ZIO®

Instructions for Use

Read this booklet to learn more about using your Zio monitor.

Apply your Zio monitor immediately and do not throw away this booklet.

MyZio app

Use the MyZio app to log symptoms, track progress, access information about your Zio monitor, and view helpful video tutorials

Scan QR code to download

1. Open the camera app on your phone.
2. Hold the camera so you can see the QR code on your screen.

   A notification should appear in your camera app.
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.

Contents

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.

Welcome to Zio monitor

Product 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
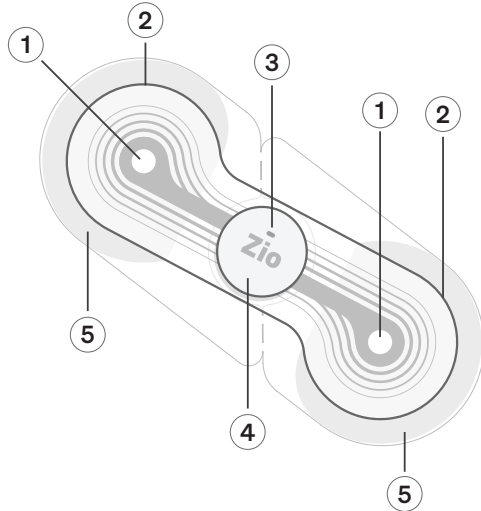
1. Electrode – acquires ECG data

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.

   Refer to Troubleshooting - flashing lights on page 17.

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.
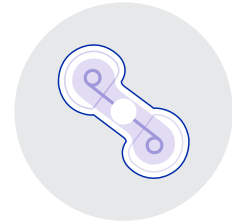
Package contents

Note: The patient must keep the device 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.

Instructions for Use,
quantity 1

Symptom Log,
quantity 1

Zio monitor,
quantity 1

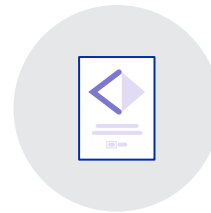Note: The Zio monitor is
within a pouch

**Prep Materials box,
quantity 1**

**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
Instructions for Use.

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

**Disposable razor,
quantity 1**

Exfoliator

**Exfoliator disc,
quantity 1**

Alcohol
Wipe

**Alcohol wipe,
quantity 2**

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.

In-clinic:

Register the patient

1. Register the patient online at www.ziosuite.com.
2. Remove the following items from the device box:
   - Pouch with Zio monitor
   - Prep Materials box
   - Symptom Log
3. Instruct the patient to keep the box. The box is used to return the device at the end of the prescribed wear period.
4. On the cover of the Symptom Log, write the patient's name, start date, and prescribed wear duration.

   The patient writes the date on the cover when they remove the Zio monitor for return.

At home:

1. Remove the following items from the device box:
   - Pouch with Zio monitor
   - Prep Materials box
   - Symptom Log
2. 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 your name and start date.
4. Refer to your welcome letter and write the number of days on the cover prescribed by your physician for wearing this Zio monitor.
5. Do not write the removal date until you remove the Zio monitor for return at the end of your prescribed wear period.

1. Position prep area

Remove the razor, exfoliator, and alcohol wipe from the prep materials box.
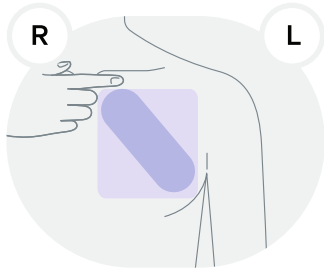
In-clinic:

1. 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.
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.

At home:

1. Make sure your chest is visible and clear in front of a mirror.
2. Find the area on your 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.

2. Prep skin
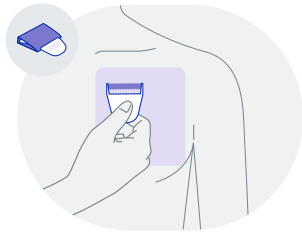
1. Shave chest area requiring skin preparation (all genders, including those with no visible hair).

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.
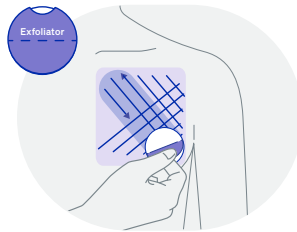
2. Exfoliate prep area:

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: both diagonal directions, up and down, and side to side.
Exfoliating may cause expected skin redness.
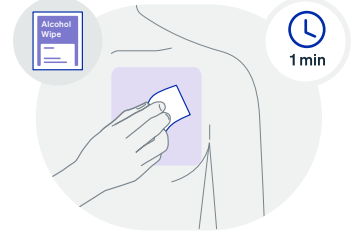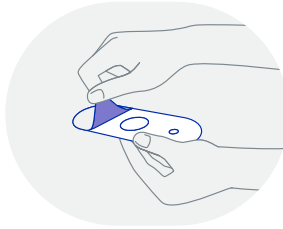
3. Clean and let dry:

a. Use an alcohol wipe to clean the prepared chest area.

Cleaning may cause a slight tingling sensation.

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

3. Apply Zio monitor
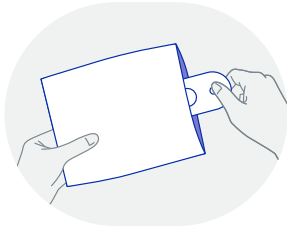
1. Open the Zio monitor pouch:

a. Tear open from either notch.

b. Remove the Zio monitor.

2. Peel clear backings:

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 in Step 5.
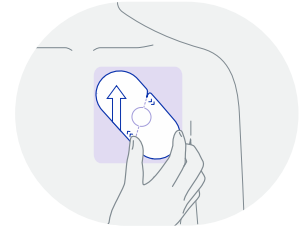
3. Apply the Zio monitor:

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 upper-left chest.
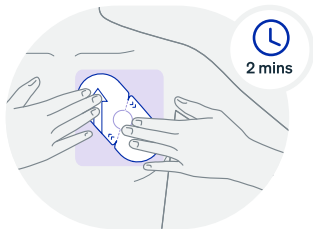
4. Massage paper tabs:

a. Massage the paper tabs on the wings of the Zio monitor firmly for 2 minutes to fully adhere the Zio monitor to the chest.

b. Do not move or remove the Zio monitor after applying it to the chest.

5. Remove paper tabs:

a. Find the double arrows located above and below the center of the Zio monitor.
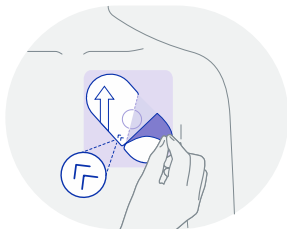
b. Peel the tab in the direction of the double arrows. Ensure the adhesive wing does not lift using your other hand.

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

c. Remove the remaining tab.

6. Massage wings again:

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

4. Activate Zio monitor
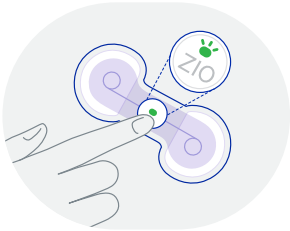
- **Press and release button:**
  a. Press and quickly release the button on the Zio monitor.
  b. Watch the light briefly flash green to indicate the Zio monitor is recording ECG data.
  c. If you do not see a green light, call Customer Care at (888) 693-2401.
  d. Retrieve the Symptom Log and write the "Start Time" on the cover.

Wearing Zio monitor

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, 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

In-clinic: review with your patient

- Ensure the patient understands the purpose and importance of the Zio ECG monitoring system.
- While towel drying after a shower, the patient should hold the Zio monitor with one hand.
- Review how to log symptoms with the patient. Refer to Logging symptoms on page 15.

MyZio app

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

Scan QR code to download the app

1. Open the camera app on your phone.
2. Hold the camera so you can see the QR code on your screen. A notification should appear in your camera app.
3. Tap on the notification to download the app.

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.

1. Press the button on your Zio monitor when you feel a symptom.

- The light does not flash when the button is pressed.
- If you forget 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, 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, download the MyZio app and continue logging symptoms.

Types of symptoms

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

Short of breath
Difficulty breathing or unable to catch breath

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

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/patients/myzio

Troubleshooting – flashing lights

> You will not see any lights or hear any sounds when your Zio monitor is functioning properly.

If an orange light is rapidly flashing (3 flashes per second):

- This indicates your Zio monitor is not working.
- Call Customer Care at (888) 693-2401.

If an orange light is slowly flashing:
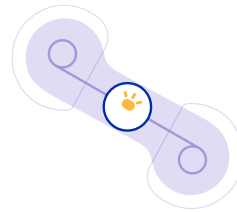
- This indicates your Zio monitor is not well attached to your skin. It does not mean something is wrong with your heart.
- Massage the adhesive wings for 3-5 minutes until the orange light disappears to secure your Zio monitor to your skin.
- If flashing persists or reoccurs, call Customer Care at (888) 693-2401.

Troubleshooting – general

My Zio monitor fell off. What should I do?

If your Zio monitor has fallen off, call Customer Care at (888) 693-2401.

Can I travel while wearing my Zio monitor?

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

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.

Can I ship with UPS or FedEx to return my Zio monitor?

If you decide not to return your Zio monitor with USPS, please send back your Zio monitor via expedited shipping (FedEx, UPS) at your own expense.

Send it to the following address:

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

Removing Zio monitor

At the end of your prescribed wear time, open the adhesive remover and follow steps below to peel off your Zio monitor

1. Gently lift the center of your Zio monitor up.

2. Starting from the center, use the adhesive remover to wipe the area between your skin and your Zio monitor.

3. Continue to wipe as you peel off your Zio monitor, one side at a time.

4. Keep your Zio monitor aside for return and refer to step 2 on page 20 for further instructions.

5. Finally, 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.

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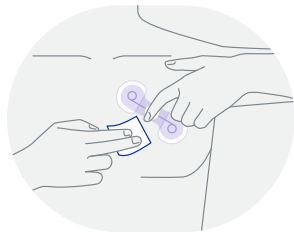
Returning Zio monitor

1. Complete your Symptom Log & survey

- On the cover of the Symptom Log, fill in the date the Zio monitor was removed.

- Fill out the survey in your Symptom Log to tell us about your experience. If you prefer to give your feedback online, go to www.ziopatient.com

2. Package your Zio monitor & Symptom Log

- Adhere your Zio monitor to the inside bottom of the Zio monitor box and place the Symptom Log on top.

- Seal the box by peeling the tape off the front of the box and press firmly on the flap to close.

- It is okay to mail your Zio monitor if it's still flashing orange.

3. Mail your Zio monitor

- Drop the Zio monitor box inside any USPS mailbox or take it to a post office.

- You can also schedule a free USPS pickup at www.ziopickup.com.

- Mail your Zio monitor back promptly so your healthcare provider can share the results with you as soon as possible.

Technical references

Patient identification

Before placing your Zio monitor in the Zio monitor box, please write your name on the line above the return address. By writing your name on the return label, you are providing another method of identification for your Zio monitor and are consenting to the potential viewing of your name on the return label. You may choose to not write your name on the return label.

Notification 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.

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 may be 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 a 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 box and in the instructions for use.
- Confirm the expiration date for the Zio monitor listed on the Zio 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 Zio monitor 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.
- Exposing the Zio monitor to any sources of infrared light, such as direct sunlight, can disrupt the recording of ECG data. Wear clothing if exposure to infrared light, such as direct sunlight, cannot be avoided.

- 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.

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	SYMBOL	SYMBOL TITLE	DESCRIPTION/ EXPLANATION
▲▲	Manufacturer	Indicates the medical device manufacturer	SN	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
QTY:	Net quantity of contents	Net quantity of contents	UDI	Unique device identifier	Indicates a carrier that contains unique device identifier information
⊘	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	🌡	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 a medical device that is intended for one use, or for use on a single patient during a single procedure

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
🧍	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
(MR)	Magnetic Resonance (MR) unsafe	A medical device which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment
🗑	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

Device specification

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
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 × 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

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	8 A/m
	65 A/m 134.2 kHz 2.1 kHz Pulse	65 A/m
	7.5 A/m 13.56 MHz 50 kHz Pulse	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

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.