Zio® AT

IMPORTANT INFORMATION

ABOUT THE ZIO AT

Zio AT data analysis

Your Zio AT data is analyzed at the iRhythm Clinical Centers. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards.

A link to these standards (42 C.F.R. Section 410.33) can be found at the iRhythm website www.irhythmtech.com.

Patient identification

Before placing your device in the prepaid envelope, please write your name on the line above the return address. By writing your name on the envelope you are providing another method of identification for the Patch and Gateway and are consenting to the potential viewing of your name on the envelope. You may choose to not write your name on the envelope.

Notice of privacy practices

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information (PHI).

Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

Indications for use

The Zio AT ECG Monitoring System is intended to capture, analyze and report symptomatic and asymptomatic cardiac events and continuous electrocardiogram (ECG) information for long-term monitoring. While continuously recording patient ECG, both patient-triggered and automatically detected arrhythmia events are transmitted to a monitoring center for reporting. After wear, a final report is generated based on beat-to-beat information from the entire ECG recording. 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. 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.

Contraindications

- Do not use Zio AT 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 for patients with known history of life threatening arrhythmias.
- Do not use the Zio AT 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 on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio AT 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 patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the Zio AT on patients residing in areas with limited to no cellular reception.
- Do not modify the Zio AT system.

Warnings (cont'd)

- The Zio AT system is MR Unsafe!

  -Do not expose the Zio AT patch or gateway to a magnetic resonance (MR) environment.

  -The Zio AT patch or gateway may present a risk of projectile injury due to the presence of ferromagnetic materials that can be attracted by the MR magnet core.

  -Thermal injury and burns may occur due to the metal components of the Zio AT patch that can heat during MR scanning.

  -The Zio AT patch may generate artifacts in the MR image.

  -The Zio AT patch or gateway may not function properly due to the strong magnetic and radiofrequency fields generated by the MR scanner.

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 Service at 1.888.693.2401

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

Precautions

- Safety and effectiveness of the Zio AT Patch 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 system on pediatric patients (younger than 18 years old) has not been established.
- The Zio AT system 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 system 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 system 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.

The patient is an intended operator

Package Contents

1 Zio AT patch

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

1 Skin Prep & Placement Kit containing:
  1 patch card template
  1 disposable razor
  1 abrader disc
  4 alcohol wipes

1 Application instructions

1 Wearing your Zio manual & button press log containing:
  1 adhesive remover wipe

Symbols Glossary

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION/EXPLANITORY 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		
	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		

Symbols Glossary (cont'd)

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION/EXPLANITORY TEXT
	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		
	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.
	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.
	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 electromagnetic 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.

Symbols Glossary (cont'd)

SYMBOL	STANDARD REFERENCE	STANDARD TITLE	SYMBOL TITLE	DESCRIPTION/EXPLANITORY 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.
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°
℞ 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

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
	≤180 bpm	≥60 seconds
Pause	-	≥4 seconds
	-	≥3 seconds back-to-back
Ventricular Tachycardia	≥ 120 bpm	≥ 30 seconds
	≥150 bpm	≥15 seconds
Complete Heart Block (day 05:00~23:00)	≤ 50 bpm	≥6 beats
Complete Heart Block (night 23:00~05:00)	≤ 47 bpm	≥6 beats
Bradycardia	≤30 bpm	≥60 seconds
Tachycardia	≥ 200 bpm	≥ 60 seconds

PATCH PERFORMANCE CHARACTERISTICS

ECG Channels	1 channel
Memory capacity	14 days
Recording Format	Continuous
Service Life	Up to 14 days
Shelf Life	2 months

ELECTRICAL CHARACTERISTICS

Medical Equipment Type	BF Applied Part
ECG Frequency Response	0.5Hz to 30Hz
ECG Input Impedance	≥ 10 MΩ
ECG Differential Range	±1.65 mV
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 < 1mW
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 < 1mW
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	14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.2 x 2.0 x 0.5 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 system records and transmits ECG for analysis after receipt of data. In the event it cannot record or transmit in a timely fashion, the Zio AT alerts the patient that functionality is impaired.

EQUIPMENT CLASSIFICATION INFORMATION

Patch IEC Classifications	Gateway IEC Classifications
Internally Powered ME Equipment	Internally Powered ME Equipment
Type BF Applied Part	-
IPX4 -	IP 22
Continuous Operation	Continuous Operation

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 3 seconds.

Electrical Safety and Compatibility

- 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.

Table 1: Guidance and manufacturer's declaration—electromagnetic emissions

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

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	Not applicable	Not applicable

Table 2: Guidance and manufacturer's declaration—electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 3: Guidance and manufacturer's declaration—electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

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Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse 9 V/m 710, 745, 780 MHz 217 Hz pulse 28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse 9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	10 V/m 28 V/m 9 V/m 28 V/m 9 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Zio AT system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Zio AT system is used exceeds the applicable RF compliance level above, the Zio AT system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Zio AT patch or gateway.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 4: Recommended separation distances between portable and mobile RF communications equipment and the Zio AT system.

The Zio AT system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Zio AT system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Zio AT system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**80 MHz to 2.5 GHz**
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations.

Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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 system 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 ensure compliance 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.

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