements from the ZEUS System are not intended to replace measurements from a 12-lead ECG. The ZEUS System does not independently diagnose drug-induced QT interval changes or QT interval prolongation.

WARNINGS

- The Zio AT device has a maximum limit of transmitting symptomatic (patient-triggered) and asymptomatic (auto-triggered) cardiac events.
  - Asymptomatic cardiac events are transmitted until the maximum limit of 500 transmissions is reached. When the transmission limit is reached, the asymptomatic cardiac events are no longer sent for review during wear.
  - Symptomatic cardiac events are transmitted until the maximum limit of 100 transmissions is reached. When the transmission limit is reached, the symptomatic cardiac events are no longer sent for review during wear.

  If a transmission limit is reached, the Zio AT monitor continues to record ECG data, including symptomatic and asymptomatic cardiac events. The data will be fully analyzed and included in the end-of-wear report.

  When the patient is approaching a maximum transmission limit, Customer Care contacts the prescribing physician's office and the patient to send the patient an additional Zio AT device.

- If a Zio AT device is activated before completing patient registration, notifications of clinically actionable arrhythmias will be delayed. To avoid delays, complete the patient registration prior to activating the Zio AT device. A completed patient registration is the prescription order for continuous ambulatory electrocardiogram (ECG) monitoring.

PRECAUTIONS

- ZEUS System QT interval measurements are likely to underestimate the global QT measurement from a 12-lead ECG. The user should consider this when interpreting the ZEUS System QT measurements.
- AF/AFL burden estimates presented during wear in the Daily Report are algorithm generated estimates. However, AF burden presented in the Final Report is human reviewed.

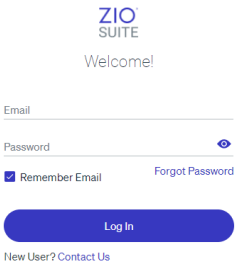
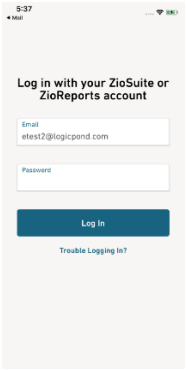
NOTICE OF PRIVACY PRACTICES

iRhythm is committed to upholding patient privacy and protecting personal information, in particular Protected Health Information (PHI) collected and processed in conjunction with our Zio Service. We commit to complying with all applicable privacy laws and allowing patients to exercise their rights via their doctor. Our full Notice of Privacy Practices, found at **https://www.irhythmtech.com/content/privacy** describes our privacy practices, our legal duties, and patients' rights concerning PHI.

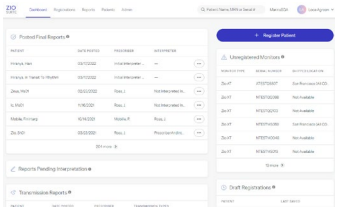
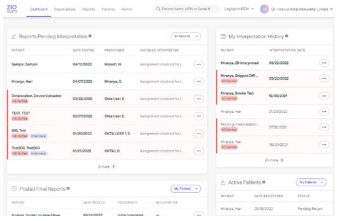
ZIOSUITE APPLICATIONS

Prior to accessing ZioSuite, a user account must be setup by your site administrator. The ZioSuite mobile application can be accessed by iPhone devices at the Apple App store and for Android devices using Google Play.

LOGIN

ZioSuite Website	
1. Open a browser and go to www.ziosuite.com. 2. Enter email address and then select “Continue”. 3. Enter password and then select “Log In”.	
ZioSuite Mobile Application	
1. Select the ZioSuite app icon on your mobile phone. 2. Enter email address and password, and then select “Log In”.	 

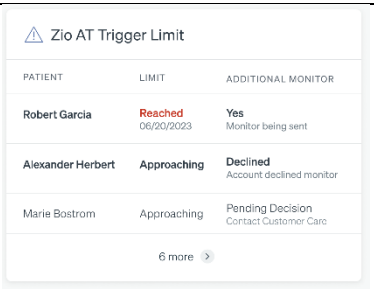
DASHBOARD

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 • Zio AT Trigger Limit [Zio AT only]* • Active Patients • Reports Pending Interpretation (Print or Download) • Transmission Reports (Download, Print, or Archive Report) [Zio AT Only] **Physicians** • Reports Pending Interpretation (Assign, Print, Download) • Posted Final Reports (Download, Print, or Archive Report) • My Interpretation History (Print or Download Report) • Zio AT Trigger Limit [Zio AT only]* • Active Patients • Transmission Reports (Download, Print, or Archive Report) [Zio AT Only] *Displays names of patients wearing the Zio AT patch who are approaching or have reached the trigger limit.	 
Zio AT Trigger Limit [Zio AT only] • **Reached** indicates the patient has reached one of the thresholds for maximum transmissions.	

- **Approaching** indicates the patient is nearing a maximum threshold.
- **Additional monitor** provides information about an additional monitor that may be sent to this patient.
  - **Yes** indicates an additional monitor is being sent to the patient.
  - **Pending Decision Contact Customer Care** indicates the patient is approaching a maximum threshold and Customer Care will contact the prescribing physician's office. If you have questions, contact Customer Care.
  - **Declined** indicates the prescribing physician's office declined the additional monitor.

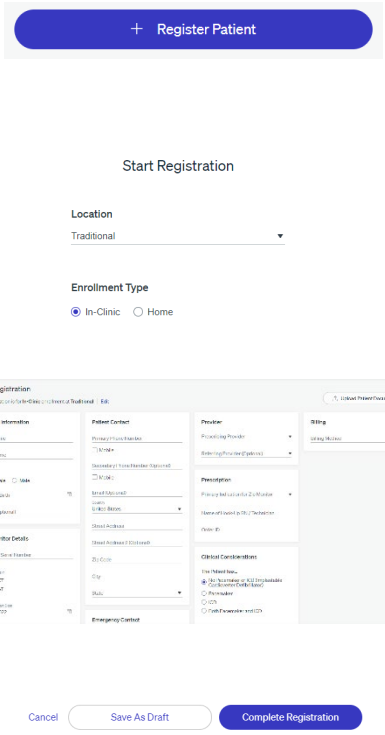
When an additional Zio AT device is activated, the patient is removed from the trigger limit dashboard.

See pages 20 to 22 for more details on trigger limits.

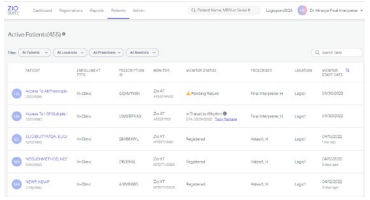
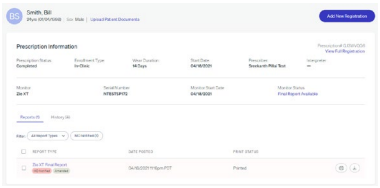


ZioSuite Mobile Application	
Located at the bottom of the application, dashboard allows the user to switch to one of the following screens: • **Reports:** List of accessible final reports. • **Interpret:** List of reports available to the logged in user pending interpretation. • **Transmissions (Zio AT Only):** List of Transmission Reports. • **Patients:** List of patient records accessible to the logged in user. • **Settings:** Change Password, PIN/Face ID Setup, Call/Email Customer Support	

ENROLLMENT

ZioSuite Website	
1. Select “+ Register Patient” on the Dashboard. Or, select “Patients>+Register Patient” from the menu. 2. Select the account location. 3. For “Enrollment Type,” select “In-Clinic” or “Home” and select “Next.” 4. Provide the enrollment details. Entries in all fields are required unless “(Optional)” is indicated. 5. To submit a completed registration, select “Complete Registration”. 6. To save entries for later completion, create a draft registration and enter only the “Last Name”, “First Name”, “Sex”, and “Date of Birth”, then select “Save As Draft”. 7. To exit registration without saving changes, select “Cancel”.	

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.	 

ZioSuite Mobile Application

1. To access the detailed view of a patient record, select the Patients tab.

2. Scroll through the patient list and select the name of the patient record of interest.

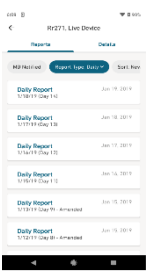
   Note: If unable to locate the patient, type the name into the search window and select the name.

3. The following information is provided in the Patient Detail screen:

   - Patient Demographics
   - Prescriptions

4. Click on a Prescription to access associate reports and Rx details.

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



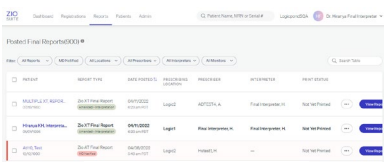
REPORT ACCESS

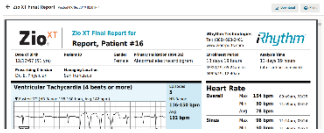
ZioSuite Website

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.



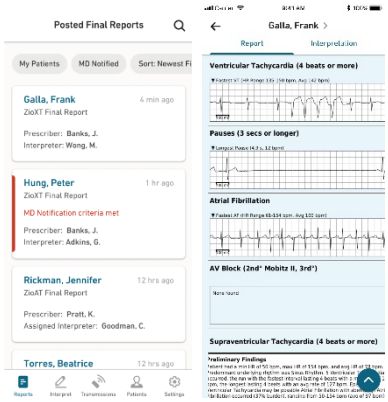


ZioSuite Mobile Application

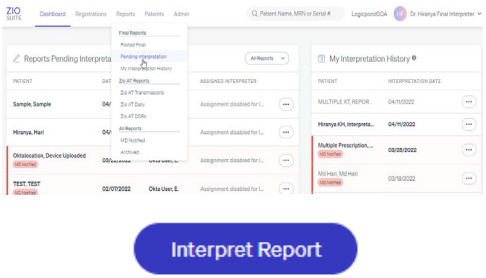
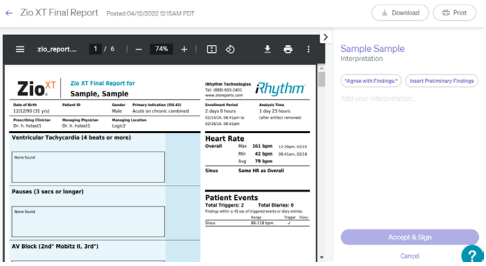
1. To access a clinical report, select the Report tab.

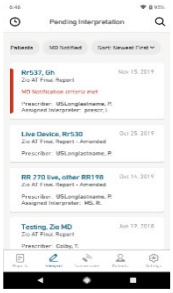
2. Scroll through the report list and select tab of interest. Note: If unable to locate the patient, type the patient name into the search window and select the associated tab.

3. Upon selection, the Clinical Report will be visible with options to view the Report and the associated interpretation.



REPORT INTERPRETATION

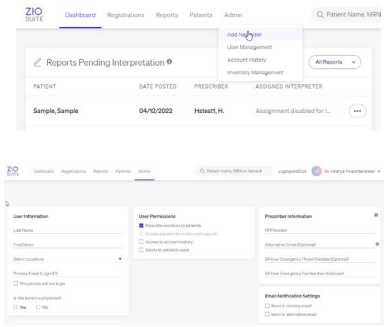
ZioSuite Website	
1. To interpret a clinical report, select the “Reports>Pending Interpretation” menu option. 2. Scroll through the report list and select “Interpret Report” of the report of interest. 3. Upon selection, the Clinical Report will be visible with options to indicate “Agree with Findings”,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

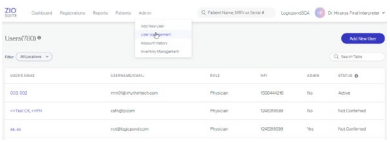
ZioSuite Mobile Application	
1. To interpret a clinical report, select the Interpret tab. 2. Scroll through the report list and select report of interest. 3. Upon selection, the Clinical Report will be visible with options to indicate “Agree with Findings”, “Insert Preliminary Findings”, as well as to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

USER MANAGEMENT

<table>
<tr><th colspan="2">ZioSuite Website</th></tr>
<tr><td>Add User

1. To add a user, select the “Admin>Add New User” menu option.

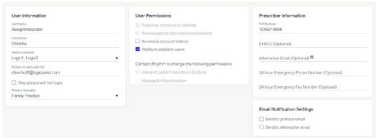
2. Fill-in the user registration details and select the “Register” option.</td><td>  </td></tr>
<tr><td>User List

1. To view the list of users, select the “Admin>User Management” menu option.</td><td>  </td></tr>
<tr><td>Deactivate/Activate User Account

1. Select the “Admin>User Management” menu option to view the list of users.

2. Select the user name of interest.

3. Select “Activate” to activate an inactive user.

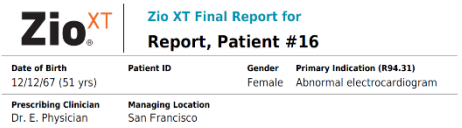
4. Select “Deactivate” to make a user inactive and unable to access ZioSuite web and mobile application.</td><td> 
 
  </td></tr>
</table>

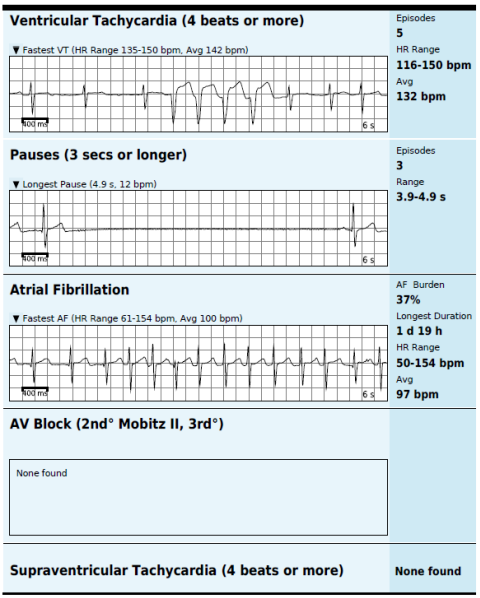
REPORT TYPES

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.

<table>
<tr>
<td>Patient Demographics
• Patient Name
• Date of Birth
• Patient ID
• Gender
• Primary Indication
• Prescribing Clinician

If applicable
• Managing Location
• Referring Physician</td>
<td> 
</td>
</tr>
<tr>
<td>Enrollment Details
• Enrollment Period
• Analysis Time</td>
<td>Enrollment Period
13 days 19 hours
03/22/19, 05:24am to
04/05/19, 12:40am

Analysis Time
13 days 19 hours
(after artifact removed)</td>
</tr>
<tr>
<td>Arrhythmia Summary
• Ventricular Fibrillation/Torsades de Pointes/Polymorphic VT
• Ventricular Tachycardia
• Pauses
• Atrial Fibrillation/Flutter
• AV Block (2nd Mobitz II, 3rd)
• Supraventricular Tachycardia</td>
<td> 
</td>
</tr>
</table>

Heart Rate Summary

- Overall maximum, minimum and average heart rate
- Sinus maximum, minimum and average heart rate

Heart Rate

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**	

Patient Events Summary

- Count of trigger events
- Count of diary events
- Range of findings for each event type

Patient Events

Total Triggers: 2 **Total Diaries: 1**

Findings within ± 45 sec of triggered events or diary entries:

	Range	Trigger	Diary
AF	59-126 bpm	✓	✓
Pause(s)	3.9 s	✓	
Sinus	56-73 bpm	✓	
SVE(s)		✓	
VE(s)			✓

Ectopic Beats Summary

- Supraventricular Ectopy
- Ventricular Ectopy

Ectopics

		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

Preliminary Findings

- Summary text of findings

Preliminary Findings

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).

Final Findings

- Clinician interpretation

Final Interpretation

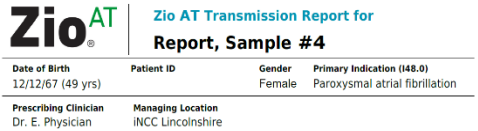
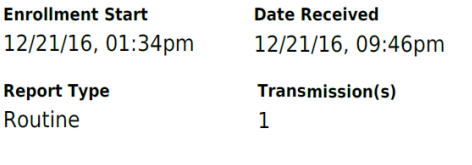
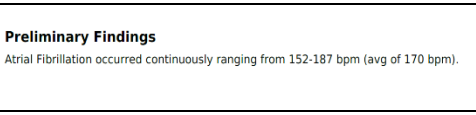
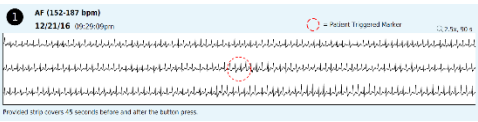
1. Agree with above interpretation
2. Underlying Sinus rhythm with normal rates average =78/min
3. 5 runs of VT some of which could be AF with aberrancy
4. Atrial fibrillation with 37% burden and longest run of 42 hours
5. Pauses of up to 4.9 seconds likely post conversion related
6. Triggered events consistent with AF, Pauses

Electronically signed by Dr. Example Physician 04/12/19 06:18 PM (CT)

SIGNATURE

Transmission Report

Transmission Reports are provided for asymptomatic, symptomatic, scheduled, and baseline transmission events during the wear period of the Zio AT service only.

<table>
<tr>
<td>Patient Demographics
• Patient Name
• Date of Birth
• Patient ID
• Gender
• Primary Indication
• Prescribing Clinician
If applicable
• Managing Location
• Referring Physician</td>
<td> 
</td>
</tr>
<tr>
<td>Enrollment Details
• Enrollment Start
• Date Received
• Report Type
• Transmission Count</td>
<td> 
</td>
</tr>
<tr>
<td>Preliminary Findings
• Summary text of findings</td>
<td> 
</td>
</tr>
<tr>
<td>Transmission Strip
• 90-second transmission</td>
<td> 
</td>
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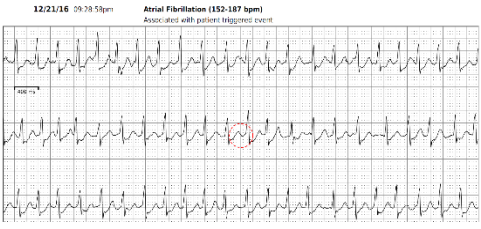
<tr>
<td>Additional Strips
• Enlarged segments of ECG</td>
<td> 
</td>
</tr>
</table>

Daily Report

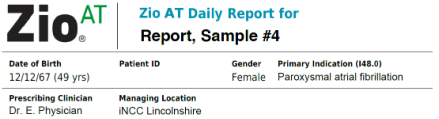
The Daily Report provides a recap of events detected and reported for the previous day. Daily Reports are available with the Zio AT service only.

Patient Demographics

- Patient Name
- Date of Birth and Age
- Patient ID
- Gender
- Primary Indication
- Prescribing Clinician

If applicable

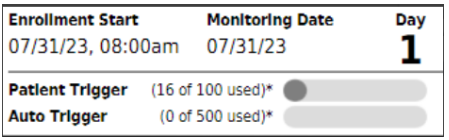
- Managing Location
- Referring Physician

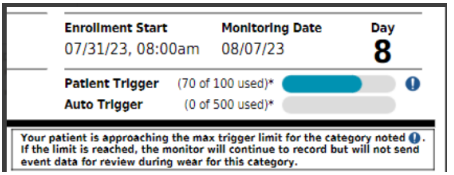
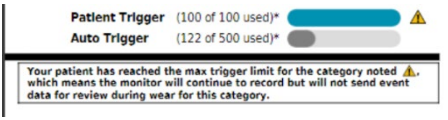
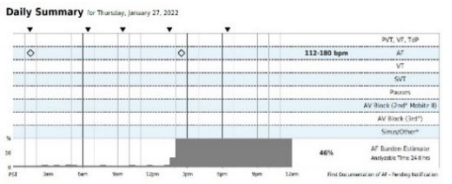


Enrollment Details

The following information is included in the report header on the first page of the Daily Report:

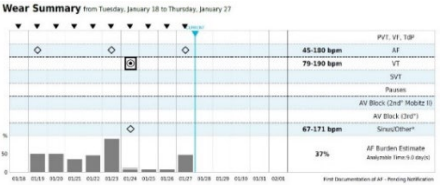
- Enrollment Start
- Monitoring Date
- Number of days since activation
- Trigger limit indicators for the quantity of triggers utilized and available for each category:
  - Patient Trigger (symptomatic triggers)
  - Auto Trigger (asymptomatic triggers)



	When the patient approaches a maximum trigger limit, the color of the bar changes and the report displays the following message for the category indicated by the alert icon (❗):  When the patient reaches a maximum trigger limit, the report displays the following message for the category indicated by the caution icon (⚠):  Note: The monitor continues to record data if the maximum limit is reached for a category. Event data will not be sent for review during wear for the category.
Daily Summary • Events across 24 hours • Half-hourly AF burden estimates*	

Wear Summary

- Events across the wear period
- Daily AF burden estimates*
- Footnote explaining maximum trigger limits for the device



Zio AT provides up to 14 days of continuous monitoring. The monitor has a maximum threshold to send data during wear for two categories of triggers: 100 Patient Triggers (button presses) and 500 Auto Triggers (auto detected ECGs). If the maximum trigger limit is reached for either category, the monitor will **NOT** continue to send event data for the category that reaches the maximum limit. The monitor will continue to send event data for the other category and the daily scheduled transmissions requested by the physician. The monitor will also continue to record ECG data, which will be analyzed and included in the end of wear Final Summary Report.

When a patient is approaching the limit for either category, iRhythm will send the patient an additional monitor and notify the account. Please instruct the patient to wear the replacement monitor. Refer to the Zio AT Clinical Reference Manual for more details.

MD Notification Criteria

- A summary of the criteria which would prompt clinician notification

MD Notification Criteria

	Range	Duration	Notification
AF	<40 bpm or >180 bpm	60s	During Business Hours Only
First Documentation of AF	Any	60s	During Business Hours Only
VT	>150 bpm	15x	Notify During Business Hours AND After Hours
SVT	>200 bpm	60s	Notify During Business Hours AND After Hours
Pauses	-	6s	Notify During Business Hours AND After Hours
AV Block (2nd° Mobitz II)	Symptomatic	Any	Notify During Business Hours AND After Hours
AV Block (3rd°)	Any	Any	Notify During Business Hours AND After Hours
Bradycardia	Symptomatic <40 bpm	30s	Notify During Business Hours AND After Hours

*AF during periods of ventricular regularity or presence of Atrial Flutter may affect the estimated AF/AFL burden reported.

RHYTHM DETECTION

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

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

In addition to this list of arrhythmias, ECG findings in the end-of-wear report are observations from a qualified monitoring service technician.

ASYMPTOMATIC ARRHYTHMIA DETECTION

Asymptomatic arrhythmia events, as detected and transmitted during the monitoring period, are defined by the following parameters:

Rhythm	Heart Rate	Duration
Atrial Fibrillation	≤40 bpm	≥60 seconds
	Between 40-180 bpm	≥60 seconds until first confirmation of AF
	≥180 bpm	≥60 seconds
Ventricular Tachycardia	≥120 bpm	≥30 seconds
	≥150 bpm	≥10 seconds
Supraventricular Tachycardia	≥180 bpm	≥60 seconds
Pause	-	≥4 seconds
	-	≥3 seconds back-to-back
Complete Heart Block	≤50 bpm	≥6 beats
Sinus Tachycardia	≥200 bpm	≥60 seconds
Sinus Bradycardia	≤30 bpm	≥60 seconds

For each of the arrhythmias listed above, the Zio AT patch will transmit up to four ECG (eight for CHB) strips per hour. Note: Following first confirmation of AF, an AF strip (any rate, ≥30 seconds) will be transmitted on a daily basis if detected on a subsequent day.

In addition to this list of arrhythmias, ECG findings in the reports provided during the monitoring period are observations from a qualified monitoring service technician.

Sensitivity (%)[1]		Positive Predictivity (%)[1]	
AHA	**MIT-BIH**	**AHA**	**MIT-BIH**
98.99	99.31	99.63	99.41

[1] TR01340.01 QRS detection (On file at iRhythm Technologies, Inc.)

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)

MEASUREMENT INTERVALS

The Zio AT service may be configured to report QT interval measurements, along with a heart rate corrected QTc, from both symptomatic and asymptomatic transmissions using one of the following QT correction factors below.

QT Interval	The time period from the onset of the QRS interval waveform to the end/offset or the ensuing T-wave.
QTc Bazett	A correction factor for heart rate applied to QT as calculated by: QT/SQRT(RR)
QTc Fridericia	A correction factor for heart rate applied to QT as calculated by: QT/(RR)^1/3
QTc Framingham	A correction factor for heart rate applied to QT as calculated by: QT + 0.154(1-RR)
QTc Hodges	A correction factor for heart rate applied to QT as calculated by: QT + 1.75(heart rate – 60)

QT Interval Measurements[2]			
Mean error	SD error	Min error	Max error
8.70 ms	7.25 ms	0.00 ms	45.00 ms

[2] TR01521.01 (On file at iRhythm Technologies, Inc.)

ALGORITHMS

ECG Deep Learning Analysis

The ECG Deep Learning Analysis algorithm (ECGDL) analyzes ECG recordings to provide beats, runs, rhythms, ECG segments, and heart rate detection.

AutoTrigger Engine

The AutoTrigger Engine (ATE) is responsible for detecting asymptomatic arrhythmia events during the monitoring period.

Algorithm Training

The source of training data for ECGDL and ATE algorithms are continuous cardiac recordings from compatible cardiac monitors. Training data is collected from thousands of recordings, which have already undergone Certified Cardiographic Technician (CCT) review.

Algorithm Validation

Proprietary databases listed below were used to validate the algorithms. These consist of Zio ECG recordings from patients at least 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 and patients who are asymptomatic.

Bourn Database (ECGDL)

The Bourn Database, a proprietary, physician-validated database used for rhythm detection verification, has been developed from unique Zio ECG records for each rhythm class.

Recording device	Zio XT Patch, Zio SR Patch
Channel(s)	Single-lead ECG (modified lead II), chest electrodes with hydrogel
Recording length	5 minutes
Environment	Ambulatory
Demographics	**Age:** Median = 68 [25%,75%] = [55,77] **Gender:** 39% Female **Regional Demographics (USA):** • West: 44% • Southwest: 5% • Midwest: 18% • Southeast: 22% • Northeast: 11%

ZBHT Database (ECGDL)

The ZBHT Database, a proprietary, physician-validated database, used for beat detection validation, has been developed from unique Zio ECG records for each beat class.

Recording device	Zio XT Patch, Zio AT Patch
Channel(s)	Single-lead ECG (modified lead II), chest electrodes with hydrogel
Recording length	30 seconds
Environment	Ambulatory
Demographics	**Age:** Median = 71 [25%,75%] = [60,78] **Gender:** 49% Female **Regional Demographics (USA):** • West: 36% • Southwest: 6% • Midwest: 19% • Southeast: 24% • Northeast: 15%

QT Database (ECGDL)

The QT database, a proprietary, physician-validated database, used for QT measurement validation, has been developed from unique Zio ECG records.

Recording device	Zio XT Patch
Channel(s)	Single-lead ECG (modified lead II), chest electrodes with hydrogel
Recording length	90 seconds
Environment	Ambulatory
Demographics	**Age:** Median = 42 [25%,75%] = [31,62] **Gender:** 61% Female **Regional Demographics (USA):** • West: 34% • Southwest: 2% • Midwest: 23% • Southeast: 25% • Northeast: 16%

ATFR Database (ATE)

The AT Full Recording (ATFR) database, used for asymptomatic event detection validation consists of multi-day ECG recordings obtained from the Zio AT Patch, along with CCT-reviewed reference labels obtained from the commercial Zio AT Service.

Recording device	Zio AT Patch
Channel(s)	Single-lead ECG (modified lead II), chest electrodes with hydrogel
Recording length	Up to 14 days (median: 13.8 days)
Environment	Ambulatory
Demographics	**Age:** Median=72 [25%,75%] = [60,80] **Gender:** 44.5% Female **Regional Demographics (USA):** • West: 18% • Southwest: 6% • Midwest: 16% • Southeast: 27% • Northeast: 33%

SECURITY

iRhythm Technologies, Inc. uses industry best practices that ensure the confidentiality, integrity, and availability of data. Hosted at Amazon Web Services, our infrastructure is highly durable, scalable, and secure. We develop, manage, and maintain all proprietary software, systems, and associated security.

We are dedicated to exceeding our customer's expectations with respect to protected health information privacy and security by adhering to all relevant security requirements.

As participants in patient health care, we are committed to maintaining the privacy of Protected Health Information (PHI) as directed by applicable federal and state law. Our full Notice of Privacy Practices, found at www.irhythmtech.com/content/privacy describes our privacy practices, our legal duties and rights concerning PHI.

Certifications, Standards, Regulations

SOC 2 Type II

Zio by iRhythm is SOC 2 Type II certified adhering to the AICPA's Trust Services Principles and Criteria for Security, Availability, Confidentiality and Privacy. The SOC 2 Type II is performed by an independent third-party and demonstrates iRhythm's commitment to Security and Privacy.

HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a highly regulated and security-conscious statute in the healthcare industry. Zio by iRhythm is committed to maintaining HIPAA compliance and is regularly audited by independent third party assessors to help ensure we remain compliant.

National Institute of Standards and Technology

FIPS 140-2 Validation

Zio by iRhythm has received the National Institute of Standards and Technology's (NIST) Federal Information Processing Standard (FIPS) 140-2 validation for data encryption. This achieves an added level of security required by specific government healthcare agencies and further demonstrates iRhythm's continued commitment to patient privacy and data security. Certificate number #3118.

CCPA

The California Consumer Privacy Act (CCPA) is a state statute intended to enhance privacy rights and consumer protection for residents of California. Zio by iRhythm performs periodic independent third party Information Security / Data Privacy assessments to help with our compliance with requirements.

GDPR

The General Data Protection Regulation (GDPR) is a regulation on data protection and privacy in the European Union. Zio by iRhythm receives regular independent third party assessments to help ensure we follow best practices in our efforts to comply with GDPR.

Privacy Shield

Zio by iRhythm has chosen to continue our participation in the EU/US Privacy Shield Framework operated by the US Department of Commerce.

Information Security

Security

- Data encrypted in motion and at rest (HTTPS, AES-256)
- Role-based access controls
- 24/7 monitoring
- Regular penetration and vulnerability testing

Cloud-Based

- AWS EC2 platform
- HL7-based EHR integration
- No on-premise hardware
- Highly scalable

Availability

- Highly durable, geographically distributed architecture
- Scalable, virtualized server environment
- Redundant systems, no single point of failure
- Encrypted backups with offsite replication

Auditing

- Comprehensive audit logging and alerting framework
- Activity tracking
- Regular risk assessments

Policies and Procedures

- Extensive internal policy, procedure and operational controls
- Business Continuity Plan, including virtualization, cloud computing and dual site configuration
- Incident Response policy and procedures
- Business Associate Agreement with vendors that are involved with the delivery of the Zio Service.

Cybersecurity Frequently Asked Questions

1) **What are the communication protocols used for ZioSuite website?**

   ZioSuite runs on any current web browser, on any standard operating system. Information is encrypted and securely transmitted using industry-standard TLS 1.2 or greater protocol using regularly reviewed cypher suites.

2) **How should I maintain or update cybersecurity?**

   ZioSuite is a Software as a Service (SaaS), cloud-based application with no on-premises hardware or software. ZioSuite.com runs on any current browser. It is recommend your browser is updated to the most current version before accessing ZioSuite.com.

3) **What actions should I take to ensure cybersecurity?**

   It is recommended that users should only access ZioSuite.com using a trusted network connection. A trusted e-mail account should be used for the account creation process. Additionally, password best practices should be followed when creating an account. Passwords must be at least 8 characters; and should include at least 3 of (i) lower-case letters, (ii) upper-case letters, (iii) numbers, and (iv) special characters

4) **What types of cybersecurity events can be detected, and will I be notified?**

   Data security is ensured using several security controls, including but not limited to, encryption at rest and in transit, firewalls, role-based access control, intrusion detection, audit logging and alerting, multi factor authentication, and complex password requirements. ZioSuite utilizes a comprehensive centralized logging and alerting system which records any data access, read, modification or removal, with associated user and timestamp. In addition, all account events are logged including, but not limited to, when and who created a customer account or related user accounts.

iRhythm complies with all relevant regulations for breach notification, particularly as applies to HIPAA and any security breach will be communicated with further instructions for next steps to mitigate.

5) What should I do if a cybersecurity event is detected or suspected?

If you were to suspect cybersecurity event, please contact Customer Support, available 24 hours a day 7 days a week, at 888-693-2401.

SYMBOLS

Serial Number	 Catalogue number	Rx ONLY Prescription use only
 Manufacturer	 Date of manufacture	QTY: Net quantity of contents
 Consult instructions for use		

Symbol	Standard Reference	Standard Title	Symbol Title	Description/ Explanatory Text
	ISO 15223-1 Clause 5.1.1	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied	Manu-facturer	Indicates the medical device manufacturer
	ISO 7000-3082	Graphical symbols for use on equipment		
Rx ONLY	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements	Prescription only	Requires prescription in the United States

Symbol	Standard Reference	Standard Title	Symbol Title	Description/ Explanatory Text
	ISO 15223-1 Clause 5.4.3	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	ISO 7000-1641	Graphical symbols for use on equipment		

TROUBLESHOOTING

FOR CUSTOMER CARE, CALL **1.888.693.2401**

ZIO® BY iRHYTHM

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Date of first issue: 2021-11 | Revised: 2025-02 LB10058.08