



SUBJECT INSTRUCTIONS

SUBJECT #: _____

INVESTIGATOR: _____

START DATE: dd / mm / yyyy **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: dd / mm / yyyy

For support, contact your Study Site at:



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.
- The ZIO® XT Patch moves slightly from its original position. A blue gel may become visible under the wings of the ZIO® XT Patch.



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

**TURN TO PAGE 7 FOR ADDITIONAL
FREQUENTLY ASKED QUESTIONS**

DESCRIPTION

The ZIO[®] ECG Monitoring System is an ambulatory Electrocardiogram (ECG) monitoring system. The ZIO ECG Monitoring System consists of two components: (1) ZIO Patch ECG Recorder and the (2) proprietary algorithm software.

The ZIO[®] XT Patch is a single-patient-use ECG monitor that provides a continuous, single-channel recording for up to 14 days. The ZIO[®] XT Patch records ECG without patient interaction, with the goal of improving patient compliance via simplicity of operation. Patients have the option of pressing a convenient trigger 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[®] XT Patch and returns it by mail to their local distributor 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.

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, presyncope, syncope, fatigue, or anxiety.

CONTRAINDICATIONS

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



iRhythm Technologies, Inc.
650 Townsend Street, Suite 500
San Francisco, CA 94103
Tel. +1.888.693.2401 (USA Only)
Tel. +1.224.543.4200 (International)
Fax +1.888.693.2402 (USA Only)



Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Tel. +31.70.345.8570
Fax +31.70.346.7299

CE MARK INFORMATION

COMPLIANCE



The ZIO® XT ECG Monitoring System bears the CE marking CE 0050, indication its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfills the essential requirements of Annex I of this directive

The medical device has been assigned to class IIa as specified in Annex IX of the Directive 93/42/EEC.

SYMBOLS



Consult instructions for use



Manufacturer



Serial Number



Temperature limitations



Do not use if package is damaged



Caution



Catalogue number



Authorized representative in the European community



Use by



Humidity limitations



Type BF applied part

IPx4

Splash-proof equipment

Rx ONLY

Prescription use only



Date of manufacture

QTY:

Net quantity of contents



Do Not Reuse



Separate collection



This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS.

DOCUMENTS

Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance of 3.3 meters away from the equipment.

Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2W yields $d=3.3$ m at an IMMUNITY LEVEL of 3 V/m.

WARNINGS

- Do not use the ZIO® XT 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® XT Patch on multiple patients. It is a single patient use device. Reuse will cause incorrect patient data and may experience skin irritation.



If skin irritation such as severe redness, itching or allergic symptoms develop, remove the ZIO® XT Patch from the patient's chest. Contact your local distributor.

Rx
ONLY

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



PRECAUTIONS

- The ZIO® XT Patch 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® XT Patch 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® XT Patch if package is damaged. Device may not perform as intended.
- Safety and effectiveness of the ZIO® XT Patch on pediatric patients (younger than 18 years old) has not been established.
- Safety and effectiveness of the ZIO® XT Patch 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.

ZIO® XT PATCH ANALYSIS

The ZIO® XT Patch heart monitor is analyzed at the iRhythm Clinical Center. 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.

NOTICE OF PRIVACY PRACTICES

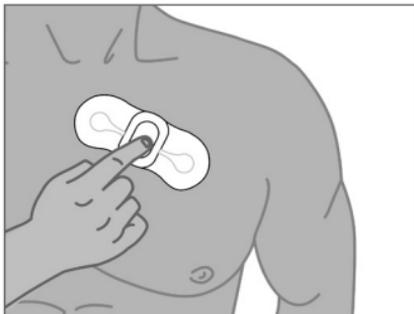
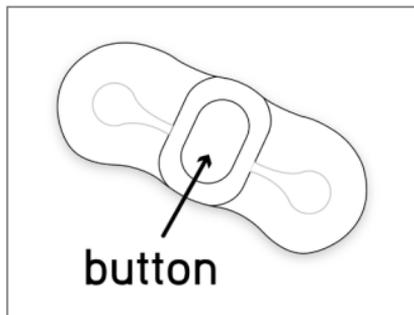
iRhythm is committed to upholding patient privacy and protecting personal information, in particular health information collected and processed in conjunction with our ZIO® Service. We commit to complying with all applicable privacy laws and allowing patients to exercise their rights via their doctor. For more information, please refer to the Notice and Consent you signed or contact your doctor.

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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 subjects, depending on activity level, sweating and prep of the skin at application.



At the End of the Enrollment Period:

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

ZIO® XT PATCH FREQUENTLY ASKED QUESTIONS

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

Wear the ZIO® XT Patch 14 days or as long as possible. **NOTE:** Based on individual wear experiences your actual wear time may be shorter than prescribed. You do not need to wear the Patch for more than 14 days.

What is the ZIO® XT Patch doing?

The ZIO® XT Patch is recording every heartbeat. Your physician will use the data from the ZIO® XT Patch to look at your heart rhythm and determine a proper course of action.

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

Contact your Study Site.

What should I do if I feel a symptom?

Press the button each time you feel a symptom.

ZIO® XT PATCH FREQUENTLY ASKED QUESTIONS(CONTINUED)

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.

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 FREQUENTLY ASKED QUESTIONS(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 FREQUENTLY ASKED QUESTIONS(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 physician's office 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 FREQUENTLY ASKED QUESTIONS(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.

ZIO® XT PATCH FREQUENTLY ASKED QUESTIONS(CONTINUED)

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.

How do I return the ZIO® XT Patch?

Return the device as directed by your Study Site. Turn to page 15 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.

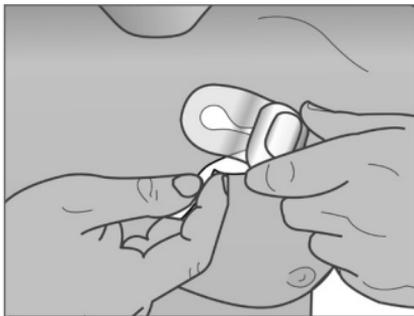
If you have any questions, please contact
iRhythm Clinical Center at
+(1) 224-543-2400 (INTERNATIONAL)
24 hours/day, 7 days/week.

NOTICE OF PRIVACY PRACTICES

iRhythm is committed to upholding patient privacy and protecting personal information, in particular health information collected and processed in conjunction with our ZIO® Service. We commit to complying with all applicable privacy laws and allowing patients to exercise their rights via their doctor.

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 Return this entire booklet, including the Patch, as directed by your Study Site.

For support, call your Study Site.

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**ADHESIVE
REMOVER**

1

**REMOVE
ZIO® XT PATCH**

2

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

3

TAPE



iRhythm™



iRhythm Technologies, Inc.
650 Townsend Street, Suite 500
San Francisco, CA 94103 U.S.A.
Tel. +1.888.693.2401 (USA Only)
Tel. +1.224.543.4200 (International)
Fax +1.888.693.2402 (USA Only)



Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands
Tel. +31.70.345.8570
Fax +31.70.346.7299



FOR SUPPORT, CALL YOUR STUDY SITE.