Zio® MCT

IMPORTANT INFORMATION

CONFIDENTIAL - DRAFT

ABOUT THE ZIO MCT

Zio MCT data analysis

Your Zio MCT 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 MCT 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 MCT 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 MCT for patients with known history of life-threatening arrhythmias.
- Do not use the Zio MCT 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 MCT on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio MCT on patients who do not have the competency to wear the device for the prescribed monitoring period.

Warnings

- Do not use the Zio MCT 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 MCT 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 MCT on patients residing in areas with limited to no cellular reception.

- Do not modify the Zio MCT system.

Warnings (cont'd)

- The Zio MCT system is MR Unsafe!

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

  -The Zio MCT 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 MCT patch that can heat during MR scanning.

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

  -The Zio MCT 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 MCT Patch from the patient's chest. Call iRhythm Customer Care 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 MCT 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 MCT system on pediatric patients (younger than 18 years old) has not been established.
- The Zio MCT system includes temperature and humidity limitations when stored/transported. If exposed during storage/transport, patients may experience degradation of adhesive performance causing the Zio MCT patch to slip or fall off during the patient wear duration.

- The Zio MCT 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 MCT 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 MCT patch

1 Zio MCT 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
	ISO 15223-1 Clause 5.1.1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
	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
	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
	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
	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
	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
	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
	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
	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
	ISO 7000-2620	Graphical symbols for use on equipment

	SYMBOL TITLE	DESCRIPTION/EXPLANITORY TEXT
	Manufacturer	Indicates the medical device manufacturer.
	Date of manufacture	Indicates the date when the medical device was manufactured
	Use-by date	Indicates the date after which the medical device is not to be used.
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.

Symbols Glossary (cont'd)

SYMBOL	STANDARD REFERENCE	STANDARD TITLE
	ISO 15223-1 Clause 5.4.2	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
	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
	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
	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
	IEC 60417-5140	Graphical symbols for use on equipment
	IEC 60601-1-2:2014, 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
	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

	SYMBOL TITLE	DESCRIPTION/EXPLANITORY TEXT
	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.
	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.
	Patient number	Indicates a unique number associated with an individual patient.
	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.
	Type BF Applied Part	To identify a type BF applied part complying with IEC 60601-1.
	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment.

Symbols Glossary (cont'd)

SYMBOL	STANDARD REFERENCE	STANDARD TITLE
	BS EN 50419:2006	Marking of electrical and electronic equipment in accordance with article 11(2) of Directive 2002/96/EC (WEEE)
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)
IP24		
IP22		
Rx ONLY	21 CFR 801.15(c)(1)(i)F	Labeling-Medical devices; prominence of required label statements

	SYMBOL TITLE	DESCRIPTION/EXPLANITORY TEXT
	Separate Collection	To indicate that the product shall be separated when disposed.
	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
		Protected against solid foreign objects of 12,5 mm diameter and greater, and protected against splashing water
		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°
	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
	Between 40–180bpm	≥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

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	0.4 Hz to 40 Hz
ECG Input Impedance	>10 MΩ
ECG Differential Range	±1.65mV
ECG A/D Sampling Rate	200 Hz
ECG Resolution	15.5 bits
Patch Short-range RF Transmit/Receive	Bluetooth Low Energy 2.4GHz ISM Band (2400-2483.5 MHz)
Patch Receiver Frequency Band	2402-2480 MHz
Patch Receive Channel Bandwidth	2 MHz
Patch Transmitter Frequency Band	2402-2480 MHz
Patch Effective Radiated Power	< 1 mW
Patch Frequency Modulation	1-Mbps GFSK
Gateway Short-range RF Transmit/Receive	Bluetooth Low Energy 2.4 GHz ISM Band (2400-2483.5 MHz)
Gateway Receiver Frequency Band	2402-2480 MHz

Gateway Receive Channel Bandwidth	2 Mhz
Gateway Transmitter Frequency Band	2402-2480 MHz
Gateway Effective Radiated Power	< 1 mW
Gateway Frequency Modulation	1-Mbps GFSK
Gateway Cellular RF Transmit/ Receive	LTE Cat M1
Gateway Downlink Frequency Band	746-756 MHz
Gateway Downlink Frequency Modulation	OFDMA
Gateway Receive Channel Bandwidth	1.4 Mhz
Gateway Uplink Frequency Band	777-787 MHz
Gateway Uplink Frequency Modulation	SC-FDMA
Gateway Effective Radiated Power	< 200 mW

POWER CHARACTERISTICS

Patch Battery Type	1 lithium manganese dioxide coin cell
Gateway Battery Type	1 Lithium Polymer Cell
Battery Life	> 14 days

PHYSICAL CHARACTERISTICS

Patch Dimensions	5.5 × 2.2 × 0.4 in
Patch Weight	10 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	64 to 80 degrees F
Storage Altitude	-1,000 to 14,000 ft
Patch IP Classification	IP24
Gateway IP Classification	IP22

ESSENTIAL PERFORMANCE

The Zio MCT system records and transmits ECG segments for analysis upon receipt at iRhythm Technologies, Inc. clinical center. In the event it cannot record or transmit as intended, the Zio MCT alerts the patient that functionality is impaired. Risks associated with failure of the device to perform as intended have been mitigated to an acceptable level.

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 MCT 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 MCT system should not be used adjacent to or stacked with other equipment.
- WARNING: The Zio MCT 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 MCT patch or gateway. Otherwise, degradation of the performance of this equipment could result.

Table 1: Manufacturer's declaration— electromagnetic emissions	
The Zio MCT system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio MCT system should assure that it is used in such an environment.	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations/ flicker emissions IEC	Not applicable

Table 2: Manufacturer's declaration— electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

Table 3: Manufacturer's declaration— electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level

Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3Vrms
	10 Vrms 150 kHz to 80 MHz in ISM bands	10Vrms

Table 4: Manufacturer's declaration— electromagnetic immunity		
The Zio MCT system is intended for use in the electromagnetic environment specified below. The customer or the user of the Zio MCT system should assure that it is used in such an environment.		
Immunity test	IEC 60601 test level	Compliance level

Continued on next page

Radiated RF IEC 61000- 4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m
	28 V/m 385, 450, 810, 870, 930 MHz 18 Hz pulse	28 V/m
	9 V/m 710, 745, 780 MHz 217 Hz Pulse	9 V/m
	28 V/m 1720, 1845, 1970, 2450 MHz 217 Hz pulse	28 V/m
	9 V/m 5240, 5500, 5783 MHz 217 Hz pulse	9 V/m

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 iRhythm Technologies Inc. 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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