

z10[®]SR

PATIENT INSTRUCTIONS

TURN OVER FOR **BUTTON PRESS LOG**



FOR SUPPORT,
CALL 1-888-693-2401

FOR SUPPORT, CALL 1-888-693-2401

If the Patch falls off, call 1-888-693-2401.

If you feel severe itching or irritation, remove the Patch then call 1-888-693-2401.

If you feel the need for immediate medical care at any time, call 911.

The ZIO® SR device will not provide any medical assistance and cannot contact medical personnel for you.

For use in the United States only.

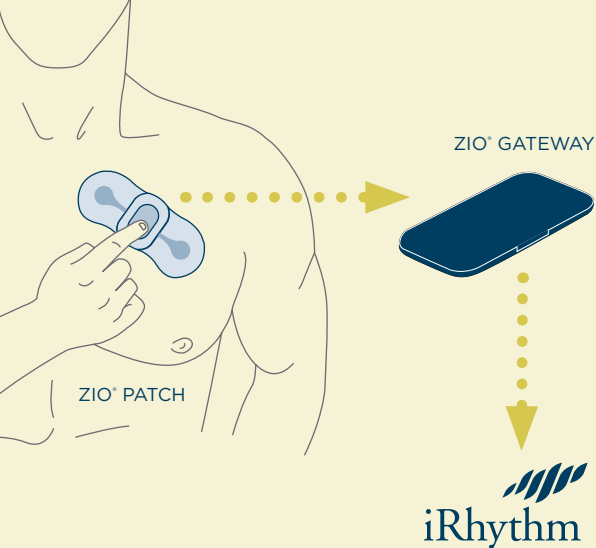
iRhythm Technologies, Inc. Clinical Centers

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Lincolnshire, IL 60069 U.S.A.

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1-888-693-2401 | irhythmtech.com |  @iRhythmTech



Both parts of the ZIO[®] monitor were turned on at your physician's office, and are now recording your heart activity. The **ZIO[®] SR Patch** records every heartbeat; each time you press the Patch button, the **ZIO[®] SR Gateway** sends that information for analysis.

Turn the page for advice on having the best possible patient experience.

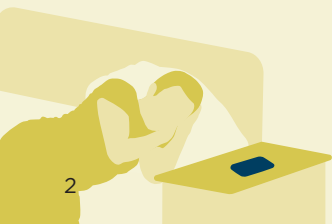
USING YOUR ZIO® SR

With the ZIO monitor, you can sleep, shower and go through your normal daily activities.

The Patch needs 24 hours to stick to your skin, so avoid any activities which cause sweating during this period. (If your skin is moist, pat it dry with a dry towel or cloth.) After those first 24 hours, you may resume normal activities, including moderate exercise.

The Patch and Gateway will not flash or make noise when they are working correctly, but you can check your transmissions using myZIO.

Turn to the next page or see the inside back cover for information about myZIO.



Three key things to keep in mind are:

1 Each time you feel a symptom, press the button on your Patch. Then note the date, time, and what you felt in this booklet or using myZIO.

2 Try to keep the Gateway close by when you can – set it down nearby, and when you are on the move, carry it with you. The Gateway is in range if it remains within 10 feet of the Patch.



3 If the Patch or Gateway lights are flashing, **it does not mean there is a problem with your heart**, only that the device may have lost its connection. Turn to the *Troubleshooting* section or call 1-888-693-2401 for support.

Other tips to having the best ZIO experience possible:



If the Patch feels a little itchy, or peels or lifts at the edges, it is okay. Press and hold the Patch to re-stick.



Excessive sweating can cause the Patch to slide, become loose, fall off, and shorten wear time – especially if the sweating occurs in the first 24 hours after the Patch is put on.



The Patch is water-resistant and should not be submerged. That means brief showering is okay, but no swimming or hot tubs. The Gateway is NOT waterproof. Please do not get it wet.



It is okay if the Gateway is temporarily out of range, but do not leave it within 6 feet of transmitting devices (such as wireless routers, baby monitors and TV senders/transmitters).



Sending heart rhythm data through the Gateway can take some time. Recent transmissions may not be available at myZIO for several hours.



Use myZIO to enter and edit your symptoms electronically, and view transmissions from your Gateway.*

iPhone® users

1. Search for 'myZIO' in the App StoreSM
2. Download app
3. Register before entering symptoms

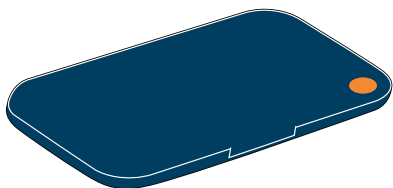
Internet Explorer® users

1. Open internet browser
2. Navigate to myZIO.org
3. Register before entering symptoms

* Recent transmissions may not be available at myZIO for several hours.

Supported on iPhone 5s, 6 and 6s (iOS 7 and 8). Internet Explorer browser supported on versions IE 8, 9, and 11. iPhone, App Store and the Apple logo are registered trademarks of Apple Inc.

TROUBLESHOOTING: GATEWAY




If the light on the outside of your Gateway is flashing, check inside.

Slow flashing

(once every 3 seconds):

Indicates that the Gateway has lost the connection to your Patch.


To remedy it, hold the star button  for 3 seconds until the orange light stays on. Then, if you see green flashing, the gateway has found connection to the Patch.

If orange flashing continues, call Customer Support at 1-888-693-2401.

Slow flashing

(once every 3 seconds):

Indicates that the Gateway does not have a cell signal.

To remedy it, move the Gateway to a place with a good cell signal (near a window or outside) and hold the star button  for 3 seconds until the orange light stays on.

Then, if you see green flashing, the Gateway has found a cell signal. Do not move the Gateway until the green flashing stops.

If it does not flash green, move the Gateway to a new place and try again.

If orange flashing continues, call Customer Support at 1-888-693-2401.

Fast or flashing

(3 times per second):

Fast flashing indicates that your Gateway is not working. Call Customer Support at 1-888-693-2401.

TROUBLESHOOTING: PATCH



Slow flashing

(once every 3 seconds):

Indicates that your Patch is not making good contact.

To remedy it, press evenly on the wings of the Patch for 3 to 5 minutes.

If orange flashing continues, call Customer Support at 1-888-693-2401.

Fast flashing

(3 times per second):

Indicates that your Patch is not recording. Call Customer Support at 1-888-693-2401.

FREQUENTLY ASKED QUESTIONS (FAQs)

About the ZIO® SR recording system

What is the Patch doing?

The Patch is recording every heartbeat. Your doctor will use the data from the Patch to look at your heart rhythm and determine the right course of action.

What is the Gateway doing?

The Gateway wirelessly sends heart rhythm data from the Patch, each time the Patch button is pressed. iRhythm receives and analyzes the data, and provides a report to your doctor.

How do I know the Patch and the Gateway are working?

When they were turned on, the staff at your doctor's office made sure that the Patch and Gateway were working. When they are working with no problems, the Patch and Gateway will not flash or make noise.

Do I need to do anything with the Gateway to send heart rhythm data wirelessly?

No, you only need to keep the Gateway in arm's reach and in view to stay connected wirelessly after you press the Patch button. The Gateway should also be kept in a place with good cell signal.

What kinds of devices can affect wireless connection with the Gateway?

Other wireless devices that use 2.4 GHz signals such as baby monitors, TV senders/transmitters, and wireless routers can interrupt communication between the Patch and Gateway if used within 6 feet.

About your activities

Can I exercise while wearing the Patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the Patch on?

Yes, but showers should be short and try to keep your back to the shower as much as possible. Keep soaps and lotions away from the Patch. When towel-drying, hold the Patch down with one hand. Press the Patch against your skin to secure it. Keep the gateway away from all water.

Can I take a bath?

Yes, but keep the Patch above water. Keep the Gateway away from all water.

Can I go swimming or in a hot tub?

No. The Patch should not be put under water and heavy sweating will shorten wear time. Keep the Gateway away from all water.

Can I travel with the Patch on?

Yes. If questioned during security screening, show the statement in the *Traveling* section. Note that the Gateway will not have cellular connection outside the United States.

Can I fly with the Gateway?

Yes, though the Gateway must be in “airplane mode”. See *Traveling*.

What activities should I avoid?

Activities that cause heavy sweating should be avoided. Sweat can cause the Patch to slide, become loose, fall off, and shorten wear time.

About recording symptoms

What should I do if I feel a symptom?

Press the button and fill out a page of the *Button Press Log* in this booklet or

using myZIO. Please try to use either the booklet or myZIO for recording symptoms and not both.

What if I don't have symptoms?

That is okay. The Patch records every heartbeat.

What if I forget to press the button when I feel a symptom?

While pressing the button is important to “tag” and wirelessly send an event, the Patch is recording every heartbeat.

What if I press the button but forget to write down the information in this booklet?

While the Button Press Log information is useful, pressing the button indicates that you felt your symptoms at that time.

What if I press the Patch button while the Gateway is not in range?

The Patch will store the data until the Gateway is in range, then the data will be sent.

What happens if I press the Patch button while the Gateway doesn't have cell signal?

The Gateway will store the data until it has cell signal, then the data will be sent.

About the Patch

What should I do if the Patch peels or lifts at the edges?

Press and hold along the edges to re-stick.

What should I do if the Patch falls off?

Call Customer Support at 1-888-693-2401.

I think I see blood under my Patch.

What should I do?

Call Customer Support at 1-888-693-2401. It is probably due to a small shaving cut when the Patch was applied to your chest.

Is it normal for the ZIO® SR Patch wings to become cloudy?

Yes, the wings of the Patch may become cloudy after a few days of wear.

Is it normal for the Patch to move slightly from its original position?

Yes. The Patch may move slightly from its original position. A blue gel may be seen under the wings of the Patch.

Is it normal to experience skin irritation or itchiness in the area of the Patch?

Most patients do not experience skin irritation or itchiness. However, some patients have reported minor skin irritation and/or itching while wearing the Patch. If the irritation or itching is severe or hives or blisters develop, remove the Patch, then call Customer Support at 1-888-693-2401.

About flashing lights

Will the Gateway show any lights or make any sounds?

No. As long as it is able to send data, the Gateway will not flash or make noise.

What if the Patch flashes orange while I am wearing it?

If you see the Patch flashing orange, this does not mean there is a problem with your heart; it just means that the Patch is not well attached. Press evenly on the wings of the Patch for 3 to 5 minutes. If the flashing continues or comes back, call Customer Support at 1-888-693-2401.

What should I do if my Gateway is flashing orange?

If you see the Gateway flashing orange, this does not mean there is a problem with your heart; it just means that the Patch cannot send information wirelessly. Turn to *Troubleshooting* or call Customer Support at 1-888-693-2401.

About returning the Patch

How long am I supposed to wear the Patch?

Wear the Patch for as long as your doctor prescribed but no longer than 14 days. NOTE: Each person's wear experience is different and actual wear time may be shorter than prescribed.

How do I return the Patch and Gateway?

You can drop off the sealed envelope at the Post Office, in a USPS (blue) mailbox or give it to your mail carrier. Turn to *Patch Removal* for return instructions.

I have removed the Patch and it is flashing orange. Is this okay?

The Patch may flash orange after removal. It is okay to mail the device while it is flashing. Turn to the *Patch Removal* for return instructions.

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm ZIO® SR Patch prescribed by their physician. This device is currently adhered to the patient's chest and is monitoring their heart. It can only be removed under the direction of their physician.

If you have any questions, please contact the iRhythm Clinical Center at


1-888-693-2401

24 hours/day, 7 days/week.


TRAVELING WITH YOUR ZIO® SR

Flying while wearing a ZIO® SR is straightforward. Simply show the security statement (opposite) during screening, and remember to put the Gateway in Airplane Mode.

To turn Airplane Mode ON

Press and hold the airplane button  inside the Gateway for 3 seconds, until the lights flash orange quickly. The airplane light on the outside of the Gateway will flash as long as it is in “Airplane Mode.”

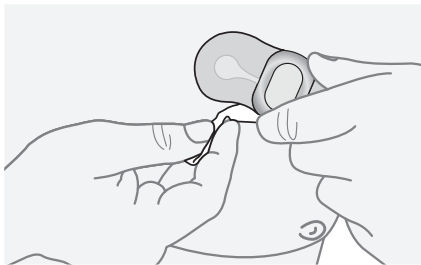
To turn Airplane Mode OFF

Press and hold the airplane button  inside the Gateway for 3 seconds, until the lights flash green quickly. The outside airplane light will stop flashing.

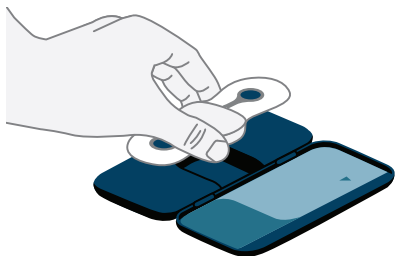
REMOVING AND RETURNING THE PATCH

When you have worn the Patch for the time prescribed by your doctor, remove it as described below.

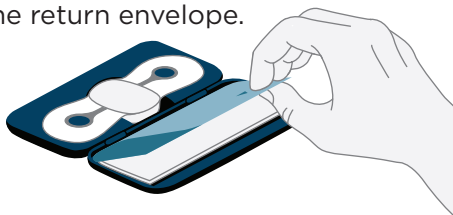
- 1 Using the adhesive remover from the opposite page, tilt the center of the Patch up and sweep between your skin and the Patch - while lifting one side from the center out. Repeat for the other side, lifting from the center out. Wash the skin with mild soap, rinse with water, and pat dry.



- 2** Place the Patch inside the Gateway as shown.



- 3** Lift panel in the Gateway to remove the return envelope.



- 4** Place only the Patch, Gateway and this booklet inside the envelope and seal. Mail it back via the U.S. Postal Service as soon as possible.

**ADHESIVE
REMOVER**

ABOUT THE ZIO® SR

ZIO® SR data analysis

Your ZIO® SR data is analyzed at the iRhythm Clinical Centers. iRhythm is an Independent Diagnostic Testing Facility (IDTF) dedicated to providing world-class diagnostic service. As an IDTF, we adhere to Medicare Independent Diagnostic Testing Facility Performance Standards.

A link to these standards (42 C.F.R. Section 410.33) can be found at the iRhythm website www.irhythmtech.com.

Patient identification

Before placing your device in the prepaid envelope, please write your name on the line above the return address. By writing your name on the envelope you are providing another method of identification for the Patch and Gateway and are consenting to the potential viewing of your name on the envelope. You may choose to not write your name on the envelope.

Notice of privacy practices

As participants in your health care, we are required by applicable federal and state law to maintain the privacy of your Protected Health Information (PHI).

Our full Notice of Privacy Practices, found at www.irhythmtech.com, describes our privacy practices, our legal duties, and your rights concerning your PHI.

Indications for use

The ZIO® SR is a prescription-only, single patient use, continuously recording ECG monitor with wireless patient event transmission that can be worn up to patients 18 years or older, patients

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.

Contraindications

- Do not use the ZIO[®] SR for patients with symptomatic episodes where instance variations in cardiac performance could result in immediate danger to the patient.
- Do not use the ZIO[®] SR for patients with known history of life threatening arrhythmias.
- Do not use the ZIO[®] SR 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[®] SR on patients with neuro-stimulator, as it may disrupt the quality of ECG data.
- Do not use the ZIO[®] SR on patients who do not have the competency to wear the device for the prescribed monitoring period.

Warnings

- Do not use the ZIO[®] SR Patch on patients with known allergic reaction to adhesives or hydrogels or with family history of adhesive skin allergies. Patient may experience skin irritation.
- Do not reuse the ZIO[®] SR. It is a single patient use device. Reuse will cause incorrect patient data and patient may experience skin irritation.
- Do not use the ZIO[®] SR on patients residing in areas with limited to no cellular reception.

If skin irritation such as severe redness, itching or allergic symptoms develop, remove the Patch.

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

Precautions

- The ZIO® SR includes temperature and humidity limitations. If exposed, patients may experience degradation of adhesive performance causing the device to slip or fall off during the patient wear duration.
- The ZIO® SR has a shelf-life date. Use of expired device may cause a degradation of ECG signal quality and/or low battery condition.
- Do not use the ZIO® SR if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® SR on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the ZIO® SR on patients receiving any form of pacing therapy has not been established. Paced cardiac rhythms may not be accurately detected and may be incorrectly classified.

Rx
ONLY

*Prescription-
Use Only*



*RF
Transmitter*



Keep Dry



*Type BF
applied part*



*Separate
collection*



*Consult
Instructions
for Use*

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device 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.

The Gateway has been tested and meets FCC RF exposure guidelines when used and operated for its intended purpose and as instructed in the manual.

I pressed the button on:

/ / : AM
PM

because I felt...

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- faint
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped or irregular beat(s)

other:
describe

for this duration...

- 1 minute or less
- 10 minutes or less
- 1 hour or less
- More than 1 hour

while I was...

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activity

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other:
describe

for this duration...

- 1 minute or less
- 10 minutes or less
- 1 hour or less
- More than 1 hour

while I was...

describe
activity

I pressed the button on:

05/22/15 10:15 AM
 PM

because I felt...

- anxious
- arm or neck pain/tingling
- chest pain or pressure
- dizziness
- faint
- light headed
- pounding
- fluttering or racing
- short of breath
- skipped or irregular beat(s)

other:
describe

for this duration...

- 1 minute or less
- 10 minutes or less
- 1 hour or less
- More than 1 hour

while I was...

describe activity getting out of bed

Enter your symptoms as shown on the sample page, or enter them using myZIO™ and enjoy these additional features:

- Review and edit your symptom history
- View Gateway transmissions
- Access and edit your patient profile
- Find patient instructions



See page 5 to get started with myZIO

z10[®]SR

BUTTON PRESS LOG

TURN OVER FOR **PATIENT INSTRUCTIONS**

Serial #

To be completed by patient

Name

Date removed

/ /

FOR SUPPORT,
CALL 1-888-693-2401