ZIO® BY iRHYTHM

Instructions for Use

Visit iRhythm's website www.irhythmtech.com/user-manuals 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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Description

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

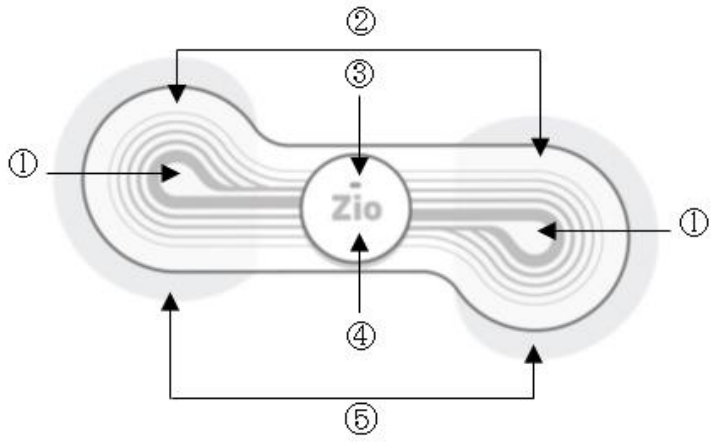
(1) Zio monitor

(2) proprietary algorithm software.

The 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 via simplicity of operation. Patients have the option of pressing a convenient button and filling out a log to document symptomatic events, which will support symptom-rhythm correlation in the diagnostic report.

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.

Example of Zio monitor



(1) Electrode – acquires ECG data

(2) Adhesive wings – adheres the Zio monitor to the upper-left chest

(3) Light – momentarily flashes green when activated and orange in the event of an error

After activation, you will not see any lights.

See also: Troubleshooting, page 21

(4) Zio button – activates the Zio monitor. The patient presses this button when a symptom is felt.

(5) Clear plastic backings – remove from back of Zio monitor and discard before applying to the chest

Intended Use

The Zio monitor is intended to capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring.

Indications for Use

The Zio monitor is a prescription-only, single-use ECG monitor that continuously records data for up to 14 days. It is indicated for use on patients who maybe asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

Contraindications

- Do not use the Zio monitor for patients with symptomatic episodes where instance 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 monitor 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 monitor on patients with neurostimulator, as it may disrupt the quality of ECG data.
- Do not use the Zio monitor on patients who do not have the competency to wear the device for the prescribed wear period.

Safety Information

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

Warnings

- Do not use the Zio monitor on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. If allergic symptoms, severe skin irritation, or signs of skin infection develop, remove the device from the patient's chest and discontinue wear. Reaction to adhesives may include severe redness and itching, hives, and blisters. Contact your healthcare provider and Customer Care to report the reaction.
- The Zio monitor is MR unsafe.

  Do not expose the Zio monitor to a magnetic resonance (MR) environment.

  - The MR magnet core can attract the ferromagnetic materials in the Zio monitor, creating a risk of projectile injury to the patient and others in proximity of the Zio monitor and MR device.
  - Metal components in the Zio monitor can heat during MR scanning, resulting in the potential for thermal injury and burns.
- Do not use the Zio monitor on patients with broken skin. Only apply to intact skin.
- Do not reuse the Zio monitor on the same patient or on multiple patients. It is a single-use device. Reuse of the device may result in mixed patient results, poor adhesion, and poor ECG signal.
- Do not modify this equipment without authorization of the manufacturer.

Precautions

- During storage and prior to prescription for a patient, do not exceed the temperature and humidity limitations for the Zio monitor. Devices exposed to environmental conditions outside the specified range may have degraded adhesive and battery performance.

  Observe the temperature and humidity specifications for transportation and storage listed on the Zio monitor box and in the instructions for use.

- Confirm the expiration date for the Zio monitor listed on the device box or pouch. Use of an expired device may cause a degradation of ECG signal quality and a low battery condition. Apply the device on or before expiration date.

- Recorded ECG data cannot be retrieved for analysis unless you return your Zio monitor. Keep the original device box. The box is designed to protect the Zio monitor and Symptom Log in the return mail when properly sealed. Follow the return instructions in this manual. If the box is damaged during opening or handling or lost, contact Customer Care.

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

- Do not use the Zio monitor on patients receiving any form of pacing therapy. Paced cardiac rhythms may not be accurately detected leading to incorrect preliminary findings.

- Carefully prepare skin on the patient's upper left chest prior to applying the Zio monitor. Observe the instructions for proper shaving, exfoliating, and cleaning. Proper placement and alignment of the Zio monitor on the patient's chest is important for recording ECG data. Carefully follow the sequence of all steps in the application instructions to ensure the device is properly positioned and securely adhered to the patient's chest.

- Avoid delays in recording ECG data. After applying the Zio monitor to the patient's chest, follow the instructions in this manual to activate recording of ECG data. If the light on the Zio monitor does not flash green after a second activation attempt, contact Customer Care.

- If the patient has a known allergic reaction to limonene, the active ingredient in the adhesive remover, use baby oil or petroleum jelly to aid removal instead of the adhesive remover wipe.

- 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.

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.

Symbols Glossary

SYMBOL	SYMBOL TITLE	DESCRIPTION/EXPLANATION
	Manufacturer	Indicates the medical device manufacturer
QTY	Net quantity of contents	Net quantity of contents
	Do not use if package is damaged and consult the instructions for use	Indicates a medical device should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information
	Use-by date	Indicates the date after which the medical device is not to be used
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information
	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
	Do not re-use	Indicates a medical device that is intended for one single use only
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Type BF Applied Part	To identify a Type BF applied part complying with IEC 60601-1. A Type BF Applied Part includes a patient connection that is intended to deliver electrical energy or an electrophysiological signal to or from the patient.
	Magnetic Resonance (MR) unsafe	A medical device which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	Recyclable	Indicates the marked item or its material is part of a recovery or recycling process
	Separate collection	To indicate that the product shall be separated when disposed.

SYMBOL	SYMBOL TITLE	DESCRIPTION/EXPLANATION
IP27	Degrees of protection provided by enclosure	Protected against solid foreign objects of 12.5 mm diameter and greater, and protected against the effects of temporary immersion in water
FC	FCC compliant radio frequency equipment	Indicates compliance with the Federal Communications Commission (FCC) rules in the United States of America The FCC identifier (ID) includes the grantee code and product code.
Rx ONLY	Prescription only	Requires prescription in the United States of America

Notice of Privacy Practices

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

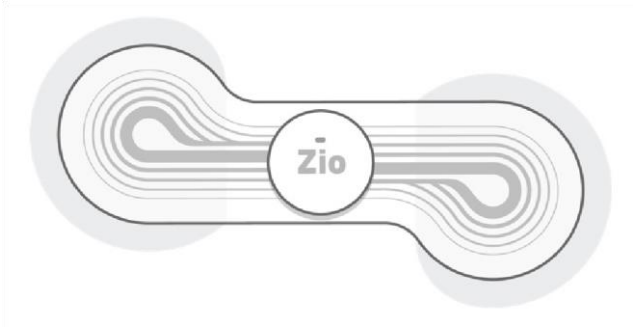
Patient Identification

At the end of the wear period, before placing the Zio monitor in the Zio monitor box, advise the patient to write their name on the line above the return address. By writing their name on the return label, the patient provides another method of identification for the Zio monitor and consents to the potential viewing of their name on the return label. The patient may choose to not write their name on the return label.

Package Contents

Note: The device box is provided to the patient. The patient must keep the box until the end of the prescribed wear period. The postage-paid box is re-used to return the device and Symptom Log to iRhythm.

- **Zio monitor,** quantity 1

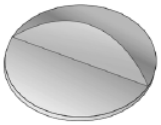


Note: The Zio monitor is within a pouch.

- **Prep Materials box**, quantity 1**:**

The Prep Materials box is within the device box and contains the following items for skin preparation:

Disposable razor, quantity 1



Exfoliator disc, quantity 1

Alcohol wipes, quantity 2

- **Postage-paid return box** (same as device box). The patient must keep this box. The Zio monitor is returned in the box at the end of the prescribed wear period.
- **Adhesive remover wipes,** quantity 2

Note: The adhesive remover wipes are in the Patient Guide.

- Patient Guide, quantity 1
- Symptom Log, quantity 1

Getting Started

The Zio monitor is an ECG monitor that continuously records the electrical activity of the heart. It is intended to be worn continuously for a time period specified by a provider for up to 14 days. Each patient's wear duration may differ due to individual wear experiences. Excessive sweating may decrease wear duration.

Instructions

Register the patient and then follow the steps to prepare the skin and apply the Zio monitor to the patient.

- Step 1: Identify the location for skin preparation, page 10
- Step 2: Prepare the patient's skin, page 10
- Step 3: Apply the Zio monitor, page12
- Step 4: Activate the Zio monitor, page 15

Register the Patient

1. Register the patient online at www.ziosuite.com.
2. Open the device box:
   a. Locate the side of the box marked "Lift from sides to open".
   b. Lift from the arrows to open the lid.
   c. Remove the following items from the box:
      - Pouch with Zio monitor
      - Prep Materials box
      - Symptom Log
   d. Instruct the patient to keep the box. The box is used to return the device at the end of the prescribed wear period.
3. On the cover of the Symptom Log, write the patient's name, start date, and prescribed wear duration.

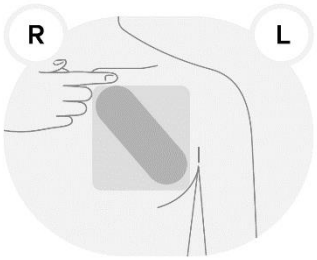
Clinic or patient entries

Patient writes date of removal

4. Instruct the patient to write the date on the cover when they remove the Zio monitor for return.

Step 1: Identify the location for skin preparation

1. Clinicians only: Request the patient stand with their arms relaxed by their sides during the Zio monitor application. If standing is not possible, the patient may sit upright.
   - If the patient is applying the Zio monitor at home, they should make sure their chest is fully visible in a mirror.
2. Locate the area on the patient's upper-left chest one finger width below the left collarbone from the center of the chest.
   - The Zio monitor will be placed diagonally on the chest after the skin is prepared.
   - The area necessary for skin preparation extends beyond where the Zio monitor will be placed.



Note: If patient anatomy requires alternative placement, the quality and duration of the ECG recording may be affected.

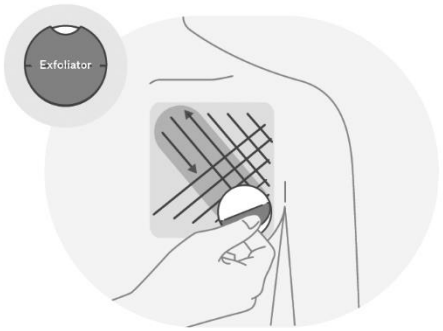
- Due to the nature of the adhesive, the Zio monitor may move slightly during the monitoring period.

Step 2: Prepare the patient's skin

1. Open the Prep Materials box and remove the contents.
2. Shave the chest area requiring skin preparation (all genders, including those with no visible hair).
   a. Hold the protective cover on the razor and pull the razor from the cover.
   b. Shave the entire area with the razor. **Shaving is necessary whether hair is visible or not visible.**

   c. Ensure the skin is fully clean and dry before you continue.

3. Exfoliate the preparation area:
    a. Lift up the plastic tab on the exfoliator to use as a handle.
    b. Gently exfoliate the entire area with the rough side of the exfoliator.



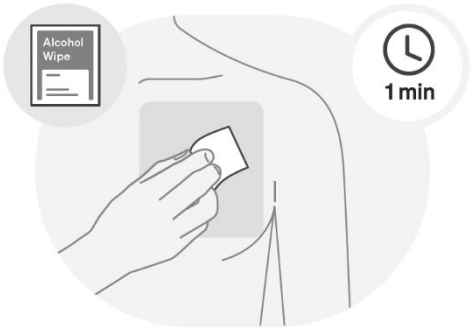
    c. Focus on the top and bottom corners; complete 40 strokes in total: up and down, side to side, and both diagonal directions.

    Exfoliating may cause expected skin redness.

4. Clean and dry the skin:
    a. Use an alcohol wipe to clean the prepared chest area.

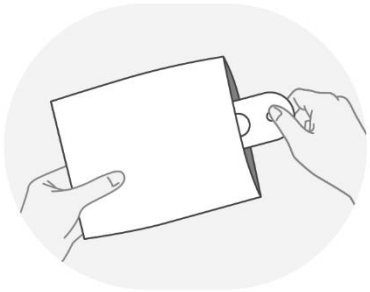
        The patient may feel a slight tingling sensation.

    b. Let the skin dry for at least 1 minute for proper adhesion.

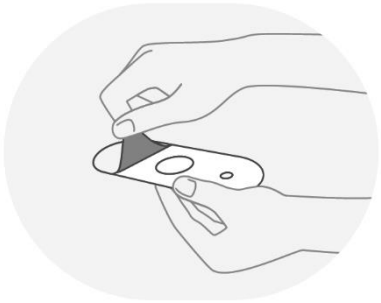


Step 3: Apply the Zio monitor

1. Open the pouch containing the Zio monitor:
   a. Tear open from either notch.
   b. Remove the Zio monitor.



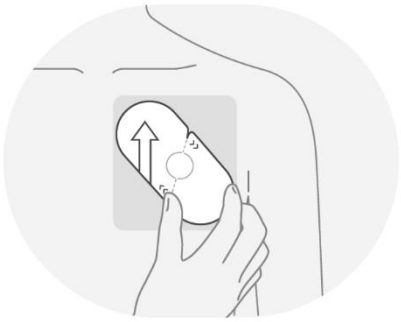
2. Peel only the clear backings from the Zio monitor:
   a. Hold the middle of the Zio monitor.
   b. Pull off the clear plastic backings carefully and avoid touching the exposed adhesive.



   c. Keep the paper tabs intact on the other side of the monitor.

      Note: Wait to remove the paper tabs later in Step 5.

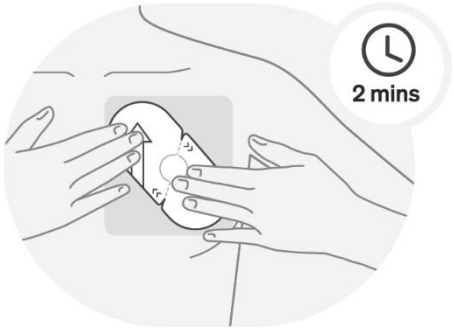
3. Apply the Zio monitor to the prepared chest area:
   a. Ensure the white arrow on the paper tab is pointing upward.



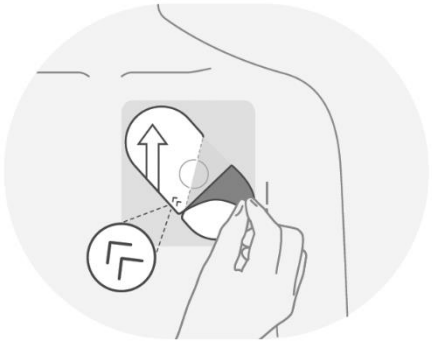
   b. Place the Zio monitor diagonally on the prepared skin area, one finger width below the left collarbone from the center of the patient's upper-left chest.

CONTINUED NEXT PAGE

4. Massage the paper tabs on the wings of the Zio monitor:
    a. Massage the paper tabs firmly for 2 minutes to fully adhere the Zio monitor to the patient's chest.



    b. Do not move or remove the Zio monitor after applying it to the patient's chest.
5. Remove the paper tabs from the front of the Zio monitor:
    a. Find the double arrows located above and below the center of the Zio monitor.



    b. Peel the tab in the direction of the double arrows. Ensure the adhesive wing does not lift using your other hand.

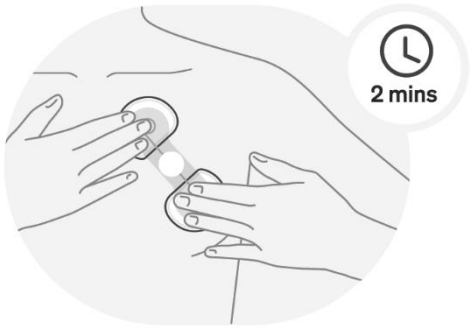
        The center of the Zio monitor may slightly lift from the skin as the tab is peeled.

    c. Remove the remaining tab.

CONTINUED NEXT PAGE

6. Massage the wings again:

   a. Massage the adhesive wings firmly onto the patient's skin for another 2 minutes to prevent the Zio monitor from slipping or falling off the patient's chest.



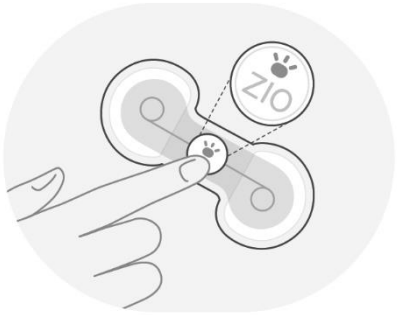
   b. If remnants of the paper tab are on the wings, peel outward from the center of the monitor.

   c. Do not move or remove the Zio monitor after applying it to the patient's chest.

Step 4: Activate the Zio monitor

1. Press and release the button at the center of the Zio monitor.

   The light briefly flashes green to indicate the patient's heartbeat is being recorded.



2. After you see the green light, help the patient practice pressing the button.
3. If the light flashes orange, massage the adhesive wings for an additional 2 minutes.
   a. Press the button again to attempt activation.
   b. If the device does not activate on the second attempt, contact Customer Care.

Wear Instructions

During the first 24 hours, avoid the following activities:

Do not swim or take a shower/bath

Avoid activities that may cause you to sweat

Do not submerge your Zio monitor in water (pool, hot tub, bath)

Do not apply soap or lotions near your Zio monitor

After the first 24 hours, the patient can continue normal activities:

Take brief showers with your back to the water

Light exercise is acceptable, but avoid excess sweating (intense exercise, sauna)

Do not submerge your Zio monitor in water (pool, hot tub, bath)

Do not apply soap or lotions near your Zio monitor

REVIEW WITH YOUR PATIENT

- Ensure the patient understands the purpose and importance of the Zio ECG monitoring system.
- Each patient's wear duration may differ due to individual wear experiences.
- Wear the Zio monitor continuously for the duration of the prescribed wear period, through sleep and showering.
- While towel drying after a shower, the patient should hold the Zio monitor with one hand.
- When properly functioning, the patient does not see any lights on the Zio monitor.

  If the patient sees lights, it does not mean that anything is wrong with their heart, refer to Troubleshooting on page 21.
- The patient should not remove the Zio monitor before the end of the prescribed wear period unless skin irritation, such as severe redness, itching, or allergic symptoms develop.

  Contact Customer Care to report allergic reaction or severe skin irritation.
- Review how to log symptoms with the patient.

  See also: Logging symptoms on page 17
- If the Zio monitor falls off the patient's chest, contact Customer Care.

Logging symptoms

Logging symptoms provides the healthcare provider with additional information to help analyze the patient's health condition and develop a plan of care. Not all patients experience symptoms.

A "symptom" is anything unusual the patient feels or experiences.

Types of symptoms include:

- **Chest pain**

  Discomfort, tightness, or pressure in the chest area

- **Fainted**

  Passed out or lost consciousness

- **Irregular beats**

  Heart is skipping beats or beating out of its normal rhythm

- **Lightheaded**

  Dizzy and/or slightly faint.

- **Racing**

  Heart is pounding or beating too fast

- **Shortness of breath**

  Difficulty breathing or unable to catch breath

REVIEW WITH YOUR PATIENT

1. When a patient feels a symptom, advise the patient to press the button on the Zio monitor.
   - The light does not flash when the button is pressed.
   - If a patient forgets to either press the button or log a symptom, the Zio monitor is recording the ECG data.
2. Log the symptom in either the MyZio app or in the Symptom Log with the following information:
   - Date and time the button was pressed
   - Symptom and length of time the symptom was felt or experienced

     Note: If the reason for the button press is not listed, the patient can select "Other" and describe the symptom.
   - Activity when the symptom was experienced (for example, walking the dog, sleeping, standing after sitting)
   - If all pages in the Symptom Log are used, the patient can download the MyZio app and continue logging symptoms.

Security Screening Statement

(Included in the Patient Symptom Log or the MyZio mobile application)

This person is wearing an iRhythm Zio monitor prescribed by their provider. This device is currently adhered to the patient's chest, where it is monitoring their heart. It can only be removed under the direction of their provider.

If you have any questions, please contact the iRhythm Customer Care.

Removal Instructions

The Zio monitor is removed by the patient at the end of the prescribed wear period and placed inside the device box for immediate return.

REVIEW WITH YOUR PATIENT

1. Retrieve the adhesive remover inside the Patient Guide.
2. Tear open the package and remove the adhesive remover.
3. Gently lift up the center of the Zio monitor.
4. Starting from the center, wipe the area between the skin and the Zio monitor with the adhesive remover.

5. Continue to wipe as you peel off the Zio monitor, one side at a time.
    - The patient's skin may feel slightly irritated after removing the Zio monitor.
    - The light briefly flashes orange on the Zio monitor during and after removal. This is not an error with the device.
6. Open the device box and with the button centered, adhere the Zio monitor to the dotted outline.
7. Wash the skin with mild soap, rinse with water, and pat dry.

Return Instructions

REVIEW WITH YOUR PATIENT

1. On the cover of the Symptom Log, fill in the date the Zio monitor was removed.
2. Complete the survey. To provide feedback online, visit www.ziopatient.com.
3. Place the Symptom Log on top of the Zio monitor in the device box.
4. Peel the tape off the front of the box and press firmly on the flap to close and seal the box.
5. Mail the postage-paid box promptly to receive results as soon as possible.
   - Drop the device box inside any USPS mailbox or take the box to a post office.
   - The patient can schedule a free USPS pickup at ziopickup.com. Alternately, the box can be sent using expedited shipping (FedEx or UPS) at the patient's own expense to the following address:

     iRhythm Technologies
     Three Parkway North, Suite 400
     Deerfield, Illinois 60015

Troubleshooting

The patient will not see any lights or hear any sounds when the Zio monitor is functioning properly.

- **If an orange light is slowly flashing:**
  - This indicates the Zio monitor is not well attached to the patient's skin. It does not mean something is wrong with the heart.
  - Massage the adhesive wings for 3-5 minutes until the orange light disappears to secure the Zio monitor to the patient's skin.
  - If flashing persists or reoccurs, call Customer Care at (888) 693-2401.
- **If an orange light is rapidly flashing (3 flashes per second):**
  - This indicates the Zio monitor is not working.
  - Call Customer Care at (888) 693-2401.
- **If the Zio monitor has fallen off, call Customer Care at (888) 693-2401.**

Technical Specifications

The Zio monitor is not manufactured with natural rubber latex.

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 to 40 Hz
ECG input impedance	>10 MΩ
ECG differential range	±1.65 mV
ECG A/D sampling rate	200 Hz
ECG resolution	15.5 bits
Gain accuracy	Maximum amplitude error +/- 10%
Gain stability	< 3% over a 24-hour period
Timing accuracy	< 30 sec over 14-day wear period

Power specifications

Battery type	1 lithium manganese dioxide coin cell
Battery life	> 14 days

Physical characteristics

Dimensions	5.5 × 2.2 × 0.4 in 139.7 x 55.8 x 10.6 mm
Weight	10 g

Environmental specifications

Operational temperature	41 to 104° F 5 to 40° C
Operational altitude	-1,000 to 10,000 ft -305 to 3,048 m
Shipping (short-term storage) temperature	-4 to 104° F 20 to 40° C
Long-term storage temperature	64 to 80° F 18 to 27° C
Operational and storage humidity	10% to 95% (non-condensing)
Storage altitude	-1,000 to 14,000 ft -305 to 4,267 m
IP classification	IP27

Essential performance

The Zio monitor continuously records ECG data during wear. After wear, the device is returned, and the complete ECG recording is extracted for analysis. If the device cannot record as intended, the Zio monitor alerts the patient that functionality is impaired. Risks associated with failure of the devices to perform as intended have been mitigated to an acceptable level.

Electrical Safety and Compatibility

- WARNING: The Zio monitor should not be used adjacent to or stacked with other equipment.
- WARNING: Portable and mobile RF communications equipment can affect medical electrical equipment. 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 monitor. Otherwise, degradation of the performance of this equipment could result.
- CAUTION: The Zio monitor needs special precautions regarding EMC and needs to be utilized according to the EMC information provided in the following tables.

The Zio monitor was tested for electromagnetic compatibility (EMC) according to the International Electrotechnical Commission (IEC) 60601-1-2 standard.

The Zio monitor meets the requirements of the standard and is suitable for a home healthcare environment.

Table 1: Manufacturer's declaration — electromagnetic emissions

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 61000-3-3	Not applicable

Table 2: Manufacturer's declaration — electromagnetic immunity

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
Proximity magnetic field IEC 61000-4-39	8 A/m 30 kHz 65 A/m 134.2 kHz 2.1 kHz Pulse 7.5 A/m 13.56 MHz 50 kHz Pulse	8 A/m 65 A/m 7.5 A/m

Table 3: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands	3 Vrms
	10 Vrms 150 kHz to 80 MHz in ISM bands	10 Vrms

Table 4: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
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

Federal Communications Commission (FCC) Compliance

FCC ID	2AFBP-MCT22P

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.

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