ZIO®

Instructions for Use

Read these Instructions for Use before preparing the patient's skin and using the Zio® monitor.

Apply the Zio monitor immediately and do not throw away these instructions.

MyZio app

Use the MyZio app to log symptoms, track progress, and access information about your Zio monitor.

Scan QR code to download the app

1. Open the camera app on your smart phone.
2. Scan the QR code with your camera.

   A notification should appear on your screen.
3. Tap the notification to download the app.

We are here to support you

- Contact Customer Care at (888) 693-2401
- Customer Care is available 24 hours a day/7 days a week to answer questions about your Zio monitor.
- Customer Care troubleshoots issues with you and reminds you to return your Zio monitor.
- Customer Care collects your feedback about the Zio monitor.

Call 911 if you require immediate medical attention.
The Zio monitor will not provide any medical assistance and cannot contact medical personnel for you.

Contents

Product Description

The **Zio® Electrocardiogram (ECG) Monitoring System** is intended for continuous, long-term monitoring of a patient's ECG data.

The **Zio ECG Monitoring System** enables services for non-critical care patients by providing the following devices for use.

- **Zio monitor**
- **Zio ECG Utilization Software (ZEUS)**

- The **Zio monitor** 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 **Zio monitor** continuously records ECG data during the wear period, with no wireless transmissions.

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

- **Zio ECG Utilization Software** provides an arrhythmia detection algorithm to analyze the ECG data. The data is reviewed at the monitoring center by qualified cardiac technicians who generate reports for the physician at the end-of-wear.

Prescribed Wear Period

- The Zio monitor is worn for **up to 14 days**.
- If an additional Zio monitor is required to complete the prescribed wear period, Customer Care contacts the patient and physician before the device is sent to the patient.

  The **patient performs the following actions** upon receipt of the additional Zio monitor:

  - Immediately remove and return the existing Zio monitor.
    Refer to instructions on pages 28 through 32.

  - Apply and activate your new Zio monitor as soon as possible.
    Refer to instructions on pages 12 through 20.

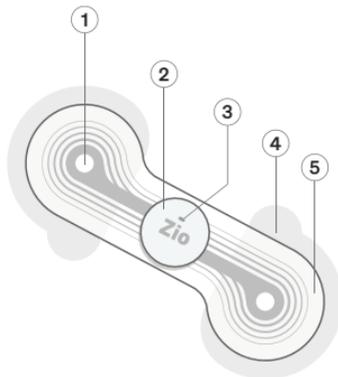# Illustration of Zio Monitor (example)
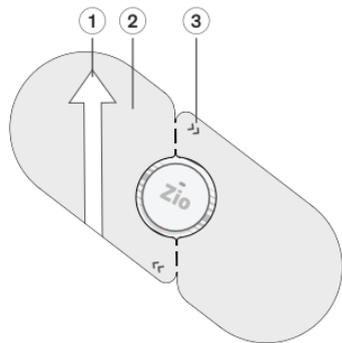
(1) White arrow for guiding placement of the Zio monitor

(2) Paper tabs covering the electrodes

(3) Double arrow indicating direction to remove paper tabs before activation

(1) Electrodes for acquiring ECG data

(2) Zio monitor button for activating the device. The button is pressed when the patient experiences a symptom.

(3) Light indicating when the Zio monitor is activated or if troubleshooting is required.

After activation, you will not see any lights unless there is an error. Refer to Troubleshooting on page 26.

(4) Clear plastic backings covering the adhesive wings

(5) Adhesive wings for adhering the Zio monitor to the patient's upper-left chest

Package contents

Contents of the device box:

Instructions for Use,
quantity 1

Symptom Log,
quantity 1

Zio monitor,
quantity 1

*The Zio monitor is
within a pouch*

The patient must keep the device box until the end of the prescribed wear period.

The device box with the prepaid return label is reused by the patient to return the
Zio monitor and Symptom Log at the end of wear.

If the device box is damaged during opening or handling, contact Customer Care.

Contents of the device box, continued:

Adhesive remover,
quantity 1

The patient removes the Zio monitor at the end of wear with the adhesive remover located on page 28.

Prep Materials box,
quantity 1

The name on the adhesive remover and alcohol wipe may vary by region; the intended use is unchanged.

The prep materials box is within the device box and contains items for skin preparation.

Dispose of the skin preparation items after applying the Zio monitor. Refer to disposal instructions on page 36.

Disposable razor,
quantity 1

Exfoliator disc,
quantity 1

Alcohol wipe,
quantity 2

Intended Use

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 18 years and 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.

Intended Patient Population
18 years or older

Intended Users
Healthcare Providers; Allied Healthcare Professionals; Patients

Intended Use Environment
Ambulatory: Out-patient

CONTRAINDICATIONS

- Do not use the Zio monitor on critical care patients because the reporting timeliness is not consistent with life-threatening arrhythmias such as ventricular fibrillation.

- The Zio monitor is not intended for use on patients under 18 years old.

- 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.

- 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 not designed for use on patients with pacing therapy or implantable cardioverter defibrillators. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified. The shocks from implantable cardioverter defibrillators may damage the Zio monitor.

- Do not expose the Zio monitor to a magnetic resonance imaging (MRI) environment.

  – The MRI device's 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 MRI device.

  – Metal components in the Zio monitor can heat during MRI scanning, resulting in the potential for thermal injury and burns.

- 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 box and in the instructions for use.

  Refer to Environmental Specifications on page 38 for temperature and humidity specifications.

Precautions, continued

- 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.

- 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.

- Recorded ECG data cannot be retrieved for analysis unless you return your Zio monitor. Keep the original 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.

- 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.

- Exposing the Zio monitor to any sources of infrared light (greater than 780 nanometers), such as direct sunlight or infrared saunas, can disrupt the recording of ECG data. Wear clothing if exposure to infrared light, such as direct sunlight, cannot be avoided.

- To avoid electromagnetic interference in the Zio monitor ECG recording, maintain a distance from electronic or surgical equipment with strong electromagnetic fields. The Zio monitor is suitable for use in a home healthcare environment.

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

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.

CLINICAL BENEFITS

Long-term, continuous ambulatory monitoring

- The Zio monitor is capable of capturing a continuous ECG recording of beat-to-beat cardiac rhythm data for up to 14 days. It facilitates detection of intermittent, infrequent, or asymptomatic arrhythmias as compared to other, shorter term ambulatory monitors.

Ease of use for the patient

- The Zio monitor is biocompatible, non-invasive, water-resistant and has no external leads or wires, and does not require battery charging or other maintenance by the patient to maintain functionality throughout the prescribed wear period.

Ambulatory monitoring

- The Zio monitor is intended for outpatient use, where variation in cardiac rhythms do not represent immediate danger to the patient.

1. Registering the Patient (Healthcare Professionals Only)

Healthcare professionals:

- **Register the patient in ZioSuite**
  - Go to the ZioSuite portal to register your patient in ZioSuite.

2. Getting Started

1. Remove the following items from the device box

- Zio monitor pouch
- Prep materials box
- Symptom Log

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2. Enter the following information on the Symptom Log cover
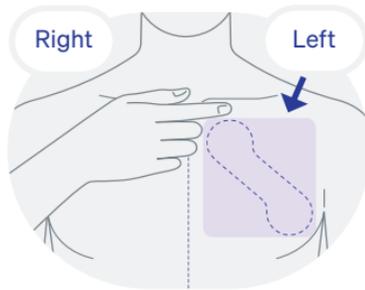
– **In-clinic:**

a. Write the patient's **Name**, **Start date**, and **Prescribed wear duration**.

b. Do not write the **Start time** until instructed on page 20.

c. Instruct the patient to complete the **Date removed** on their last day of wear.

– **At home:**

a. Write your **Name** and **Start date** on the cover. The date is when you apply the Zio monitor to your chest.

b. Refer to your welcome letter and write the number of days prescribed by your physician for wearing this Zio monitor in the **Prescribed wear duration**.

c. Do not write the **Start time** until instructed on page 20.

d. Complete the **Date removed** on your last day of wear.

3. Preparing the Skin

Remove the razor, exfoliator, and alcohol wipe from the prep materials box.

The illustration shows the skin preparation area and where the Zio monitor will be placed diagonally.
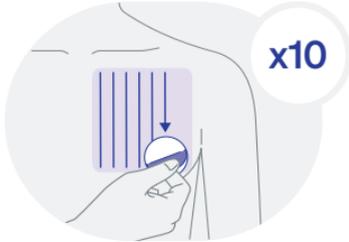
1. Identify skin preparation area

– **In-clinic:** Request the patient stand with arms relaxed by their sides. If standing is not possible, the patient may sit upright.

– **At home:** Look in a mirror to view your bare chest.

a. Locate the area on the upper-left chest, one finger width below the left collarbone and from the center of the chest.

b. Do not proceed to the next step if the skin has the following conditions:
   • an active skin rash (for example, psoriasis or eczema)
   • an active, ongoing sensation of burning or stinging (lasting more than five minutes)
   • a visible skin injury or broken skin
   • skin with damage and a discharge of clear fluid or pus

c. If a skin infection exists anywhere on the body, wait until the infection is fully treated before applying the Zio monitor.
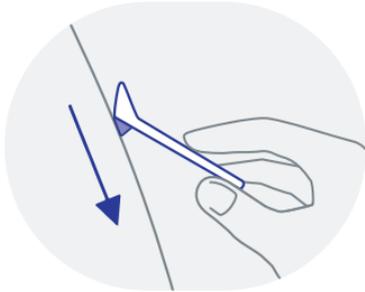
2. Shave chest area

Shaving is required for all genders, including chests with no visible hair, to ensure the Zio monitor can be securely adhered to the chest.

a. Hold the protective cover on the razor and pull the razor from the cover.

b. Shave the area shown in the outline only one time.

c. If hair is still visible, repeat shaving one more time.

d. Remove the hair shavings from skin preparation area.

e. Make sure the skin is dry before you continue.

f. If shaving causes a nick or cut, stop the bleeding and proceed.

3. Exfoliate skin preparation area

Exfoliation removes dead skin to ensure a quality ECG signal from the Zio monitor.

a. **Lift up** the plastic tab on the exfoliator to use as a handle. The **textured surface** is for exfoliating the skin.

b. Exfoliate the surface of the skin with

   20 strokes across the entire preparation area as described:
   – Up and down (10 times)
   – Left-to-right (10 times)

c. If any discomfort occurs, decrease the pressure applied to the exfoliator.

d. If the skin surface is compromised (for example, bleeding) or if discomfort continues, stop exfoliating the skin and do not apply the Zio monitor.
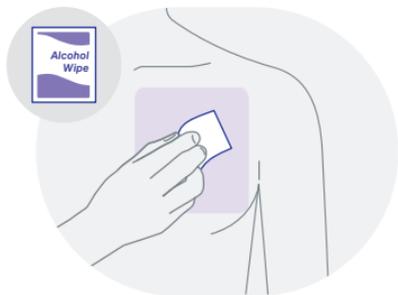
4. Clean the skin

a. Tear open the package and remove the alcohol wipe.

b. Clean the prepared skin area thoroughly with the alcohol wipe. The patient may feel a temporary, mild sensation of burning or stinging, and the patient's skin may look slightly red.
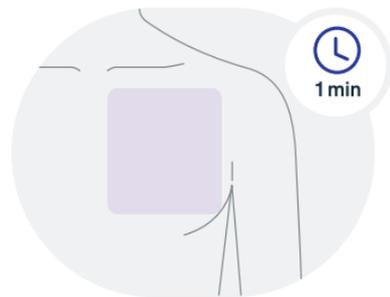
5. Wait one minute for skin to dry

a. **Wait** at least one minute for the skin to fully dry to resolve any symptoms of discomfort before applying the Zio monitor to the skin.

b. Do not apply the Zio monitor on skin with the following conditions:
  - an active skin rash (for example, psoriasis or eczema)
  - an active, ongoing sensation of burning or stinging (lasting more than five minutes)
  - a visible skin injury or broken skin
  - skin with damage and a discharge of clear fluid or pus

c. If a skin infection exists anywhere on the body, wait until the infection is fully treated before applying the Zio monitor.

4. Applying Zio Monitor
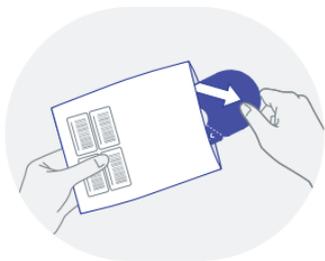
1. Open the pouch

- Tear open the pouch from either notch and remove the Zio monitor.
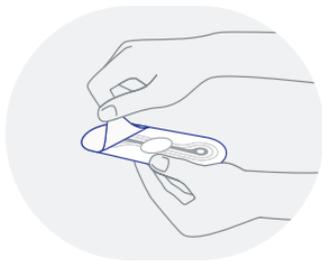
2. Peel clear plastic backings

a. Hold the Zio monitor with the clear plastic backings facing up.

b. Peel both clear plastic backings from the Zio monitor, and avoid touching the exposed adhesive.

c. Do not remove the paper tabs on the front of the Zio monitor in this step.
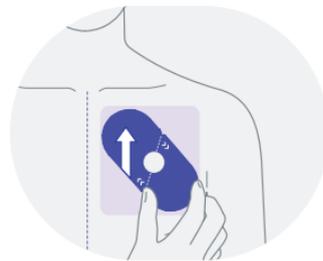
3. Apply the Zio monitor

a. Make sure the white arrow on the paper tab is pointing up as shown.

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

4. Massage both paper tabs

a. Massage both paper tabs firmly for two minutes to fully adhere the Zio monitor to the chest.

b. Do not move or remove the Zio monitor after it's applied.
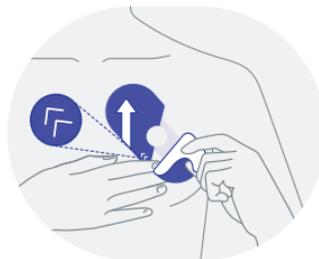
5. Remove paper tabs

a. Peel the tab away from the wing (in the direction indicated by the double arrows).

b. While peeling the tab, hold the adhesive wing in position with your other hand.

6. Massage wings again

a. Massage the adhesive wings firmly for another two minutes to prevent the Zio monitor from falling off.

b. Do not move or remove the Zio monitor.

c. If you see an orange light on the Zio monitor, refer to page 26.

5. Activating Zio Monitor

1. Press and quickly release button

a. Press and quickly release the button on the Zio monitor.
   The light briefly flashes green when the Zio monitor
   is activated.
b. If you do not see the light briefly flash green,
   call Customer Care at (888) 693-2401.
c. Retrieve the Symptom Log and write the **Start time** on the cover.

Healthcare professionals:

5a. Review with patient

- Help the patient practice pressing the button on the Zio monitor.

- Discuss the removal date on the Symptom Log cover, and review the Symptom Log and Survey.

- Instruct the patient to keep the device box for returning the device and Symptom Log at the end of the wear period.

5b. Ensure the device box is sent home with the patient and contains the following items:

- Instructions for Use (including adhesive remover on page 28)

- Symptom Log

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

Wear clothing to avoid exposure to sources of infrared light, such as direct sunlight

After the first 24 hours, you 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

Wear clothing to avoid exposure to sources of infrared light, such as direct sunlight

Reminders during Wear

Visually check your Zio monitor daily for flashing lights

You will **not see** any lights on your Zio monitor when functioning properly.

Refer to pages 26 through 27 for troubleshooting.

Log Symptoms

If you feel a symptom, refer to pages 24 through 25.

Traveling

If questioned about your Zio monitor, show the Security Screening Statement found in your Symptom Log or the MyZio app.

Wear as prescribed

- Wear your Zio monitor for **up to 14 days** as prescribed by your healthcare professional.

  The prescribed wear period is on the cover of the Symptom Log.

- Keep the device box to return your Zio monitor and Symptom Log.

Logging Symptoms

If you feel a symptom, complete the following steps.
Log symptoms in either the Symptom Log or MyZio app.

1. Press the button on the Zio monitor

- The light does not flash when the button is pressed.
- Not all patients experience symptoms.

2. Log the reason for the button press

- Date and time of button press
- Reason for button press; refer to next page
- Duration of symptom
- Activity when the symptom was experienced (for example, while sleeping, resting, or exercising)
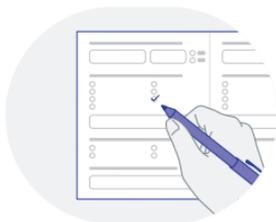
If you forget to press the button or log a symptom, the Zio monitor continues to record ECG data.

Logging symptoms provides your physician additional information to help develop a plan of care.

Reasons for Button Press

Chest pain
Discomfort, tightness, or pressure in the chest area

Racing
Heart is pounding or beating too fast

Fainted
Passed out or lost consciousness

Lightheaded
Dizzy and/or slightly faint

Irregular beats
Heart is skipping beats or beating out of its normal rhythm

Other
Select and write the reason for button press, if not listed

Short of breath
Difficulty breathing or unable to catch breath

Any writing outside of the requested entries on the Symptom Log or on any materials included with the device will not be documented or shared.

Contact your physician to share additional information with them. If you have questions or concerns about your Zio monitor, visit https://www.irhythmtech.com/us/en/patients/patient-support-faq

Zio Monitor: Troubleshooting Flashing Lights

If you see an orange light flashing on your Zio monitor, refer to the following troubleshooting instructions.

- **Orange light slowly flashes:**

- The Zio monitor is not well attached to your skin. Or,
- You are exposed to infrared light, such as direct sunlight.
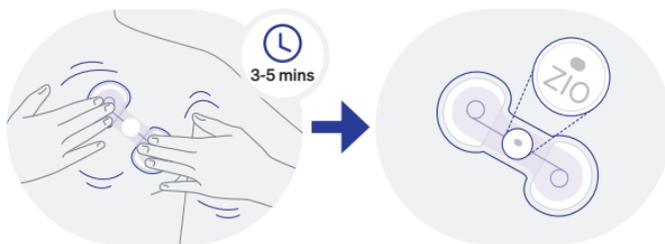
1. Massage the adhesive wings for 3 to 5 minutes until the orange light disappears to secure your Zio monitor to your skin.
2. If exposed to infrared light, such as direct sunlight, wear clothing over your Zio monitor.
3. If flashing persists or reoccurs, call Customer Care at (888) 693-2401.

- **Orange light rapidly flashes (3 times per second):**

Your Zio monitor is not working.

- **If your Zio monitor has fallen off:**

- Call Customer Care at (888) 693-2401.
  If an additional Zio monitor is required,
  refer to **Prescribed Wear Period** on page 3
  for additional information.

- Call Customer Care at (888) 693-2401.
  If an additional Zio monitor is required,
  refer to **Prescribed Wear Period** on page 3
  for additional information.

Removing Zio Monitor

1. Locate your device box with the prepaid return label

- If the device box is damaged or lost, contact Customer Care at (888) 693-2401.

2. At the end of the prescribed wear time, tear open the adhesive remover package

- Remove the wipe.

Limonene is an active ingredient in the adhesive remover. Refer to precautions on page 9.

3. Grasp the Zio monitor by both sides of the button, and gently lift upward, including the plastic film below the button

4. Wipe the skin with the adhesive remover

- Starting from the center, wipe the skin below the Zio monitor.

5. Remove one adhesive wing at a time

- Continue to wipe your skin as you peel off each adhesive wing.

It is expected for your Zio monitor to flash orange as you remove it.

6. Place inside device box

- Adhere your Zio monitor to the outline located inside the device box with the button centered.
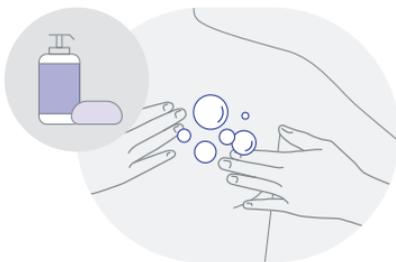
7. Wash your skin

- Wash your skin with mild soap, rinse with water, and pat dry.

It is expected for your skin to feel slightly irritated after removing your Zio monitor.

Returning Zio Monitor

1. Complete your Symptom Log cover & survey

a. When you remove the Zio monitor, write the **Date removed** on the front cover of your Symptom Log.

b. Fill out the survey in the Symptom Log.

   If you prefer to give your feedback online, go to https://www.ziopatient.com

c. Place the Symptom Log in the box with the Zio monitor.

2. Close and seal box

a. Confirm the Zio monitor and your Symptom Log are in the device box with the prepaid return label.

b. Peel the strip from the box to expose the adhesive.

c. Press the lid against the adhesive to seal the box.

3. Return the box immediately

- Send the box promptly so your healthcare provider can share results with you as soon as possible.

- Return your box through the shipping service shown on the prepaid return label located on the box. For example:

  - Return a box with a prepaid USPS label to any USPS mailbox or post office. Or, schedule a free USPS pickup at www.ziopickup.com.

  - Return a box with a prepaid UPS label to any UPS shipping service.

If you prefer a different expedited shipping service, return your box at your own expense to this address:

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

Technical Description

PRINCIPLES OF OPERATION

The Zio monitor is an adherent, patient-worn device containing electrodes to continuously collect the patient's ECG data. The ECG data is analyzed after the patient removes and returns the device at the end of the prescribed wear time.

The device facilitates storage of the ECG data. When the patient feels or experiences a symptom and presses the button on the Zio monitor, the device firmware records the button press with the ECG data.

The device firmware indicates the status of the device by the LED light on the Zio monitor. When the device is properly functioning, the patient does not see any lights on the Zio monitor.

CYBERSECURITY

The Zio monitor data cannot be accessed by patients through any means without compromising the integrity of the device. There is no network or data connection during the wear period. Data can only be accessed by iRhythm after the device is returned post use. The device does not connect externally or update firmware as its only function is to capture ECG data.

SYMBOLS GLOSSARY

SYMBOL	SYMBOL TITLE	DESCRIPTION/ EXPLANATION	SYMBOL	SYMBOL TITLE	DESCRIPTION/ EXPLANATION
▲▲	Manufacturer	Indicates the medical device manufacturer	UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information
⋀⋁	Date of manufacture	Indicates the date when the medical device was manufactured	MD	Medical device	Indicates the item is a medical device
QTY:	Net quantity of contents	Net quantity of contents	🌡	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed
⧗	Use-by date	Indicates the date after which the medical device is not to be used	⌀%	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed
LOT	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified	⊗	Do not reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
REF	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified	📖	Consult instructions for use	Indicates the need for the user to consult the instructions for use
SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified			

SYMBOL	SYMBOL TITLE	DESCRIPTION/EXPLANATION	SYMBOL	SYMBOL TITLE	DESCRIPTION/EXPLANATION
⚠	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	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
🕱	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1	FCC	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.
MR	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment	Rx ONLY	Prescription only	Requires prescription in the United States of America
☂	Keep dry	Indicates a medical device that needs to be protected from moisture	⊘	Do not use if package is damaged	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
🗑	Separate collection	To indicate that the product shall be separated when disposed			

DISPOSAL INSTRUCTIONS

Item	Disposal Method
Device box	Return at end of wear
Instructions for Use	Recycle according to local guidance for paper products
Symptom Log	Return at end of wear
Pouch	Dispose according to local guidance for municipal waste
Zio monitor	Return at end of wear
Paper tabs	Recycle according to local guidance for paper products
Plastic backings	Recycle according to local guidance for products with plastic
Adhesive remover and package	Do not flush Dispose according to manufacturer's instructions and according to local guidance for municipal waste
Prep materials box	Recycle according to local guidance for paper products
Disposable razor	Recycle according to local guidance or dispose of according to municipal waste for sharp objects made of plastic and stainless steel
Protective cover	Recycle according to local guidance for paper products
Exfoliator disc	Dispose according to local guidance for municipal waste
Alcohol wipes and package	Do not flush Dispose according to manufacturer's instructions and according to local guidance for municipal waste
Printed labels affixed to the packaging	Remove prior to disposal Dispose according to local guidance for municipal waste

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 Hz to 40 Hz
ECG input impedance	> 10 MΩ
ECG differential range	± 1.65 mV
ECG A/D sampling rate	200 Hz
Gain accuracy	Maximum amplitude error ± 10%
Gain stability	< 3% over a 24-hour period
Timing accuracy	< 5 sec over a 24-hour 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 × 55.8 × 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, Zio monitor	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

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- 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.

- WARNING: The device has not been tested for immunity to 5G cellular electromagnetic emitters operating in frequency range 2 and thus the risk to the device from 5G signals in frequency range 2 has not been evaluated.

- 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, which includes the use of a cell phone while wearing the device, as shown in Tables 3 and 4.

GUIDANCE AND MANUFACTURER'S DECLARATION FOR ELECTROMAGNETIC EMISSIONS

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

Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Zio 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 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 system is intended for use in the electromagnetic environment specified on pages 40 through 43. The customer or the user of the Zio 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 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V 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	**Test 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

FEDERAL COMMUNICATIONS COMMISSION (FCC) COMPLIANCE

- The Zio 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.

- Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

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iRhythm Technologies, Inc.
699 8th Street, Suite 600
San Francisco, CA 94103
USA
www.irhythmtech.com

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