



SUBJECT INSTRUCTIONS & BUTTON PRESS LOG

STUDY NAME: _____

SUBJECT ID #: _____

INVESTIGATOR: _____

START DATE: / / **TIME:** _____

REMOVAL: Investigator prescribed duration of _____ days
 Subject to wear as long as possible (up to 14 days)

TO BE COMPLETED BY SUBJECT

DATE REMOVED: / /

For support, contact your Study Site at:

S/N STICKER HERE

Rx
ONLY



IT IS OKAY IF...

- The ZIO® XT Patch peels or lifts at the edges. Try to press and hold along the edges to re-stick.
- You experience some itching.

CALL YOUR STUDY SITE IF...

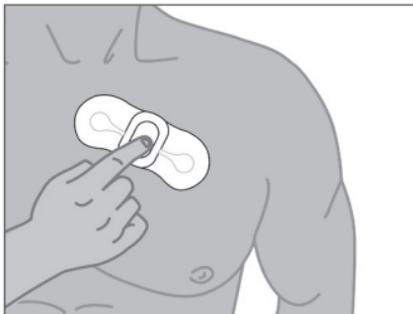
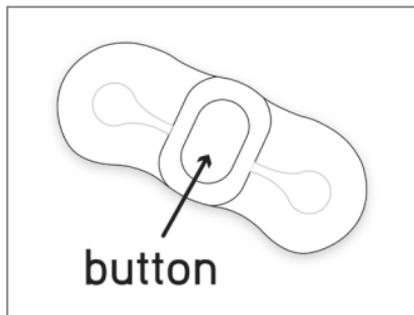
- The ZIO® XT Patch falls off.
- You experience severe itching or irritation.
- The ZIO® XT Patch is flashing orange.
This does not mean there is a problem with your heart; it just means that the Patch is not well attached.

TURN TO PAGE 2 FOR ADDITIONAL FAQs

SUBJECT INSTRUCTIONS

During Recording:

Wear the ZIO® XT Patch during your normal daily activities, even while showering and sleeping. The wear experience is different for all patients, depending on activity level, sweating and prep of the skin at application.



If directed by Study Site, press the button each time you feel a symptom.

At the End of the Enrollment Period:

Turn to the end of this booklet for removal and return instructions.

ZIO® XT PATCH FAQs

How long am I supposed to wear the ZIO® XT Patch?

Wear the ZIO® XT Patch according to your directed wear time but no longer than 14 days.

NOTE: Based on individual wear experiences your actual wear time may be shorter than prescribed.

What should I do if the ZIO® XT Patch falls off?

Call your Study Site.

What should I do if I feel a symptom?

If directed by Study Site, press the button each time you feel a symptom and fill out a page of the *Button Press Log* in this booklet.

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

While pressing the button is important, the ZIO® XT Patch is recording every heartbeat.

ZIO[®] XT PATCH FAQs (CONTINUED)

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 don't have symptoms?

That's okay. The ZIO[®] XT Patch records every heartbeat.

Can I exercise while wearing the ZIO[®] XT Patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the ZIO[®] XT Patch on?

Yes, but showers should be brief. Keep soaps and lotions away from the ZIO[®] XT Patch. When towel-drying, hold the ZIO[®] XT Patch down with one hand. Press the ZIO[®] XT Patch against your skin to secure it.

ZIO[®] XT PATCH FAQs (CONTINUED)

Can I take a bath?

Yes, but keep the ZIO[®] XT Patch above water.

Can I go swimming or in a hot tub?

No. The ZIO[®] XT Patch should not be submerged in water.

Is it normal for the ZIO[®] XT Patch to move slightly from its original position?

Yes. The ZIO[®] XT Patch may move slightly from its original position. A blue gel may become visible under the wings of the ZIO[®] XT Patch.

Is it normal to experience skin irritation or itchiness in the area of the ZIO[®] XT Patch?

Some patients have reported minor skin irritation and/or itching while wearing the ZIO[®] XT Patch. If the irritation or itching is severe or hives or blisters develop please call your Study Site.

ZIO[®] XT PATCH FAQs (CONTINUED)

Is it normal for the ZIO[®] XT Patch wings to become cloudy?

Yes, the wings of the ZIO[®] XT Patch may become cloudy after a few days of wear.

What activities should I avoid?

Activities that cause excessive sweating can cause the ZIO[®] XT Patch to slide, become loose, fall off, and shorten wear time.

How do I know the ZIO[®] XT Patch is working?

When it was applied, the staff at your Study Site made sure that the ZIO[®] XT Patch was working correctly. If it is working properly, the Zio[®] XT Patch will not flash or make noise.

ZIO® XT PATCH FAQs (CONTINUED)

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

If you see the ZIO® XT 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 ZIO® XT Patch for 3 to 5 minutes. If flashing persists or reoccurs, call your Study Site.

Can I travel with the ZIO® XT Patch on?

Yes. If questioned during security screening, show the statement on the following page.

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

The ZIO® XT Patch may blink orange after removal. It is okay to mail the device while it is blinking. Turn to the end of this booklet for return instructions.

ZIO[®] XT PATCH FAQs (CONTINUED)

How do I return the ZIO[®] XT Patch?

You can return the device as directed by your Study Site. Turn to the end of this booklet for removal and return instructions.

Who do I call if I have questions about the ZIO[®] XT Patch?

Call your Study Site.

WARNING

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

SECURITY SCREENING STATEMENT

This person is wearing an iRhythm ZIO® XT 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.

BUTTON PRESS LOG

I pressed the button on...

05 / 29 / 13

07 : 45 AM
PM

...because I felt:

- | | |
|--|---|
| <input type="checkbox"/> anxious | <input type="checkbox"/> pounding |
| <input type="checkbox"/> arm or neck pain/tingling | <input checked="" type="checkbox"/> fluttering or racing |
| <input type="checkbox"/> chest pain or pressure | <input type="checkbox"/> short of breath |
| <input checked="" type="checkbox"/> dizziness | <input type="checkbox"/> skipped beat(s), irregular beats |
| <input type="checkbox"/> fainted | <input type="checkbox"/> other (describe): |
| <input checked="" type="checkbox"/> light headed | <input type="text"/> |

...for this duration:

- | | |
|---|---|
| <input checked="" type="checkbox"/> 1 min or less | <input type="checkbox"/> 1 hour or less |
| <input type="checkbox"/> 10 mins or less | <input type="checkbox"/> More than 1 hour |

...while I was

describe activity

getting out of bed

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m	/	d	d	/	y	y	h	h	:	m	m	<input type="checkbox"/>	PM

...because I felt:

- | | |
|--|---|
| <input type="checkbox"/> anxious | <input type="checkbox"/> pounding |
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| <input type="checkbox"/> light headed | <input type="text"/> |

...for this duration:

- | | |
|--|---|
| <input type="checkbox"/> 1 min or less | <input type="checkbox"/> 1 hour or less |
| <input type="checkbox"/> 10 mins or less | <input type="checkbox"/> More than 1 hour |

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m		d	d		y	y	h	h		m	m		PM

...because I felt:

- | | |
|--|---|
| <input type="checkbox"/> anxious | <input type="checkbox"/> pounding |
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- | | |
|--|---|
| <input type="checkbox"/> 1 min or less | <input type="checkbox"/> 1 hour or less |
| <input type="checkbox"/> 10 mins or less | <input type="checkbox"/> More than 1 hour |

...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m		d	d		y	y	h	h		m	m		PM

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describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m	/	d	d	/	y	y	h	h	:	m	m	<input type="checkbox"/>	PM

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...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m		d	d		y	y	h	h		m	m		PM

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describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m		d	d		y	y	h	h		m	m		PM

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...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m	/	d	d	/	y	y	h	h	:	m	m	<input type="checkbox"/>	PM

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...while I was

describe activity

BUTTON PRESS LOG

I pressed the button on...

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
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...while I was

describe activity

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<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	:	<input type="text"/>	<input type="text"/>	<input type="checkbox"/>	AM
m	m	/	d	d	/	y	y	h	h	:	m	m	<input type="checkbox"/>	PM

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describe activity

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 PM

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- | | |
|--|---|
| <input type="checkbox"/> 1 min or less | <input type="checkbox"/> 1 hour or less |
| <input type="checkbox"/> 10 mins or less | <input type="checkbox"/> More than 1 hour |

...while I was

describe activity

ZIO® XT PATCH ANALYSIS

Your ZIO® XT Patch Heart monitor is analyzed at the iRhythm Clinical Center in Lincolnshire, IL. 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

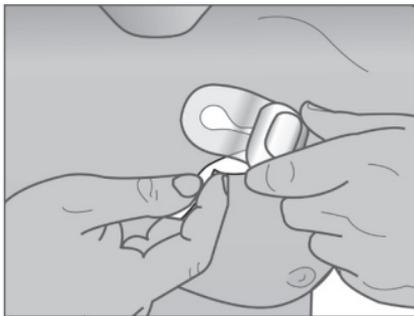
After sealing the device into the ZIO® XT Patch box, please write your Subject ID Number on the line above the return address.

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.

REMOVING THE ZIO® XT PATCH

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



2 Stick the ZIO® XT Patch to the area shown on the right. It will stick on its own.

3 Place this entire booklet, including the Patch, into the postage-paid return box. Seal the box shut with the tape provided. Return as directed by your Study Site.

For support, call your Study Site.



ADHESIVE
REMOVER

1

**REMOVE
ZIO® XT PATCH**

2

STICK ZIO® XT PATCH HERE
(ZIO® XT PATCH MAY FLASH ORANGE)

3

TAPE



iRhythm Technologies, Inc.

Clinical Centers

650 Townsend St., Suite 380
San Francisco, CA 94103

2 Marriott Drive
Lincolnshire, IL 60069

363 N. Sam Houston Parkway East
Suite 125
Houston, TX 77060

1-888-693-2401 | irhythmtech.com | [@iRhythmTech](https://twitter.com/iRhythmTech)

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

INDICATIONS FOR USE:

The ZIO® XT Patch is a prescription-only, single patient use, continuously recording ECG monitor that can be worn 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, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

CONTRAINDICATIONS:

The ZIO® XT Patch has no known contraindications.

WARNINGS:

Do not use the ZIO® XT Patch: on patients with known allergic reactions to adhesives or hydrogels or have a family history of adhesive skin allergies; in combination with external cardiac defibrillators or high frequency surgical equipment; near strong magnetic fields or devices such as MRI; on patients with a neuro-stimulator, as it may disrupt the quality of ECG data; on patients who do not have the competency to wear the device for the prescribed monitoring period. The ZIO® XT Patch and associated ZIO® analysis system efficacy has not been established on pediatric patients (younger than 18 years old).

FOR SUPPORT, CALL YOUR STUDY SITE.