ZIO®

Zio® ECG Utilization Service (ZEUS) System

Instructions for Use

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

Features available are dependent on your account settings.

Contents

Zio ECG Monitoring Service Description

The Zio® ECG Monitoring Service System is an ambulatory Electrocardiogram (ECG) monitoring system. The Zio ECG Monitoring System consists of two components:

- Zio monitor
- Proprietary algorithm software (Zio ECG Utilization (ZEUS) Service System software)

A Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance through simplicity of operation.

After conclusion of the wear period (up to 14 days), the patient removes the Zio monitor and returns it by mail to iRhythm for processing. After receipt, the data is analyzed by iRhythm's proprietary algorithm before a Certified Cardiographic Technician (CCT) reviews the results and generates a report of the key findings.

Zio ECG Utilization Service (ZEUS) System

Zio ECG Utilization Service (ZEUS) System is a medical device which consists of a collection of software modules designed to store and analyze data from compatible cardiac monitoring devices to create a report of preliminary findings intended for use by physicians as an aid in arrhythmia diagnosis and management. Certified Cardiographic Technicians (CCTs) review the ECG analysis conducted by the ZEUS System prior to publishing the cardiac information in a “preliminary findings” report.

This preliminary, end-of-wear report is provided to physicians through a secure website for their review and final interpretation. The preliminary report is made available for the prescribing physician to review and interpret relative to the patient’s clinical history, symptoms, and medications, but does not contain diagnostic interpretation applicable to the patient.

The analysis of cardiac data is provided in the report for review by the physician to render a diagnosis based on their clinical judgment, physician experience, patient medical history, and patient baseline cardiac rhythms. The report contains cardiac information including beats, ectopic runs, ECG segments, rhythms, and heart rate measurements, as well as the detected arrhythmias and their associated ECG strips.

ZioSuite

ZioSuite is a web portal for healthcare professionals to manage and streamline clinical workflows associated with the Zio Service. The Zio Service consists of a long-term cardiac recording using a prescribed Zio device in combination with the “ZEUS System” (Zio ECG Utilization Service [ZEUS] System), 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 register patients into the Zio Service, access clinical reports, manage and perform clinical report interpretation, and administer user settings and access.

Intended Use

The Zio ECG Utilization Service (ZEUS) System is intended to analyze and report symptomatic and asymptomatic cardiac events stored on a Zio monitoring device. A preliminary, end-of-wear report is generated on the beat-to-beat information from the entire ECG recording. It is not intended for use for patients in critical care.

Indications for Use

The Zio ECG Utilization Service (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. The reports are provided for review by the intended user to render a diagnosis based on clinical judgment, experience, and a patient's medical history.

Intended Patient Population

18 years or older

Intended Users

Physician, Healthcare Provider

Intended Use Environment

Professional use only

Contraindications

- Do not use the Zio ECG Utilization Service (ZEUS) System for patients in critical care because the reporting timeliness is not consistent with life-threatening arrhythmias such as ventricular fibrillation.
- Do not use the Zio ECG Utilization Service (ZEUS) System 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.

Warnings

- Registering a patient with the wrong Zio monitor serial number may result in misdiagnosis due to incorrect statistics or data in the preliminary report. To avoid registering a patient with the wrong Zio monitor serial number, perform registration at the time the Zio monitor is applied to the patient.
- 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.

Precautions

- Return the Zio monitor immediately at the end of wear to enable timely generation of a preliminary, end-of-wear report.

Serious Incident Reporting

If you become aware of any malfunction of our device which has resulted or could result in serious health consequences for the user, patient, or any other person, please inform us immediately and inform the Competent Authority of your country.

Principles of Operation

The Zio ECG Utilization Service (ZEUS) System is a combination of software modules used by iRhythm Certified Cardiographic Technicians to analyze and archive the recorded ECG data.

Continuous ECG data are downloaded and processed through the Zio ECG Utilization Service (ZEUS) System rhythm and beat detection software, which uses an artificial intelligence (AI) algorithm capable of detecting arrhythmias and sinus (i.e., normal) rhythms.

Refer to page 16 for a complete list of detected arrhythmia types.

The algorithm-labeled ECG data are sent to Certified Cardiographic Technicians (CCTs) as a secondary quality review. All algorithm outputs are assessed and, where appropriate, reclassified by the CCTs during the Quality Assurance review. The CCT then generates a report of the preliminary ECG findings contained with the ECG strips for the physician as an aid in arrhythmia diagnosis and management. Cardiac information including beats, ectopic runs, ECG segments, rhythms, and heart rate measurements, as well as the detected arrhythmias and their associated ECG strips are captured in a report provided to physicians through a secure website.

Clinical Benefits

- **Long-term continuous ambulatory monitoring:** The Zio ECG monitor is capable of capturing a continuous recording of beat-to-beat cardiac rhythm data for ambulatory monitoring 24 hours a day for up to 14 days. It facilitates detection of infrequent or asymptomatic arrhythmias as compared to other, shorter term ambulatory monitors.
- **Ambulatory monitoring:** The Zio ECG monitor is intended for outpatient use, where variation in cardiac rhythms do not represent immediate danger to the patient.
- **Ease of Use for the Physician:** The Zio Service offers a comprehensive, quality assured report for managing staff time burden.

Regulatory Compliance Statement

CE 2797

The Zio ECG Utilization Service System bears the CE marking CE-2797, indicating its conformity with the provisions of EU Medical Device Regulation (MDR) 2017/745 and fulfills the general safety and performance requirements of Annex I of EU MDR 2017/745.

The medical device software has been assigned to Class IIa as specified in Annex VIII of EU MDR 2017/745.

This CE marking applies to the following medical device software modules:

- SFW0073 ECGDL Algorithm
- SFW0037 ZEUS QA Tool
- SFW0030 Clinical Web Service and ZEUS Report
- SFW0075 Clinical Analysis Service

The CE mark does not apply to:

- SFW0089 ZioSuite Website

ZEUS System Reference Number - S100

Product Identification (BUDI-DI) - 00850043907ZEUSSYSTEM01EP

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

Symbols Glossary

SYMBOL	SYMBOL-TITLE	DESCRIPTION/EXPLANATION
	Manufacturer	Indicates the medical device manufacturer.
	Authorized representative in the European Community/European Union	Indicates the authorized representative in the European Community/ European Union
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland
	Importer	Indicates the entity importing the medical device into the locale
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Medical device	Indicates the item is a medical device
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Conformity marking for the European Union	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation (EU) 2017/745 and other applicable European Union harmonization legislation for its affixing
	Prescription only	Requires prescription in the United States of America

Accessing Zio Service through ZioSuite

Important! You **must register** the patient on the ZioSuite website.

At the end of the patient's monitoring period, you can view and interpret clinical reports on the ZioSuite website.

Prerequisites

- Browser with website access
  - ZioSuite is compatible with current web browsers and tested for compatibility with Google Chrome and Microsoft Edge.
- A user account with a specific email address and password is set up by the administrator at your site.
  - Call Customer Care at the telephone number listed on the back cover with any questions about your account.
- In these instructions, a term in **bold** indicates the name of a selection or menu option on the website.

Logging On

1. From a web browser, access the ZioSuite website for your country.
   - **Austria**: www.ziosuite.at
   - **Switzerland**: www.ziosuite.ch
   - **Spain**: www.ziosuite.es
   - **Netherlands**: www.ziosuite.nl
   - **United Kingdom**: www.ziosuite.co.uk
   - **United States**: www.ziosuite.com
2. Enter your email address and password.
3. Click **Continue** and then click **Log In**.

   A dashboard specific to your user role is shown.

Examples of Screens Accessible from the Dashboard

Screen	Description
Registration	Register your patient in ZioSuite
	View draft registrations View unregistered monitors
Reports	Download, print, or archive posted final reports Search function for locating a specific patient
	List of reports pending interpretation for the logged-in user Assign, print, or download a report pending interpretation
	Amend reports in **My Interpretation History**
Patients	Detailed view of a patient record, including information about the patient demographics and prescription details. Accesses reports associated with the patient
	View of all active patients Search function for locating a specific patient

Registering a Patient

Important! You **must register** the patient on the ZioSuite website.

Prerequisites

- Review the registration form to gather the necessary patient and physician information required for registration.
  - Unless marked as **(Optional)**, all entries on the form are required to complete registration.
- Locate the serial number of the Zio monitor on the device box.

Registration Procedure

1. Log on to ZioSuite.

   Refer to page 12 for logon instructions.

2. Click **Register Patient** on the dashboard, or select the **Registrations>New Registration** menu option.
3. Select your clinic's location.
4. If required, select the enrollment type (for example, for Zio monitors applied in-clinic, click **In-Clinic**.)
5. Enter the registration details on the form.

   Note: Position the pointer over an informational icon ( ) to view tips available.

6. To submit a completed registration, select **Complete Registration**.
7. To save entries for later completion, enter the following minimum required fields for a draft registration and then select **Save As Draft**.
   - **Last Name**
   - **First Name**
   - **Sex**
   - **Date of Birth**
8. To exit registration without saving changes, select **Cancel**.

Viewing and Downloading a Report

The end-of-wear report provides the physician with cardiac information from the recorded and processed ECG data, including:

- Beats
- Ectopic runs
- ECG segments
- Rhythms
- Heart rate measurements
- Detected arrhythmias with associated ECG strips

The physician can request modifications to the report content and add their clinical interpretation to the report.

1. Log on to ZioSuite.

   Refer to page 12 for logon instructions.

2. Select the **Reports>REPORT TYPE** menu option.
3. Scroll through the report list and then click **View Report**.

   Note: If you are unable to locate the report, click the search icon and then enter the patient's name.

4. To download the report, click the download button on the top right of the webpage.

Interpreting a Report

1. Log on to ZioSuite.

   Refer to page 12 for logon instructions.

2. Select the **Reports>Pending Interpretation** menu option.

3. Scroll through the report list and then click **Interpret Report**.

   Note: If you are unable to locate the report, click the search icon and then enter the patient's name.

4. Accept the report as provided or enter comments:

   - To accept the report as provided, click **Agree with Findings**.
   - To enter comments or edit the **Preliminary Findings**, click the interpretation box and then enter the physician's interpretation.

5. Click **Accept & Sign** to electronically accept and sign the interpretation.

Technical Specifications

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

Arrhythmias noted in addition to this list and included in the end-of-wear report are observations from Certified Cardiographic Technicians.

Rhythm Detection Performance[1]

Rhythm Class[2]	Episodic Sensitivity[3]	Episodic Positive Predictive Value[3]	Number of Episodes[4]
Atrial Tachycardia *Includes Atrial Fibrillation/Flutter, Supraventricular Tachycardia*	90.40%	72.75%	1,459
Ventricular Rhythms *Includes Ventricular Tachycardia, Idioventricular Rhythm*	89.02%	68.19%	583
Pause	89.72%	89.19%	360
Sinus *Includes Sinus, Ectopic Atrial Rhythm, Junctional Rhythm*	97.71%	87.04%	10,107
Ventricular Patterns *Includes Ventricular Bigeminy, Ventricular Trigeminy*	90.40%	79.30%	698
AV Block *Includes Complete Heart Block, AV Block Type II, Wenckebach*	88.99%	86.32%	2,479

[1]Performance results reflect ECGDL2 algorithm performance prior to quality review by Certified Cardiographic Technicians.

[2]The 14 detected rhythm types detected by ECGDL2 grouped into six classes for performance testing.

The validation dataset was enriched (above background arrhythmia prevalence) to ensure adequate assessment of performance for each rhythm class.

[3]Sensitivity and Positive Predictive Value reflect the algorithm's labeling of episodes as compared to expert annotations.

[4]The independent validation dataset was developed from proprietary ECG recordings. Reference data were generated through independent annotation by two Certified Cardiographic Technicians (CCTs) and confirmed by a board-certified cardiologist or electrophysiologist.

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)

Cybersecurity

The Zio monitor was developed with careful consideration of cybersecurity risks and their compensating controls. Industry-standard encryption is employed for protecting data at rest, post-wear. Patient data is protected during wear through use of proprietary data storage formats and physically protected data ports. Once returned to iRhythm for processing, data integrity checks are used to ensure the integrity of all recorded data.

For Information Technology (IT) security measures, monitoring, encryption, and iRhythm two-step login process (e.g., multi-factor authentication (MFA), Single-Sign On (SSO), complex password requirements) are established for ZEUS.

End-of-Wear Report

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

The end-of-wear report includes the following information:

Information	Description
Patient Information	• Patient Name • Date of Birth • Patient ID • Gender • Primary Indication • Prescribing Clinician
Heart Rate Summary	• Overall maximum, minimum and average heart rate • Sinus maximum, minimum and average heart rate
Patient Events Summary	• Count of trigger events • Count of diary events • Range of findings for each event type
Arrhythmia Summary	• Ventricular Fibrillation / Torsades de Pointes / Polymorphic VT • Ventricular Tachycardia • Pauses • Atrial Fibrillation/Flutter • AV Block (2nd Mobitz II,3rd) • Supraventricular Tachycardia
Ectopic Beats Summary	• Supraventricular Ectopy • Ventricular Ectopy
Preliminary Findings	• Summary text of findings
Final Interpretation	• Clinician interpretation

ZIO® BY iRHYTHM

Customer Care

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Spain: 900 75 14 51
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Visit iRhythm's website **https://irhythmtech.co.uk/user-information/** to view and download documents pertinent to privacy notices, product warranty, terms of service, and other product information, including additional copies of user manuals.

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