ZIO®

Instructions for Use

Read the Instructions for Use before preparing the patient's skin for application of the Zio® monitor. Instructions for wearing, removing, and returning the Zio monitor are included for the patient.

Send the patient home with these Instructions for Use.

Contents

Welcome to Zio monitor 2

Examples of Zio monitor 3

Package contents 4

For Patients: Zio monitor support 6

What to expect 7

1. Planning and Positioning 8

2. Prepping Skin 10

3. Applying Zio monitor 12

4. Activating Zio monitor 15

Logging symptoms 17

Reasons for button press 18

Troubleshooting 19

Removing Zio monitor 20

Returning Zio monitor 22

Product Information 24

Intended Use 24

Safety Information 25

Principles of Operation 26

Cybersecurity 27

Symbols Glossary 28

Disposal Instructions 30

Technical Specifications 31

Welcome to Zio monitor

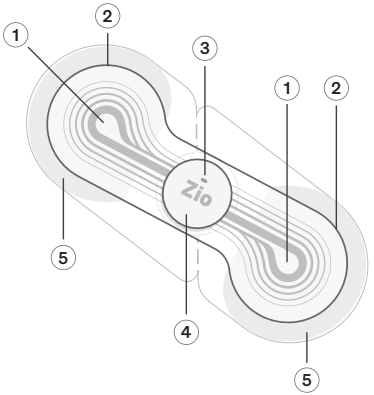
Product Description

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

  (1) Zio monitor

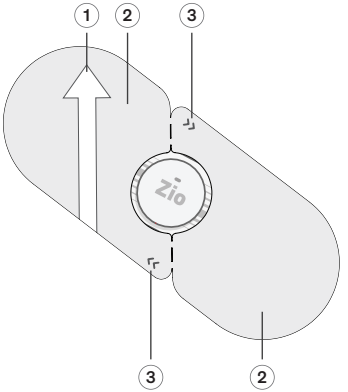
  (2) proprietary algorithm software.
- The Zio monitor is a single-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The Zio monitor records ECG data without patient interaction, with the goal of improving patient compliance through simplicity of operation.
- Patients 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 final 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.

Examples of Zio monitor



1. Electrode – acquires ECG data
2. Adhesive wings – adheres Zio monitor to the chest
3. Light – momentarily flashes green when activated and flashes orange in the event of an error

   After activation, you will not see any lights.
4. Zio monitor button – activates the device. The patient presses this button when a symptom is felt.
5. Clear plastic backings – remove from back of Zio monitor prior to application

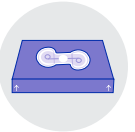


1. White arrow – points upward during application
2. Paper tabs – covers the electrodes. Massage the paper tabs to adhere the adhesive wings to the chest.
3. Double arrow – indicates direction to remove paper tabs before activation

Package contents

Contents of outer container:

Instructions for Use, quantity 1



Device box, quantity 1

Symptom Log, quantity 1

Clinician note:
Write the start date and prescribed wear period on the cover of the Symptom Log. At the end of the wear period, the patient writes the date the device is removed from their chest.

Within the outer container is the device box, the Instructions for Use, and the Symptom Log, which are sent home with the patient. The patient must keep the device box until the end of the prescribed wear period. The postage-paid device box is re-used by the patient to return the device and Symptom Log to iRhythm.

Package contents

Contents of postage-paid device box:

Zio monitor, quantity 1

Note: The Zio monitor is within a pouch.

Adhesive remover, quantity 1

Note: The patient removes the Zio monitor with the adhesive remover.

Prep materials box, quantity 1

Clinician note:
The Prep Materials box is used only in the clinic and not sent home with the patient.

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.

Disposable razor, quantity 1

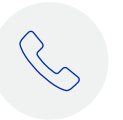
Exfoliator disc, quantity 1

Alcohol wipe, quantity 2

For Patients: Zio monitor support

We are excited to partner with you on your health journey.

- Your Zio monitor will help your healthcare provider understand your heart's rhythm with accurate data. Your Zio monitor will record every heartbeat.
- Follow the instructions in this manual to wear and return your Zio monitor.



We are here to support you with anything you need.

- Customer Care is available 9:00 a.m. to 6:00 p.m. on weekdays to provide tips on wearing your Zio monitor, remind you to return your Zio monitor, troubleshoot issues, and collect feedback on your Zio monitor experience.
- Customer Care telephone numbers are listed on the back cover of this manual.

What to expect

Prep and Apply

- Instructions for skin preparation and how to apply the monitor to the chest are included in this manual.
- The patient keeps the device box to return the Zio monitor.

Wear

- After activation, the patient will not see any lights or hear any sounds when the Zio monitor is properly functioning.

  Refer to Troubleshooting, page 19.
- The patient presses the Zio monitor button when a symptom is felt and logs the reason in the Symptom Log.
- The patient's prescribed wear period is on the cover of the Symptom Log.

Remove and Return

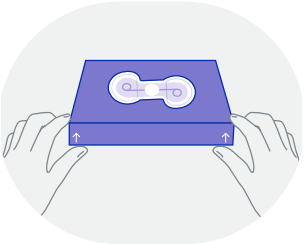
- Remove the Zio monitor and place it in the postage-paid device box at the end of the wear period.
- Return the Zio monitor so our experts can analyze the ECG data.

1. Planning and Positioning

ZIO SUITE

1. Clinicians only:

- Register the patient in ZioSuite



2. Open the device box

a. Locate the front side of the box with arrows pointing up.

b. Lift from the arrows to open the lid.

c. Remove the following items from the box:

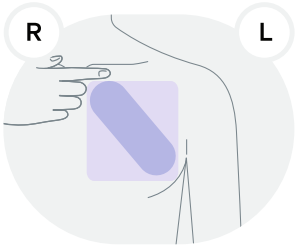
- Zio monitor pouch
- Prep materials box

Note: Keep the box and the adhesive remover wipe inside the box for the patient's use.

3. Clinicians only:

a. On the cover of the Symptom Log, write the initials of the patient's first and last names. Include the start date and prescribed wear duration.

b. Instruct the patient to write the date on the Symptom Log cover when the Zio monitor is removed at the end of wear.



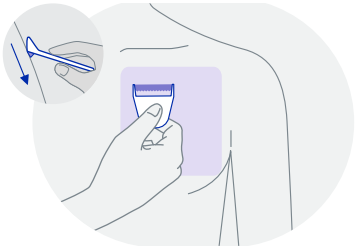
4. Identify skin preparation area

a. Request the patient stand with arms relaxed by their sides. If standing is not possible, the patient may sit upright.

b. 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.

2. Prepping skin

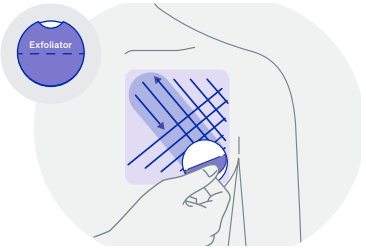


1. Shave chest area (all genders, including those with no visible hair)

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

b. Shave the entire area. Shaving is required if hair is visible or not.

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



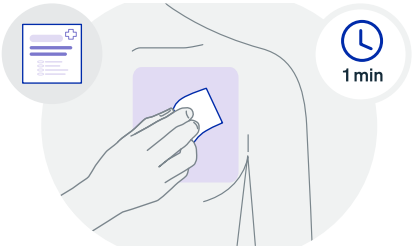
2. Exfoliate skin preparation area

a. Lift up the plastic tab on the exfoliator to use as a handle.

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

c. Gently exfoliate the entire area using the rough side of the exfoliator.

Exfoliating may cause expected skin redness.



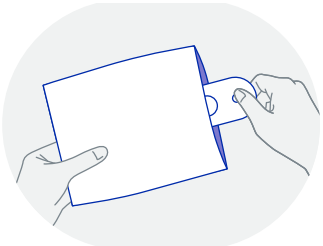
3. Clean and dry skin

a. Use an alcohol wipe to clean the prepared skin area. The patient may feel a slight tingling sensation.

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

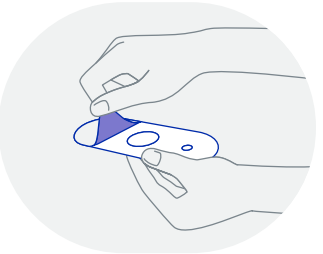
Instructions continue on next page

3. Applying Zio monitor



1. Open the pouch

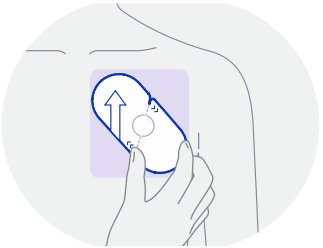
- Tear open from either notch, then take the Zio monitor out of the pouch.



2. Peel clear backings

- Hold the Zio monitor and peel only the clear plastic backings.

  Keep the paper tabs on the other side intact.



3. Apply the Zio monitor

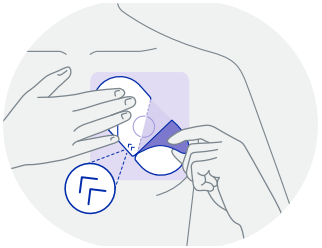
a. Ensure the white arrow on the paper tab is pointing upward.

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

4. Massage wings

a. Massage the paper tabs on the Zio monitor firmly for 2 minutes, this will allow the Zio monitor to fully adhere to the patient's chest.

b. Do not move or remove the Zio monitor after it's applied.

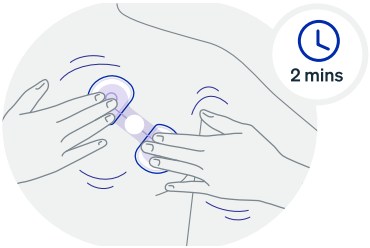


5. Remove paper tabs:

a. Find the small double arrows on the paper tabs, located above and below the button.

b. Peel the tabs in the direction of the double arrows.

c. Use your other hand to hold the adhesive wing in position while peeling the tab.



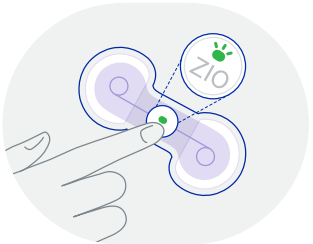
6. Massage wings again

a. Massage the adhesive wings firmly onto the patient's skin for another 2 minutes, this will prevent the Zio monitor from falling off.

b. Do not move or remove the Zio monitor after it's applied.

If you see an orange light refer to page 19.

4. Activating Zio monitor



1. Press and release button

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

b. The light on the button will briefly flash green to indicate the Zio monitor is now recording the patient's heartbeat.

c. If you do not see a green light, call Customer Care.

Clinicians only:

1. After you see the green light, help the patient practice pressing the button.
2. Review the Symptom Log and Survey with the patient. The expected wear period is written on the cover of the log.
3. Ensure the device box is sent home with the patient and contains the following items:
    - Instructions for Use
    - Symptom Log
    - Adhesive remover
4. Instruct the patient to keep the box. The postage-paid box is used to return the device at the end of the prescribed wear period.

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

Logging symptoms

When you feel a symptom...

1. Press the button on your Zio monitor

- 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 continues to record the ECG data.
- Logging your symptoms while wearing the Zio monitor provides your physician with additional information to help analyze your health condition and develop a plan of care. Not all patients experience symptoms.

2. Log the reason for button press in the Symptom Log:

- Date and time the button was pressed
- Reason for button press:
  - A selection is available to indicate if the button was accidentally pressed.
  - A selection is available if the reason for the button press is not listed (other).
- Duration of symptom
- Activity when the symptom was experienced (for example, while sleeping, resting, or exercising)

Reasons for button press

Chest pressure or pain

Discomfort, tightness, or pressure in the chest area

Fainted

Passed out or lost consciousness

Palpitations

Heart is skipping beats or beating out of its normal rhythm

Short of breath

Difficulty breathing or unable to catch breath

Fast heartbeat

Heart is pounding or beating too fast

Dizzy

Dizzy and/or slightly faint

Accidental button press

Unintended press of the Zio monitor button

Other

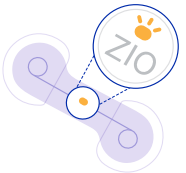
Select if reason for button press is not listed

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, contact Customer Care.

Troubleshooting

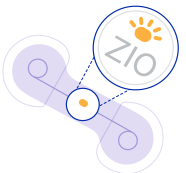
If you see a flashing light on your Zio monitor, follow these troubleshooting steps.



If you see an orange light flashing slowly:

This indicates your Zio monitor is not well attached to your skin. It does not mean something is wrong with your heart.

1. Massage the adhesive wings for 3-5 minutes until the orange light disappears to secure your Zio monitor to your skin.
2. If flashing persists or reoccurs, call Customer Care at the telephone number listed on the back cover.



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

This indicates your Zio monitor is not working.

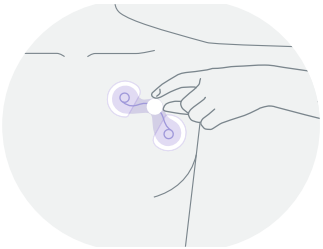
- Call Customer Care at the telephone number listed on the back cover.

My Zio monitor fell off. What should I do?

If your Zio monitor has fallen off, call Customer Care at the telephone number listed on the back cover.

Removing Zio monitor

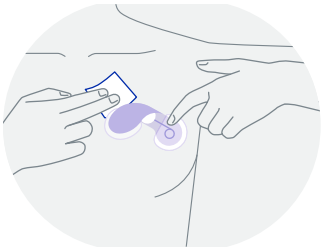
At the end of the prescribed wear time, the patient retrieves the adhesive remover from the device box and follows the steps below.



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

2. Wipe the skin with the adhesive remover.

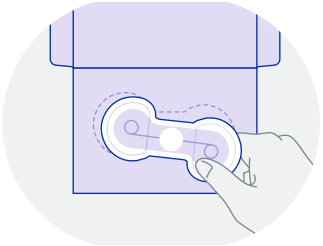
- Starting from the center, wipe the skin below the Zio monitor.



3. Remove one side at a time

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

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



4. Place in device box

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

5. 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.

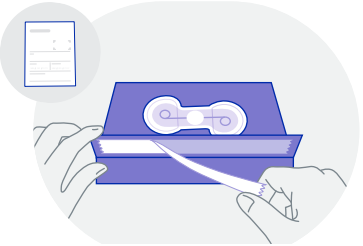
Returning Zio monitor

1. Complete your Symptom Log and survey

a. Write the date on the front cover of your Symptom Log when the Zio monitor was removed.

b. Fill out the survey in the Symptom Log to tell us about your experience.

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



2. Close and seal the box

a. Confirm the Zio monitor and your Symptom Log are in the postage-paid box.

b. Peel the strip on the side of the box to expose adhesive.

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

3. Mail your Zio monitor box immediately

- A postage-paid shipping label is on the outside of the box.

It is okay to mail your Zio monitor if it is flashing orange.

Product Information

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, lightheadedness, pre-syncope, syncope, fatigue, or anxiety.

Intended Patient Population

18 years or older

Intended Users

Physician; Allied Healthcare Provider; Patient

Intended Use Environment

Ambulatory: Out-patient

Contraindications

- Do not use 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 with pacing therapy.
- 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 compatible with magnetic resonance imaging (MRI) equipment. 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.
- 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.
- The Zio monitor is not intended for use on patients under 18 years old.
- 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.
- 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 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.

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 was developed with careful consideration of cybersecurity risks and their compensating controls. Industry-standard encryption is employed for protecting data at rest, post-wear. Patient data is protected during wear through use of proprietary data storage formats and physically protected data ports. Once returned to iRhythm for processing, data integrity checks are used to ensure the integrity of all recorded data.

SYMBOLS GLOSSARY

SYMBOL	SYMBOL-TITLE	DESCRIPTION/EXPLANATION
	Manufacturer	Indicates the medical device manufacturer
	Authorized representative in the European Community/ European Union	Indicates the authorized representative in the European Community/ European Union
	Authorized representative in Switzerland	Indicates the authorized representative in Switzerland
	Importer	Indicates the entity importing the medical device into the locale
QTY:	Net quantity of contents	Net quantity of contents
	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
	Use-by date	Indicates the date after which the medical device is not to be used
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified

SYMBOL	SYMBOL-TITLE	DESCRIPTION/EXPLANATION
	Unique device identifier	Indicates a carrier that contains unique device identifier information
	Medical device	n/a
	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 reuse	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure
	Consult instructions for use	Indicates the need for the user to consult the instructions for use
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
	Type BF applied part	To identify a type BF applied part complying with IEC 60601-1
	Magnetic Resonance (MR) unsafe	Keep away from magnetic resonance imaging (MRI) equipment
	Keep dry	Indicates a medical device that needs to be protected from moisture

SYMBOL	SYMBOL-TITLE	DESCRIPTION/EXPLANATION
CE 2797	Conformity marking for the European Union	A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in Regulation (EU) 2017/745 and other applicable European Union harmonization legislation for its affixing
CE	Conformity marking for the European Union	A manufacturer's declaration of product compliance with applicable requirements set out in Regulation (EU) 2017/745 and other applicable European Union harmonization legislation for its affixing
	Separate collection	To indicate that the product shall be separated when disposed
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

DISPOSAL INSTRUCTIONS

Item	Disposal Method
Outer container	Recycle according to local guidance for paper products
Instructions for Use	Recycle according to local guidance for paper products
Symptom Log	Return at end of wear
Device box	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 (clinic only)	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 (The shelf life is the "use-by" date located on the device box. The date is in a YYYY-MM-DD format.)	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
Zio monitor 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, CW 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 80% AM at 1kHz	3 Vrms
	6 Vrms 150 kHz to 80 MHz in ISM bands 80% AM at 1kHz	6 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 80% AM at 1 kHZ	10 V/m
	27 V/m 385 MHz 18 Hz pulse	27 V/m
	28 V/m 450 MHz FM mod, ±5 kHz dev, 1 kHz sine	28 V/m
	28 V/m 810, 870, 930 MHz 18 Hz pulse	28 V/m

Table 4: Manufacturer's declaration — electromagnetic immunity		
Immunity test	**IEC 60601 test level**	**Compliance level**
Radiated RF IEC 61000-4-3	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, 5785 MHz 217 Hz pulse	9 V/m

This system complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this system may not cause harmful interference, and (2) this system must accept any interference received, including interference that may cause undesired operation.

This page is intentionally blank.

This page is intentionally blank.

ZIO® BY iRHYTHM

Customer Care

Japan: 050-3625-8223 (calls are free of charge)

Visit iRhythm's website
www.irhythmtech.com/jp-jp/user-information/
to view and download documents pertinent to privacy notices, product warranty, terms of service, and other product information, including additional copies of user manuals.

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

EC REP

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands

CE 2797

 | Date of first issue: 2025-02 | Revised: 2025-02 LB10247.01