Zio® AT

CLINICAL REFERENCE MANUAL

Rx ONLY

Clinicians, advise your patients:

If you feel the need for immediate medical attention at any time, call 911. The Zio AT device will not provide any medical assistance and cannot contact the medical personnel for you. Please take your gateway with you to the emergency room.

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Table of Contents

Description

The **Zio AT® Electrocardiogram (ECG) Monitoring System** is intended for continuous, long-term monitoring of a patient's ECG data with the ability to provide symptomatic and asymptomatic transmissions of potential arrhythmias during wear time.

The **Zio AT ECG Monitoring System** enables ambulatory Mobile Cardiac Telemetry (MCT) services for non-critical care patients by providing the following devices for use.

- The **Zio AT device** consists of the Zio AT patch and Zio AT wireless gateway:
    - **Zio AT Patch**

      The Zio AT patch is a single-use ECG monitor applied to the patient's chest, in-clinic or at home, and worn for up to 14 days without any required patient interaction for maintenance, such as replacing or charging a battery.

      The patch continuously records ECG data and transmits symptomatic and asymptomatic cardiac events through the Zio AT wireless gateway during the wear period.

      After the wear period concludes, the patient removes and returns the patch to the monitoring center, an Independent Diagnostic Testing Facility (IDTF), for analysis and end-of-wear reporting.

    - **Zio AT Wireless Gateway**

      The Zio AT wireless gateway securely receives ECG data from the Zio AT patch using Bluetooth technology. The gateway securely transmits ECG data through cellular technology for subsequent processing.
- **Zio ECG Utilization Service** provides an arrhythmia detection algorithm to analyze the ECG data. The data is reviewed at the monitoring center by Certified Cardiographic Technicians who generate reports for the physician during wear and at the end-of-wear.

Indications For Use

The Zio AT device is intended to capture and transmit symptomatic and asymptomatic cardiac events and record continuous electrocardiogram (ECG) data for long-term monitoring. It 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. It is not intended for use on critical care patients.

Contraindications

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

Warnings

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

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- Do not use the Zio AT device on patients who do not have the competency to wear the device for the prescribed monitoring period.

  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.

If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Zio AT patch from the patient's chest. Call iRhythm Customer Care at 1.888.693.2401.

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

ELECTRICAL SAFETY COMPATABILITY

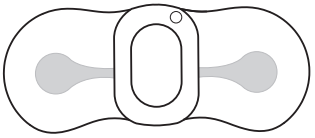
Refer to the tables and safety information beginning on page 30.

Precautions

- Safety and effectiveness of the Zio AT device on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.
- Safety and effectiveness of the Zio AT device on pediatric patients (younger than 18 years old) has not been established.
- The Zio AT device includes temperature and humidity limitations when stored/transported. If exposed during storage/transport, patients may experience degradation of adhesive performance causing the Zio AT patch to slip or fall off during the patient wear duration.
- The Zio AT device has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the Zio AT device if package is damaged. Device may not perform as intended.
- Keep device and packaging away from young children. Contents may be harmful if swallowed. Patch contains button cell batteries that are not accessible during normal use but, if exposed, are known choking hazards and may cause severe tissue injury if ingested.
- Registration errors may result in limited functionality or erroneous ECG reporting. Utmost caution should be applied to ensure that patient registration is accurate and complete.

Package Contents

1 Zio AT patch

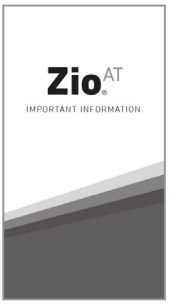


1 Zio AT gateway, containing:
- 1 postage-paid return envelope

Skin preparation kit containing:
- 1 patch card template
- 1 disposable razor
- 1 abrader disc
- 4 alcohol wipes

1 Application instructions

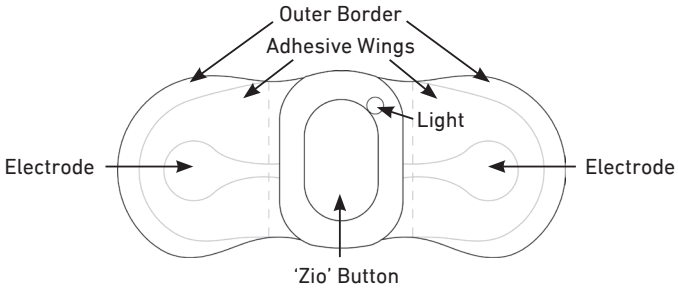
1 Important information pamphlet



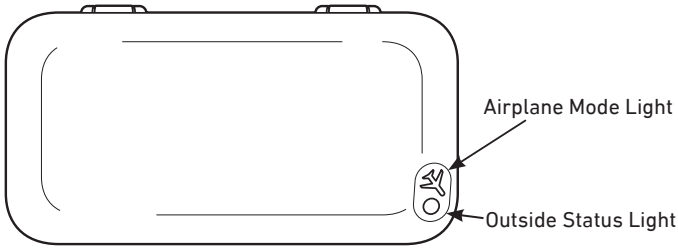
1 Wearing Your Zio manual & button press log containing:
- 1 adhesive remover wipe
- 1 patient consent form
- 1 patient survey

Device Diagrams

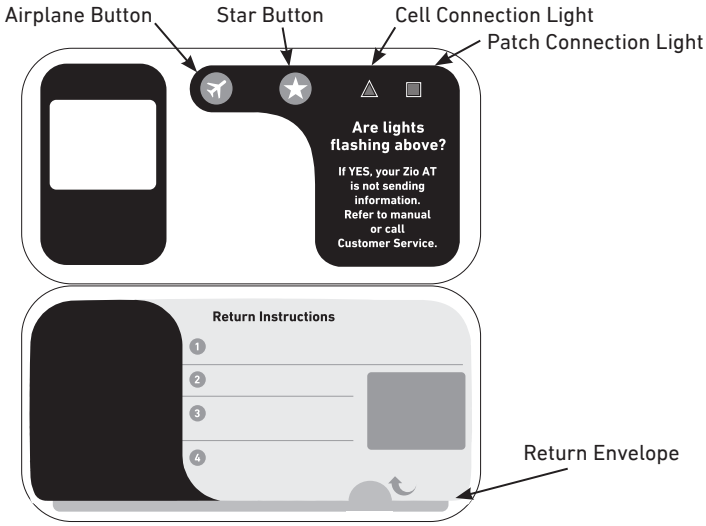
Zio Patch



Zio Gateway Exterior



Zio Gateway Interior



Account Setup

To allow effective use of the Zio AT ECG monitoring system, an account on iRhythm's patient management system (www.ziosuite.com) is assigned to the clinic.

Ensure you can access iRhythm patient management system via provided username and password. If you are unable to access ziosuite.com, please contact Customer Care at **1.888.693.2401.**

During Patient Visit

Registration

Register patient online at **www.ziosuite.com**.

Customer Care may contact the patient if any additional information is required.

Application Instructions

The Zio AT package contains instructions on how to apply the patch and activate the patch and gateway.

During Monitoring

During monitoring, the Zio AT device will record continuous beat-to-beat ECG information and transmit patient-triggered ECG data and asymptomatic ECG data to provide arrhythmia detection.

If additional patient data needs to be accessed by the physician during the wear period, contact Customer Care at 1.888.693.2401.

Reports

Zio AT REPORTS

All Zio AT Reports are available in www.ziosuite.com.

Note: Reporting timelines may vary depending on possible error conditions listed on page 24, including if the patient keeps the gateway within the required range for connection to the patch and within the coverage area of the cellular service. Transmission reports are provided after receipt and analysis of ECG strips at the monitoring center.

This device is not intended for use in critical care patients because the reporting timeliness is not consistent with life-threatening arrhythmias such as ventricular fibrillation.

Asymptomatic Arrhythmia Detection

Asymptomatic arrhythmia events that are auto-detected (auto-triggered events) and transmitted during wear, are defined in the table below:

Rhythm	Heart Rate	Duration
Atrial Fibrillation	≤40 bpm	≥60 seconds
	Between 40–180 bpm	≥60 seconds until first documentation 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

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

For each of the arrhythmias listed above, the Zio AT patch will transmit up to four ECG strips per hour.

[1] TR00689.01 (On file at iRhythm Technologies, Inc.)

Troubleshooting

For customer support, call **1.888.693.2401**

Frequently Asked Questions

HEALTHCARE PROVIDER QUESTIONS

1. **How long is the patient supposed to wear the Zio AT patch?**

   The patient can use the Zio AT for as long as prescribed. Each Zio AT patch can be worn for up to 14 days. For longer monitoring prescriptions, additional Zio AT monitors will be provided.

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

2. **Who should the patient call if they have questions about the Zio AT patch or gateway?**

   The patient can read the *Wearing your Zio Manual & Button Press Log* or call Customer Care at 1.888.693.2401.

3. **What if the patient does not have symptoms?**

   The Zio AT patch continuously records ECG data. It also automatically detects and transmits asymptomatic arrhythmias, even if the patient does not feel them.

4. **Does the patient need to do anything with the Zio gateway to send heart rhythm data wirelessly?**

   The patient only needs to keep the gateway within 10 feet of the patch and within range of a good cellular connection. No action is required for the gateway to send symptomatic heart rhythm data other than pressing the Zio button on the patch.

5. **Are there tests or treatments that are not compatible with the Zio AT patch?**

   Yes. The following are not recommended during wear of the Zio AT patch:

   a. Magnetic Field(s): Magnetic Resonance Imaging (MRI); MRI Technician; Any job where the patient may be exposed to a large magnetic field

   b. Neuromuscular Stimulators: Brain Stimulator; Neurostimulator; Spinal Stimulator; TENS Unit

   c. External Cardioversion/Defibrillation

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

6. Can the Zio AT patch be left on a patient during Cardioversion/ Defibrillation?

No, the Zio AT patch should be removed if the patient requires Cardioversion or Defibrillation.

PATIENT QUESTIONS

The Zio AT Device

7. What is the patch doing?

The patch is continuously recording ECG data. Your doctor will use the heart rhythm data from the patch to determine the right course of action.

8. What is the gateway doing?

The gateway sends the heart rhythm data recorded by your patch to the monitoring center using a cellular connection. A Certified Cardiographic Technician (CCT) analyzes the data and provides a report to your doctor.

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

Your patch and gateway are designed to be discrete. Once they are activated during the application process, neither the patch nor the gateway will display lights when functioning as designed.

If you see a light on the patch flashing orange, the patch may not be well attached or may not be recording, or the gateway may not be sending heart rhythm data.

Refer to Troubleshooting on pages 19 through 21 for a description of the flashing lights and required action

10. What happens if I am in an area with poor or no cellular service?

If you are in an area with poor or no cellular service, the gateway will not transmit data from the patch. If the monitoring center does not receive data for a sustained period of time, Customer Care will reach out to the patient to troubleshoot.

If the cellular connection is not re-established, data (both auto-triggered events and patient-triggered events) will NOT be transmitted to the monitoring center

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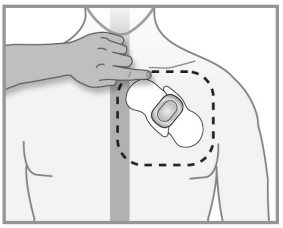

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2. **Who should the patient call if they have questions about the Zio AT patch or gateway?**

   The patient can read the *Wearing your Zio Manual & Button Press Log* or call Customer Care at 1.888.693.2401.

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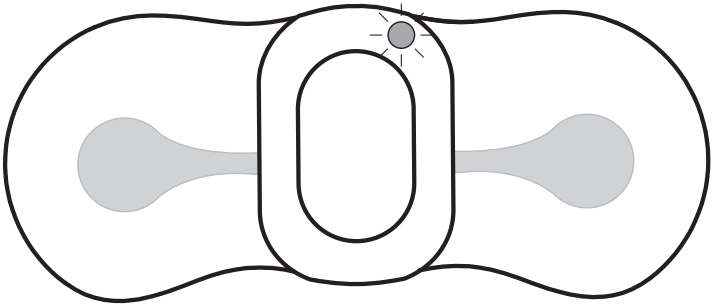
Troubleshooting the Patch

Follow these instructions to troubleshoot a light flashing orange on the Zio AT patch.

If a light is also flashing on the Zio AT gateway, refer to pages 20 through 21 for additional troubleshooting instructions.



SLOW FLASHING LIGHT
(Light on patch flashes orange once every 3 seconds):

Indicates the patch is not making good contact with the skin.

1. **To remedy it,** massage the wings of the patch for 3 to 5 minutes.
2. **If the light continues to slowly flash orange,** call Customer Care at 1.888.693.2401.

FAST FLASHING LIGHT
(Light on patch flashes orange 3 times per second):

Indicates the patch is not recording ECG data.

- Call Customer Care at 1.888.693.2401.

3 CONSECUTIVE FLASHES FOLLOWED BY A PAUSE
(Light on patch flashes orange 3 times in 3 seconds, followed by a 5 second pause and then the sequence repeats):

- **Indicates** the patch is recording ECG data, but cannot send the data. Call Customer Care at 1.888.693.2401.

Troubleshooting the Gateway

Follow these instructions to troubleshoot a light flashing **orange** on the exterior of the Zio AT gateway. Open the gateway and check inside.

A light flashing **white** on the exterior of the Zio AT gateway indicates airplane mode is on.

If a light is also flashing on the Zio AT patch, refer to page 19 for additional troubleshooting instructions.

SLOW SQUARE FLASHING LIGHT (□)
(Square light (□) inside the gateway flashes orange once every 3 seconds):

Indicates the gateway has lost the connection to the patch.

1. **To reconnect,** hold the star button ✪ for 3 seconds until the orange light stays on.

   When the gateway reconnects to the patch, the light flashes green.

2. **If the light continues to flash orange,** call Customer Care at 1.888.693.2401.

SLOW TRIANGLE FLASHING LIGHT (△)

(Triangle light (△) inside the gateway flashes orange once every 3 seconds):

Indicates the gateway does not have a cellular connection.

1. **To reconnect,** move the gateway to a location with a good cellular connection (near a window or outside).
2. Hold the star button ✪ for 3 seconds until the orange light stays on.

   When the gateway reconnects to the cellular service, the light flashes green.
3. Do not move the gateway until the light stops flashing green.
4. If the light does not flash green, move the gateway to a new location and try again.
5. **If the light continues to flash orange**, call Customer Care at 1.888.693.2401.

FAST SQUARE (□) AND TRIANGLE (△) FLASHING LIGHTS

(Both the square light (□) and triangle light (△) inside the gateway flash orange 3 times per second):

Indicates the gateway is not working.

- Call Customer Care at 1.888.693.2401.

Zio AT Service Notes

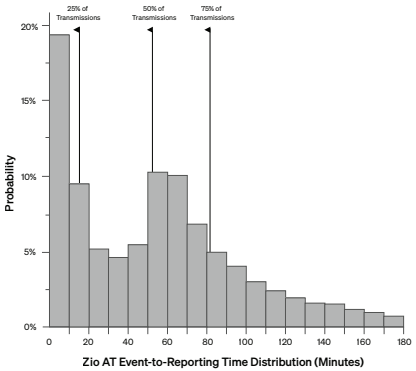
Situation	Note
Patient Timeline – Paper Booklet Diary Entries	For patients with the Zio AT Patch, ZioSuite provides a timeline screen that displays along with Transmission, DDR, Daily, and Final reports, patient provided diary entries. For each diary entry the date and time of the symptom reported is displayed. In the event that a patient does not provide the date/time for a symptom on the paper booklet, the timeline will display a date with a year starting in 3000. Dates that have a year of 3000 or greater indicate that the patient did not provide the timestamp of the symptom experienced. (SYS-2315)

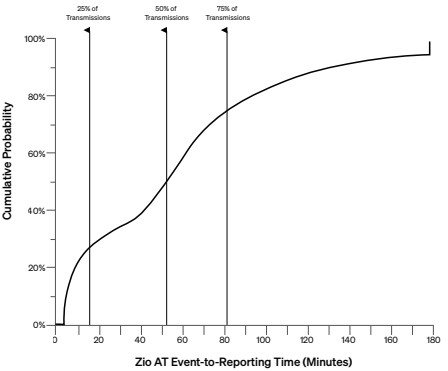
Zio AT Service Reporting

The expected timeliness of Zio AT service reporting is defined as the time between a patient-triggered or auto-triggered cardiac event and the posting of a quality-reviewed report for the physician by the Independent Diagnostic Testing Facility (IDTF).

The following histogram, Cumulative Probability Distribution, and summary table reflect both the device transmission and clinical review and reporting time involved in communicating events and are based on real-world data to ensure transparency and appropriate usage of Zio AT service.

Typical Expected Timelines — Distribution and Quantiles[1]





	25th Percentile	50th Percentile	75th Percentile
Zio AT Event-to-Reporting Time Distribution	15 minutes	53 minutes	82 minutes

[1] Data on file, based on observed results from October 2023 through September 2024.

Error Conditions That May Affect the Typical Expected Timelines

The Zio AT patch and Zio AT gateway provide visual cues when an error condition occurs. The error conditions outlined in this section may impact the timeliness of report posting by the IDTF.

iRhythm Customer Care may also initiate communication with the healthcare provider and the patient prior to the patient recognizing the visual cues.

Refer to Troubleshooting on pages 19 through 21 for information about the alerts provided by the LED indicators (lights) on the devices. Troubleshooting information is also provided in the Wearing Your Zio manual and the Important Information pamphlet for the patient.

Should an error condition occur as evident by the LED Indicator, please contact iRhythm Customer Care.

Zio AT Patch and Zio AT Gateway

Error Condition	Zio AT patch LED Indicator	Zio AT Gateway LED Indicators
Maximum transmission limits reached[1]	• Light consecutively flashes orange 3 times in 3 seconds, followed by a 5 second pause and then the sequence repeats • The patch continues recording ECG data, but may not transmit.	---
Potential battery issue, patch[1]	• Light flashes orange 3 times per second (fast flashing light)	---
Potential battery issue, gateway[1]	• No LED indication • The patch is recording ECG data, but the gateway cannot send the data.	• Both the square light (☐) and triangle light (△) inside the gateway flash orange 3 times per second (fast flashing lights)
Device not activated by healthcare provider or patient[2]	• Light flashes orange 5 times if the patch did not activate successfully	• After activating the gateway, both the square light (☐) and triangle light (△) inside the gateway continuously flash orange if the gateway does not connect to the patch
Patch leads off, not contacting skin, poor signal quality[2]	• Light flashes orange once every 3 seconds (slow flashing light)	---
Gateway out-of-range from patch (not kept within range by patient)[2]	• No LED indication • The patch continues recording ECG data, but cannot send the data until the gateway is within range.	• Square light (☐) inside the gateway flashes orange (slow flashing light)
Poor or no cellular connection[2]	• No LED indication • The patch continues recording ECG data and sending data to the gateway.	• Triangle light (△) inside the gateway flashes orange (slow flashing light) • The gateway stores ECG data and then automatically sends the data when cellular connection is reestablished.

Error Condition	Zio AT Patch LED Indicator	Zio AT Gateway LED Indicators
Patient forgets to turn off airplane mode on the gateway[2]	• No LED indication • The patch continues recording ECG data and sending data to the gateway.	• Airplane light on exterior of the gateway continuously flashes white when airplane mode is on. • If the patient does not turn off airplane mode after 12 hours: • Status light on exterior of the gateway flashes orange. • Triangle light (△) inside the gateway also flashes orange (slow flashing) • The gateway cannot send the ECG data until airplane mode is off and cellular connection is re-established

[1] Customer Care contacts the healthcare provider and sends another Zio AT patch with instructions to the patient.

[2] Customer Care contacts the patient when error condition is detected.

ZioSuite Portal and Daily Report

Error Condition	ZioSuite Portal or Daily Report
Maximum transmission limits reached[1]	ZioSuite Portal and Daily Report provide information to the healthcare provider
Incomplete registration of patient by the healthcare provider's account[2]	ZioSuite Portal indicates unregistered devices at the healthcare provider's account

[1] Customer Care contacts the healthcare provider and sends another Zio AT patch with instructions to the patient.

[2] Customer Care contacts the healthcare provider while the Independent Diagnostic Testing Facility processes and reports clinically actionable arrhythmia notifications.

Notice of Privacy Practices (NOPP)

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 www.irhythmtech.com, describes our privacy practices, our legal duties, and patients' rights concerning PHI.

Cybersecurity Measures and Controls

As a connected medical device, the Zio AT patch was developed with careful consideration of cybersecurity risks and their compensating controls. Key measures include manufacturing steps to exclusively pair one AT patch with one Gateway, thus preventing Bluetooth communication with any other devices, and to configure encryption of all transmissions between these devices. Similarly, encryption of all cellular communication between the Gateway and the cloud is configured during manufacturing.

iRhythm regularly evaluates the integrity of our cloud-based infrastructure through both vulnerability and penetration testing of all internet-accessible servers. Industry-standard encryption is employed for all data transfers to, from and within the Cloud, and for protecting data at rest.

Patient data is protected during wear through use of proprietary data storage formats and access methods, and physically protected data ports. Once returned to the monitoring center for processing, data integrity checks are used to ensure the integrity of all recorded data.

Device Specifications

PATCH PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	6 months

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.67 Hz to 40 Hz
ECG Input Impedance	>10 MΩ
ECG Differential Range	3.3 mV p-p
ECG A/D Sampling Rate	200 Hz
ECG Resolution	10 bits
Patch Short-range RF Transmit/ Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power <1 mW
Frequency Band of Transmission	2.4 GHz
Bandwidth of the Receiver	2400-2480 MHz
Type and Frequency of Modulation	1-Mbps GFSK
Gateway Short-range RF Transmit/ Receive	2.4 GHz Bluetooth Low Energy Effective Radiated Power <1 mW
Gateway Cellular RF Transmit/ Receive	750 MHz LTE Cat M1 Effective Radiated Power < 200 mW

POWER CHARACTERISTICS

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

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.1 x 0.6 inches
Patch Weight	24.7 g
Gateway Dimensions	6.2 x 3.4 x 0.8 inches
Gateway Weight	158 g

ENVIRONMENTAL CHARACTERISTICS

Operational Temperature	41 to 104 degrees F
Operational Altitude	-1,000 to 10,000 ft
Operational & Storage Humidity	10% to 95% (non-condensing)
Shipping (Short-term Storage) Temperature	-4 to 104 degrees F
Long-term Storage Temperature	55 to 85 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IP24
Gateway IP Classification	IP22

ESSENTIAL PERFORMANCE

The Zio AT device records and transmits ECG segments for analysis., If recording or transmission is not as intended, the Zio AT device alerts the patient that functionality is impaired.

For information about the alerts provided by lights on the devices, refer to “Troubleshooting” on pages 19 through 21.

HEART RATE CALCULATIONS

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

PAUSE DETERMINATION

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

Electrical Safety and Compatability

- CAUTION: The Zio AT system needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.
- CAUTION: Portable and mobile RF communications equipment can affect medical electrical equipment.
- WARNING: The Zio AT system should not be used adjacent to or stacked with other equipment.
- WARNING: The Zio AT system may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSIONS requirements.
- WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Zio AT patch or gateway. Otherwise, degradation of the performance of this equipment could result.

Guidance and Manufacturer's Declaration for Electromagnetic Emissions

Table 1: Guidance and Manufacturer's Declaration for Electromagnetic Emissions

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

Guidance and Manufacturer's Declaration for Electromagnetic Immunity

The Zio AT system is intended for use in the electromagnetic environment specified on pages 32 through 35. The customer or the user of the Zio AT system should assure that it is used in such an environment.

Table 2: Guidance and Manufacturer's Declaration— Electromagnetic Immunity

Phenomenon	Basic EMC standard or test method	Immunity level
Electrostatic Discharge	IEC 61000-4-2	±8 kV contact ±15 kV air
Radiated RF EM fields	IEC 61000-4-3	10 V/m 80 MHz – 2.7 GHz 80% AM at 1 kHz
Conducted disturbances induced by RF fields	IEC 61000-4-3	3 V/m 0.15 MHz – 80 MHz 6 V/m in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz
Rated power frequency magnetic field	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz

Table 3: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Basic EMC Standard or Test Method: IEC 61000-4-3					
Phenomenon	**Frequency (MHz)**	**Band (MHz)**	**Service**	**Modulation**	**Immunity Level (V/m)**
Proximity Fields from RF Wireless Communications Equipment	385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
	450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	28
	710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
	745				
	780				
	810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
	870				
	930				
	1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	28
	1845				
	1970				
	2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
	5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
	5500				
	5785				

Table 4: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Basic EMC Standard or Test Method: IEC 61000-4-3				
Phenomenon	**Frequency (MHz)**	**Band (MHz)**	**Modulation**	**Immunity Level (V/m)**
5G Proximity Fields from RF Wireless Communications Equipment	600	663-698 (n71)	Pulse modulation 217 Hz	28
	1500	1432-1517 (n50)		
	1600	1626-1660 (n24)		
	2000	1995-2020 (n70)		
	2100	2110-2170 (n1, n65)		
	2300	2305-2360 (n30)		
	3500	3550-3700 (n48)		
	3700	3300-4200 (n77, n78)		
	4900	4400-5000 (n79)		
	5900	5855-5925 (n47)		

Table 5: Guidance and Manufacturer's Declaration—Electromagnetic Immunity

Basic Standard or Test Method: IEC 61000-4-39			
Phenomenon	**Frequency**	**Modulation**	**Immunity Test Level (A/m)**
Proximity Magnetic Immunity	30 kHZ	CW	8
	134.2 kHz	Pulse modulation 2.1 kHz	65
	13.56 MHz	Pulse modulation 50 kHz	7.5

- This system complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This system may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- For body worn operation, this system has been tested and meets FCC RF exposure guidelines when used with an accessory that contains no metal, such as the belt clip provided, and that positions the Gateway a minimum 1 cm from the body. Use of other accessories may not ensurecompliance with FCC RF exposure guidelines.
- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- The gateway has been tested and meets FCC RF exposure guidelines when used and operated for its intended purpose and as instructed in the manual.

Symbols Glossary

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, labelling and information to be supplied	Manufacturer	Indicates the medical device manufacturer.
	ISO 7000-3082	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.3	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Date of manufacture	Indicates the date when the medical device was manufactured
	ISO 7000-2497	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Use-by date	Indicates the date after which the medical device is not to be used.
	ISO 7000-2607	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.5	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	ISO 7000-2492	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.1.6	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	ISO 7000-2493	Graphical symbols for use on equipment		

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
SN	ISO 15223-1 Clause 5.1.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	ISO 7000-2498	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Keep dry	Indicates a medical device that needs to be protected from moisture.
	ISO 7000-0626	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.7	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	ISO 7000-0632	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.3.8	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.
	ISO 7000-2620	Graphical symbols for use on equipment		
	ISO 15223-1 Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	ISO 7000-1051	Graphical symbols for use on equipment		

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, labelling 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		
	IEC 60601-1 Table D.1, Symbol 11	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	ISO 15223-1 Clause 5.4.4	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	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. of reasons, be presented on the medical device itself.
	ISO 7000-0434	Graphical symbols for use on equipment		
	IEC 60601-1 Table D.1, Symbol 10	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	ISO 15223-1 Clause 5.7.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied	Patient number	Indicates a unique number associated with an individual patient.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
	BS EN 50419:2006	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)	Separate Collection	To indicate that the product shall be separated when disposed.
	IEC 60417-5140	Graphical symbols for use on equipment	Non-ionizing electromagnetic radiation	To indicate generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF lectromagnetic energy for diagnosis or treatment. lectromagnetic energy for diagnosis or treatment.
	IEC 60601-1-2:2007, Clause 5.1.1	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests		
	IEC/TR 60878-5140	Graphical symbols for electrical equipment in medical practice		
	IEC 60417-5333	Graphical symbols for use on equipment	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1.
	IEC 60601-1, Table D.1, Symbol 20	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance		
	ASTM F2503-13	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION / EXPLANATORY TEXT
IPN1N2	IEC 60601-1, Table D.3 Symbol 2 IEC 60529	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance Degrees of Protection Provided by Enclosures (IP Code)	Degrees of protection provided by enclosure	Manufacturer-determined degree of particle and water ingress protection, where: N1 = Degrees of protection against access to hazardous parts N2 = Degrees of protection against water
IP24				Protected against solid foreign objects of 12,5 mm diameter and greater, and protected against splashing water
IP22				Protected against solid foreign objects of 12,5 mm diameter and greater, and protected against vertically falling water drops when enclosure tilted up to 15°
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

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ALB0031.12 | Date of first issue: 2018-11 | Revised: 2025-04