

Overall Zio Patch Checklist

In clinic

- Assess eligibility ► Track number eligible/ineligible
- Administer questionnaire
- Day 1 is the day patch is applied. If ppt declines patch on clinic day, offer (1) ppt chance to return to clinic on another day. If no, (2) offer to visit ppt at home. If no, (3) offer to mail patch to ppt. If ppt opts for last option, call ppt 3 days after mailing out patch to guide ppt with patch application ► Track number eligible who decline participation

Day 3 phone call

- Ask whether ppt is still wearing patch.
 - If no, offer (1) ppt chance to return to clinic for another patch. If no, (2) offer to visit ppt at home. If no, (3) offer to mail patch to ppt. If ppt opts for last option, call ppt 3 days after mailing out patch to guide ppt with patch application
 - Track number not wearing patch on Day 3. Of these track number who are willing to wear another patch
 - If still wearing patch, (1) clarify any questions, (2) encourage wearing until 14 days.

Day 10 phone call

- Ask whether ppt is still wearing patch.
 - If not, remind ppt to return patch and booklet to iRhythm if ppt has not returned the patch and booklet
 - If still wearing, (1) clarify any questions, (2) encourage wearing until 14 days and return patch and booklet to iRhythm

Receipt of Zio Patch and retrieval phone calls

- 8 business days after Day 14, check iRhythm website. If report is available, send check to ppt. If report is not available, call ppt to remind ppt to return patch to iRhythm (first phone call).
- If report is not available 8 business days after the first phone call, issue a second phone call. Repeat the above until participant returns the patch by mail. ► Track no. with final report

Results reporting and alert notification

- Check CDART daily for determination of (1) normal results, (2) abnormal results, and (3) alerts. For (3), EPICARE will also send email to Field Center PI, Co-I, and field center staff. ► Track no. of (1), (2), and (3)
- For (1), mail cover letter plus 1st page of Zio report, and (2), mail cover letter plus 1st page of Zio report
- (3), Fed Ex cover letter plus entire Zio report AND Field Center PI or Co-I to call ppt

Other issues

- For support regarding patch, contact iRhythm (Martha Livingston, Tel: 224-543-427, mlivingston@irhythmtech.com)
- For questions regarding project, contact PI (Lin Yee Chen, Tel: 612-625-4401, chenx484@umn.edu)

ARIC Zio Patch Study

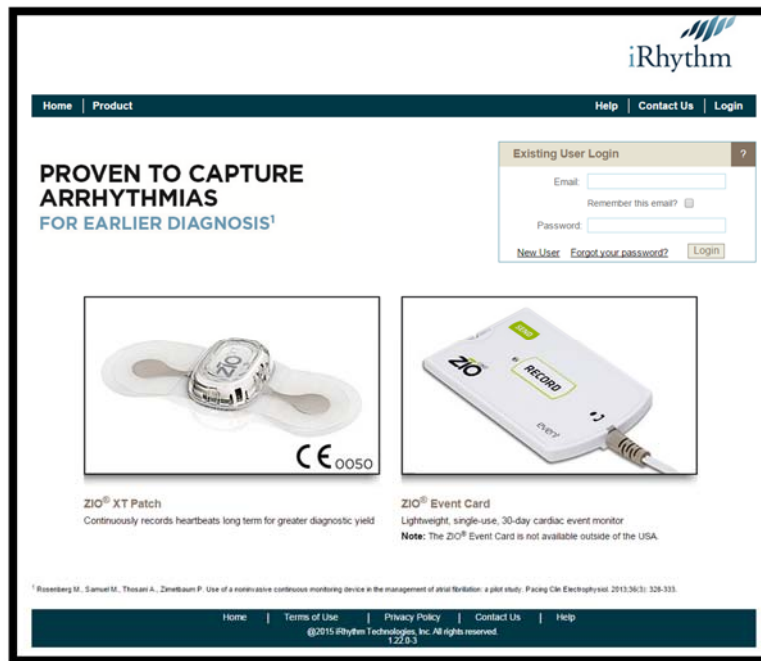
Participant Enrollment Checklist:

1. Has subject been enrolled into the iRhythm Zioreports website?
2. Has subject been advised to push the subject trigger button upon feeling symptoms and to documents symptoms in the diary?
3. Has subject been advised that if they have any questions while wearing the Patch they are to call their study coordinator?
4. Has subject been advised on Patch removal? The Adhesive remover located in the Patient Instruction Booklet should be used when removing the Patch.
5. Has subject been advised that they should return the device directly to the study site?

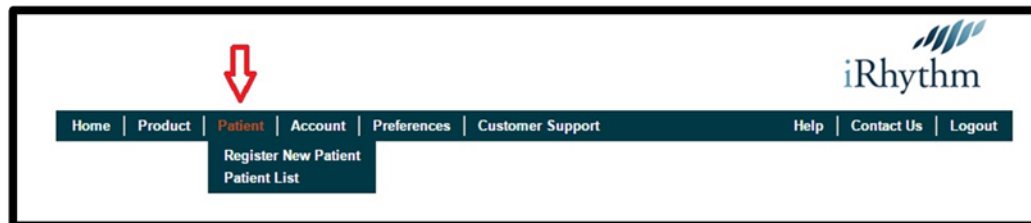
ARIC Zio Patch Study

Study Site Instructions for Subject Registration

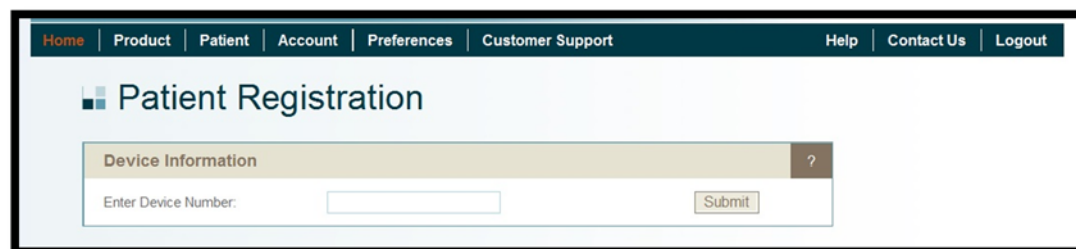
1. Log-in to ZioReports (www.Zioreports.com) using your email address and individual password



2. Select the “Patient” tab in the header menu and then select “Register New Patient”.
Note: The “Patient List” option will allow you to view all registered patients at your site, the device status (received or not), and also view/save patient reports in a PDF format.



3. Submit the Zio® XT Patch Device Number. The device serial number can be found in numerous places within the Zio® XT Patch Kit, the back of the Zio XT® Patch, the inside of the Skin Prep & Placement Kit and the cover of the Subject Instruction Booklet included in the Zio® XT Patch kit.



4. You will now see the Subject Enrollment screen.

Required Fields:

- Last Name: Enter Subject ID#.
 - First Name: Enter Subject ID#.
 - Gender: Male (for all participants)
 - DOB: Enter 01/01/1930
 - Patient ID number: Enter Subject ID number
 - Primary Phone Number: Enter your site's phone number.
 - Address: Enter your site's address.
 - Prescribing Office: Select your site.
 - Prescribing Physician/Non-Physician: Select your Field Center Principal Investigator.
 - Primary Indication: ARIC Study
 - Paced by ICD or Pacemaker: Select "yes" or "no".
 - iRhythm staff to provide hook-up service: Select "no".
 - Patch Start Date: Enter patch start date in MM/DD/YYYY format.
 - Prescribed Wear Duration (Days): Enter up to 14 days
- After all required information is entered; select "Execute" in the lower right hand corner. This will complete the registration of the device.

Patient Enrollment

Account: **iNCC Chicago** Serial Number: **P222910034 {research}**

Patient Information		Prescribing Information	
Last Name:*	Subject ID#	Prescribing Office:*	--Select Location--
First Name:*	Subject ID#	Prescribing Physician/Non-Physician:*	--Select Prescriber--
Gender:*	--Select Gender--	Primary Indication:*	Palpitations - 785.1
DOB (mm/dd/yyyy):*		ICD or Pacemaker?:*	No
Patient ID Number:	Subject ID#	iRhythm staff to provide hook-up service:*	Yes
Primary Phone Number:*	() () ()	List Referring Clinician on Report?	<input type="checkbox"/>
Secondary Phone Number:	() () ()	ZIO Patch Information	
Email:		Patch Start Date (mm/dd/yyyy):*	
Confirm Email:		Prescribed Wear Duration (Days):*	1
Address:			
Street Address 1:*	Site Address		
	Street Address, P. O. Box		
Street Address 2:	Suite, Unit, Building, Floor		
City:*			
State (e.g. AZ):*	--		
Zip Code:*			
Country:	United States		
Did the patient request restricted use of PHI? No			
		Continue Execute	

Fields marked with an * are required.

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Script for 3-Day, 10-Day & Retrieval Telephone Calls

3-DAY TELEPHONE CALL

Before starting the call, check which studies the participant is enrolled in.

- ☐ Participant in Zio Patch Study
- ☐ Participant in Physical Activity & Falls Study

If you are speaking to an answering machine:

Hello, this is <<staff name>> and I am calling from the ARIC study to speak with <<participant first and last name>>. <<Participant first name>>, we are calling to see if you have started to wear your physical activity and heart patch monitor(s) and if you have questions about these devices or the monthly falls calendar. Please call us back at your earliest convenience. We can be reached at << Telephone number>>. We will call you again tomorrow if we do not hear back from you.

Thank you and we look forward to speaking with you soon.

End of call

If Person is reached

Hello, may I speak with <<name of participant>>?

Participant is UNAVAILABLE

Ask when you may call back to speak with <<name of participant>>.

Participant is AVAILABLE

Hello, this is <<staff name>> and I am calling from the ARIC Study to talk with you about the Physical Activity & Falls and/or Heart Patch Monitor Studies.

A. HEART MONITOR PATCH (Zio Patch Monitor)

1a. *“Are you still wearing the Heart Patch monitor?”*

→ **IF YES**

“Great, thank you” (go to question 2)

→ **IF NO**

1b. *“Would you be willing to come in again to have the patch monitor applied?”*

→ **IF YES**

Please schedule an appointment

→ **IF NO**

1c. *“Would it be OK for us to come to your house to help put on the patch monitor?”*

→ **IF YES**

Please schedule an appointment

→ **IF NO,**

“We can also mail this patch monitor to you. We will call you in a few days afterward to guide you with the application of the patch monitor. Is this OK?”

2. *“Do you have any questions about the Heart Patch monitor?”*

→ **IF NO**

“Please continue to wear the patch monitor for up to 2 weeks. We will call you again in 1 week. Thank you for participating in this study.” (go to B. Physical Activity questions, if applicable)

→ **IF YES**

<<Trouble shoot with participant. Below is a list of frequently asked questions with responses>>.

	ZIOPATCH FAQ	RESPONSES
1.	What should I do if the patch monitor falls off?	<i>Call us.</i>
2.	What should I do if I feel a symptom?	<i>Press the button each time you feel a symptom and fill out a page of the Button Press Log in the instructions/button press log booklet.</i>
3.	What if I forget to press the button when I feel a symptom?	<i>While pressing the button is important, the patch monitor is recording every heartbeat</i>
4.	What if I press the button but forget to write down the information in this booklet?	<i>While the Button Press Log information is useful, pressing the button indicates that you felt your symptoms at that time.</i>
5.	What if I don't have symptoms?	<i>That's okay. The patch monitor records every heartbeat.</i>
6.	Can I exercise while wearing the patch monitor?	<i>Yes, but excessive sweating may shorten wear time.</i>
7.	Can I shower with the patch monitor on?	<i>Yes, but showers should be brief. Keep soaps and lotions away from the patch monitor. When towel-drying, hold the patch monitor down with one hand. Press the patch monitor against your skin to secure it.</i>
8.	Can I take a bath?	<i>Yes, but keep the patch monitor above water.</i>
9.	Can I go swimming or in a hot tub?	<i>No. The patch monitor should not be submerged in water.</i>
10.	Is it normal for the patch monitor to move slightly from its original position?	<i>Yes. The patch monitor may move slightly from its original position. A blue gel may become visible under the wings of the patch monitor.</i>
11.	Is it normal to experience skin irritation or itchiness in the area of the patch monitor?	<i>Some patients have reported minor skin irritation and/or itching while wearing the patch monitor. If the irritation or itching is severe or hives or blisters develop, please call us.</i>
12.	Is it normal for the patch monitor wings to become cloudy?	<i>Yes, the wings of the patch monitor may become cloudy after a few days of wear.</i>
13.	What activities should I avoid?	<i>Activities that cause excessive sweating can cause the patch monitor to slide, become loose, fall off, and shorten wear time.</i>
14.	What if the patch monitor flashes orange while I am wearing it?	<i>If you see the patch monitor 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 patch monitor for 3</i>

		<i>to 5 minutes. If flashing persists or reoccurs, call us.</i>
15.	Can I travel with the patch monitor on?	<i>Yes. If questioned during security screening, show the statement on page 8 of the instructions/button press log booklet.</i>

END CALL IF NOT ENROLLED IN PA and FALLS

"Please continue to wear the patch monitor for up to 2 weeks. We will call you again in 1 week. Thank you for participating in this study."

B. RED ACTIVITY MONITOR (Accelerometer)

1. ***"Have you started to wear the red activity monitor? The activity monitor is the small device that is worn on a black elastic belt around your waist."***

→ IF YES

"Great, thank you." (go to question 2)

→ IF NO, HAS NOT STARTED TO WEAR

"That is OK, do you think you could start wearing it today (or within next two days) for 7 consecutive days?"

→ IF NO

<<Troubleshoot with participant. If they are unable to start wearing the activity monitor within the next 4-5 days, ask the participant to return the activity monitor and materials to the Field Center site using the pre-paid and addressed padded envelope>>.

2. ***"Do you have any questions about the red activity monitor?"***

→ IF NO

"OK" (Go to question 3)

→ IF YES

<<Troubleshoot with participant. Below is a list of frequently asked questions with responses>>.

	Activity Monitor FAQ	RESPONSES
1.	Do I need to turn the activity monitor on or off?	<i>No, the activity monitor is turned on, and it can stay on, for as long as you have it.</i>
2.	My monitor used to blink a little green light, but now it doesn't. Is it broken?	<i>No, the blinking is only a technical feature of the monitor. The device is monitoring your activity even if it is not blinking.</i>

3.	I forgot to put my monitor on when I got up this morning. Should I go home and put it on?	<i>If at all possible, yes. We would like for you to wear the monitor during all waking hours. Remember to record the time you put on/take off the device. If this is not possible, please remember to wear the monitor tomorrow.</i>
4.	I forgot to wear my monitor yesterday. Should I start wearing it again today?	<i>Yes. We ask that you wear the monitor for 7 consecutive days. If you forget a day, start wearing the monitor the next day. If you accidentally skip a day, make it up by wearing the monitor for an additional day at the end of the week. Please record this additional day in your Activity Monitor Tracking Log.</i>
5.	Does it matter if I wear my monitor in the same place each day?	<i>It is ideal that you wear the monitor in the same place. Please wear the device as close to your right hip as possible each day.</i>
6.	The belt for my monitor is too short (or too long) to go around my waist. How do I lengthen (or shorten) it?	<i>Pull the belt through the black plastic tabs to shorten or lengthen the belt. Please do not make any other alterations to the belt.</i>
7.	I've accidentally dropped my monitor a couple of times. Is it okay?	<i>The activity monitor is a delicate piece of equipment and should be handled with care. However, minor accidents should not impair its functioning.</i>
8.	My monitor is hard to keep in place when I wear skirts and dresses. Do you have any suggestions to make this easier?	<i>Most people find that wearing the monitor with pants is the most comfortable. If the pants have belt loops, you can string you monitor and belt through the loops as if it were a normal belt. You can also wear the activity monitor under a dress or skirt, if necessary.</i>

3. “Do you have any questions about the Activity Monitor Tracking Log?”

→ **IF NO,**

OK, great. (Go to C. Falls Calendar Questions)

→ **IF YES**

<<Trouble shoot with participant. Below is a list of frequently asked questions with responses>>.

	Tracking Log FAQ	Responses
1.	I forgot to complete the record for a day.	<i>That's OK, if you remember approximately when you put the monitor on and took it off, please record those</i>

		<i>times in the Activity Monitor Tracking Log.</i>
2.	I forgot to wear the monitor for the day.	<i>If you accidentally skip a day, make it up by wearing the monitor for an additional day at the end of the week. Please record this additional day in your Activity Monitor Tracking Log.</i>
3.	Oftentimes, I change outfits during the day. Should I record these instances on my Activity Monitor Tracking Log ?	<i>If you removed the device to change clothes, and it was off for 30 minutes or longer, please record these times in your Activity Monitor Tracking Log.</i>
4.	I took the activity monitor off for >30 minutes but forgot to record the times that I took it off and put it back on in the Activity Monitor Tracking Log.	<i>That's OK, if you remember approximately when you took the monitor off and put it back on, please record those times in the Activity Monitor Tracking Log.</i>

C. FALLS CALENDAR

1. “**Did you hang up your falls calendar in a convenient location so you can mark it each day?**”

→ **IF YES**

“Ok, Great” (go to question 2).

→ **IF NO**

“That’s OK. We have found that if the calendar is placed in a convenient location, it’s easier for individuals to remember to fill it out each day.”

2. “**Have you started marking on your falls calendar each day to indicate if you did or did not fall?**”

→ **IF YES**

“Ok, Great” (go to question 3).

→ **IF NO, HAS NOT STARTED TO TRACK FALLS**

“Ok, are there any questions we can answer about your falls calendar to help you get started?” <<Troubleshoot with participant if they are unable to start tracking their falls. See FAQ below to answer questions they may have.>>.

3. “**Do you have any questions about tracking your falls?**”

→ **IF YES**

<<See FAQ below for answers to possible questions related to using the falls calendar.>>.

→ **IF NO**

“Ok” (go to question 4).

4. “Do you have any questions about returning your falls calendar at the end of each month?”

→ **IF NO**

End the call.

→ **IF YES**

<<See FAQ Below for answers to possible questions related to using the falls calendar.>>.

	Falls Calendar FAQ	Responses
1.	I forgot to track my falls	<i>If you accidentally skip a day, it's ok. Just mark the calendar for the days that you missed. It's helpful if you place the calendar in a convenient spot where you can see it each day and remember to mark it – like hanging it on your refrigerator or wall in the kitchen or bedroom.</i>
2	What should I mark on the calendar on days that I fall?	<i>Mark “F” on the date that you fell. Then complete the questions below the calendar about your fall. You only need to complete this</i>
3	What should I mark on the days that I do NOT fall?	<i>Mark “N” on the days that you do not fall.</i>
4.	What if I trip, but I don't fall down. Do I mark that as a fall?	<i>Do NOT mark this as a fall. Only mark it as a fall if you unintentionally come down/fall down to the ground or a lower level (such as a step or piece of furniture). This does not include falls that occurred because of a seizure</i>
5.	When should I mark something as a “fall”?	<i>Only mark it as a fall if you unintentionally come down/fall down to the ground or a lower level (such as a step or piece of furniture). This does not include falls that occurred because of a seizure.</i>
6	Why do I need to track my falls every day?	<i>We found that participants were more likely to accurately track their falls if they got in the habit of marking their calendar every day.</i>

7	What if I fall more than once? How do I answer the questions on the calendar?	<i>You can answer the questions for either the first or second fall. We prefer that you answer the questions for the fall that you remember the best.</i>
8	What if I fall and I forget to answer the questions, and then I fall again?	<i>You can answer the questions for either the first or second fall. We prefer that you answer the questions for the fall that you remember the best.</i>
9	What if I forget to complete the calendar and I did NOT fall that month?	<i>You can simply check the box on the calendar that reads "I did not fall this month".</i>
10	When should I return my calendar?	<i>At the end of each month, please tear off the calendar page for that month, fold the calendar and seal it. The calendar is already addressed and stamped. To mail it, just place it in the mail box.</i>
11	How should I mail/return back my monthly calendar?	<i>Please tear off the calendar page for that month, fold the calendar and seal it. The calendar is already addressed and stamped. To mail it, just place it in the mail box.</i>
12	What if I misplace or lose my calendar?	<i>Call us. We will send you another one!</i>

End of Call

"Please continue to wear the patch monitor for up to 2 weeks. We will call you again in 1 week. Thank you for participating in this study."

10-Day Telephone Call

Before starting the call, check which studies the participant is enrolled in.

- ☐ Participant in Zio Patch Study
- ☐ Participant in Physical Activity & Falls Study

If you are speaking to an answering machine:

"Hello, this is <<staff name>> and I am calling from the ARIC study to speak with <<participant first and last name>>. We are calling to see if you have questions about your heart patch monitor. Also, If you have not yet returned the red activity monitor in the white padded envelope, please drop it in the mail today. <<Participant first name>>, please call us back at your earliest convenience. We can be reached at << Telephone number>>. We will call you again tomorrow if we do not hear back from you.

Thank you and we look forward to speaking with you soon."

Person is reached

"Hello, may I speak with <<name of participant>>?"

Participant is UNAVAILABLE

Ask when you may call back to speak with <<name of participant>>.

Participant is AVAILABLE

"Hello, this is <<staff name>> and I am calling from the ARIC Study to talk with you about the Physical Activity & Falls and Heart Patch Monitor Studies."

A. HEART MONITOR PATCH (Zio Patch Monitor)

1. "Are you still wearing the Heart Patch monitor?"

→ IF YES

"Great, thank you" (go to question 2)

→ IF NO

"Have you returned the device using the labeled return box?"

→ IF YES

"Great, thank you"

→ IF NO

"Please put the patch monitor and instructions/button press log booklet in the labeled return box and drop it in a mail box."

2. For participants who are still wearing the monitor - "Do you have any questions about the Heart Patch monitor?"

→ **IF NO**

"Please continue to wear the patch monitor for another 4 more days up to a total of 2 weeks."

→ **IF YES**

<<Trouble shoot with participant. Below is a list of frequently asked questions with responses>>.

	Zio Patch FAQ	Responses
1.	What should I do if the patch monitor falls off?	<i>Call us.</i>
2.	What should I do if I feel a symptom?	<i>Press the button each time you feel a symptom and fill out a page of the Button Press Log in the instructions/button press log booklet.</i>
3.	What if I forget to press the button when I feel a symptom?	<i>While pressing the button is important, the patch monitor is recording every heartbeat</i>
4.	What if I press the button but forget to write down the information in this booklet?	<i>While the Button Press Log information is useful, pressing the button indicates that you felt your symptoms at that time.</i>
5.	What if I don't have symptoms?	<i>That's okay. The patch monitor records every heartbeat.</i>
6.	Can I exercise while wearing the patch monitor?	<i>Yes, but excessive sweating may shorten wear time.</i>
7.	Can I shower with the patch monitor on?	<i>Yes, but showers should be brief. Keep soaps and lotions away from the patch monitor. When towel-drying, hold the patch monitor down with one hand. Press the patch monitor against your skin to secure it.</i>
8.	Can I take a bath?	<i>Yes, but keep the patch monitor above water.</i>
9.	Can I go swimming or in a hot tub?	<i>No. The patch monitor should not be submerged in water.</i>
10.	Is it normal for the patch monitor to move slightly from its original position?	<i>Yes. The patch monitor may move slightly from its original position. A blue gel may become visible under the wings of the patch monitor.</i>
11.	Is it normal to experience skin irritation or itchiness in the area of the patch monitor?	<i>Some patients have reported minor skin irritation and/or itching while wearing the patch monitor. If the irritation or itching is severe or hives or blisters develop please call us.</i>
12.	Is it normal for the patch monitor wings to become cloudy?	<i>Yes, the wings of the patch monitor may become cloudy after a few days of wear.</i>
13.	What activities should I avoid?	<i>Activities that cause excessive sweating can cause the patch monitor to slide, become loose, fall off, and shorten wear time.</i>
14.	What if the patch monitor flashes orange while I am wearing it?	<i>If you see the patch monitor 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 patch monitor for 3 to 5 minutes. If flashing persists or reoccurs, call us.</i>

15.	Can I travel with the patch monitor on?	Yes. If questioned during security screening, show the statement on page 8 of the instructions/button press log booklet.

If only participating in ZIOPATCH, END CALL: *“Please remember to return the patch monitor and instructions/button press log booklet using the labeled return box when you have completed 14 days of monitoring. Thank you for participating in this study.”*

B. RED ACTIVITY MONITOR

1. ***“Have you returned the activity monitor and Activity Monitor Tracking Log to the Field Center Site, yet? The activity monitor was the small red device that you wore for 7 days on a black elastic belt.”***

→ IF NO

<<Troubleshoot with participant for successful return (e.g., drop off at field center or mail another padded envelope to the participant so they can return the monitor)>>.

→ IF YES

“Great, we sincerely appreciate your participation!”

C. FALLS CALENDAR

1. ***“Did you hang up your falls calendar in a convenient location so you can mark it each day?”***

→ IF YES

“Ok, Great” (go to question 2).

→ IF NO

“That’s OK. We have found that if the calendar is placed in a convenient location, it’s easier for individuals to remember to fill it out each day.”

2. ***“Have you started marking on your falls calendar each day to indicate if you did or did not fall?”***

→ IF YES

“Ok, Great” (go to question 3).

→ IF NO, HAS NOT STARTED TO TRACK FALLS

“Ok, are there any questions we can answer about your falls calendar to help you get started?”

<<Troubleshoot with participant if they are unable to start tracking their falls. See FAQ below to answer questions they may have.>>.

3. “Do you have any questions about tracking your falls?”

→ **IF YES**

<<See FAQ below for answers to possible questions related to using the falls calendar.>>.

→ **IF NO**

“Ok” (go to question 4).

4. “Do you have any questions about returning your falls calendar at the end of each month?”

→ **IF NO**

End the call.

→ **IF YES**

<<See FAQ Below for answers to possible questions related to using the falls calendar.>>.

	Falls Calendar FAQ	Responses
1.	I forgot to track my falls	<i>If you accidentally skip a day, it's ok. Just mark the calendar for the days that you missed. It's helpful if you place the calendar in a convenient spot where you can see it each day and remember to mark it – like hanging it on your refrigerator or wall in the kitchen or bedroom.</i>
2	What should I mark on the calendar on days that I fall?	<i>Mark “F” on the date that you fell. Then complete the questions below the calendar about your fall. You only need to complete this</i>
3	What should I mark on the days that I do NOT fall?	<i>Mark “N” on the days that you do not fall.</i>
4.	What if I trip, but I don't fall down. Do I mark that as a fall?	<i>Do NOT mark this as a fall. Only mark it as a fall if you unintentionally come down/fall down to the ground or a lower level (such as a step or piece of furniture). This does not include falls that occurred because of a seizure</i>

5.	When should I mark something as a “fall”?	<i>Only mark it as a fall if you unintentionally come down/fall down to the ground or a lower level (such as a step or piece of furniture). This does not include falls that occurred because of a seizure.</i>
6	Why do I need to track my falls every day?	<i>We found that participants were more likely to accurately track their falls if they got in the habit of marking their calendar every day.</i>
7	What if I fall more than once? How do I answer the questions on the calendar?	<i>You can answer the questions for either the first or second fall. We prefer that you answer the questions for the fall that you remember the best.</i>
8	What if I fall and I forget to answer the questions, and then I fall again?	<i>You can answer the questions for either the first or second fall. We prefer that you answer the questions for the fall that you remember the best.</i>
9	What if I forget to complete the calendar and I did NOT fall that month?	<i>You can simply check the box on the calendar that reads “I did not fall this month”.</i>
10	When should I return my calendar?	<i>At the end of each month, please tear off the calendar page for that month, fold the calendar and seal it. The calendar is already addressed and stamped. To mail it, just place it in the mail box.</i>
11	How should I mail/return back my monthly calendar?	<i>Please tear off the calendar page for that month, fold the calendar and seal it. The calendar is already addressed and stamped. To mail it, just place it in the mail box.</i>
12	What if I misplace or lose my calendar?	<i>Call us. We will send you another one!</i>

END OF CALL: *“Please remember to return the patch monitor and instructions/button press log booklet using the labeled return box when you have completed 14 days of monitoring. Thank you for participating in this study.”*

RETRIEVAL TELEPHONE CALL

If you are speaking to an answering machine:

<<Participant first name>>, we are calling to see if you have returned your red activity and/or heart patch monitor(s). Please call us back at your earliest convenience. We can be reached at << Telephone number>>. We will call you again tomorrow if we do not hear back from you.

Red Activity Monitor in the white padded envelope, please drop it in the mail today.

Or the Heart Monitor Patch in the box provided, please drop it in the mail today.

These two monitors are mailed to different places so please make sure to use the mailing material provided to you for mailing these back. Do not mail them back in a package together.

Thank you and we look forward to speaking with you soon.

End of call

Person is reached

Hello, may I speak with <<name of participant>>?

Participant is UNAVAILABLE

Ask when you may call back to speak with <<name of participant>>.

Participant is AVAILABLE

Hello, this is <<staff name>> and I am calling from the ARIC Study to talk with you about the Physical Activity & Falls and Zio Patch Studies.

A. HEART MONITOR PATCH (Zio Patch Monitor)

1. Have you returned the device using the labeled return box?

→ IF YES

"Great, thank you for participating in this study"

→ IF NO

"Please put the patch monitor and instructions/button press log booklet in the labeled return box and drop it in a mail box."

- 8 business days after Day 14: first retrieval phone call
- 8 business days after first retrieval phone call: second retrieval phone call
- Repeat above until participant returns patch monitor and instructions/button press log booklet by mail

B. Red ACTIVITY Monitor (to follow 2 reminder postcards, call on 28 days after expected date of return)

- Not returned with 14 days of expected: post card 1

- Not returned within 21 days of expected: postcard 2
 - Not returned within 28 days of expected: retrieval phone call
1. ***“We have not received your activity monitor and/or Activity Monitor Tracking Log at the Field Center Site. The activity monitor was the small red device that you wore for 7 days on a black elastic belt? Did you return the activity monitor and/or Activity Monitor Tracking Log.”***

→ IF NO

<<Troubleshoot with participant for successful return, if no addressable solution is found,>>

“Thank you, I’m sure we will receive it soon. Thank you.”

→ IF YES

“Great, thank you, we look forward to it arriving at the Field Center site, soon.”



SUBJECT INSTRUCTIONS & BUTTON PRESS LOG

STUDY NAME: _____

SUBJECT ID #: _____

INVESTIGATOR: _____

START DATE: _____

/ /

TIME: _____

REMOVAL:

☐

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...

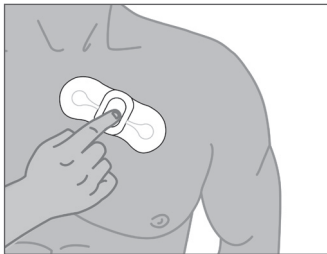
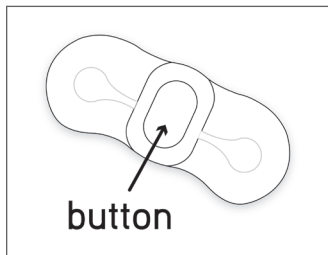
- The ZIO® XT Patch falls off.
- You experience severe itching or irritation.
- The ZIO® XT Patch is flashing orange.
This does not mean there is a problem with your heart; it just means that the Patch is not well attached.

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^X AM
PM

...because I felt:

☐

anxious

☐

pounding

☐

arm or neck
pain/tingling

☒

fluttering or racing

☐

chest pain
or pressure

☐

short of breath

☒

dizziness

☐

skipped beat(s),
irregular beats

☐

fainted

other (describe):

☒

light headed

...for this duration:

☒

1 min or less

☐

1 hour or less

☐

10 mins or less

☐

More than 1 hour

...while I was

describe
activity

getting out of bed

BUTTON PRESS LOG

I pressed the button on...

/ / : AM
 PM

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

/ / : AM
m m d d y y h h m m PM

...because I felt:

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

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

/ / : AM
 PM

...because I felt:

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

...because I felt:

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

/ / : AM
m m d d y y h h m m PM

...because I felt:

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

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

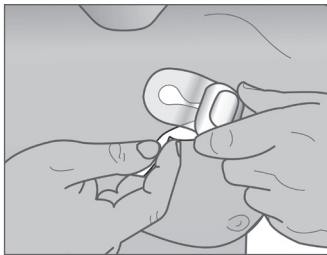
After sealing the device into the ZIO® XT Patch box, please write your Subject ID Number on the line above the return address.

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.

APPENDIX 5

Abnormal findings

- 1) Atrial fibrillation
- 2) Atrial flutter
- 3) Supraventricular ectopy (SVE)/Premature atrial contractions (PACs) – state only if >1%
- 4) Supraventricular couplets – state only if >1%
- 5) Supraventricular triplets – state only if >1%
- 6) Supraventricular tachycardia
 - a. If a single episode is >30 seconds
 - b. If on average, >1 episode per day
- 7) Ventricular ectopy (VE)/Premature ventricular contractions (PVCs) – state only if >1%
- 8) Ventricular couplets – state only if >1%
- 9) Ventricular triplets – state only if >1%
- 10) Nonsustained ventricular tachycardia
 - a. If a single episode is >15 seconds and ≤30 seconds
 - b. If on average, >1 episode per day
- 11) 2nd degree AV block, Mobitz I (AV Wenkebach)
- 12) Paced beats

Alerts

- 1) Wide QRS tachycardia >120 bpm and sustained for >30 seconds (includes monomorphic ventricular tachycardia, polymorphic ventricular tachycardia, ventricular fibrillation)
- 2) Complete heart block
- 3) 2nd degree AV Block, Mobitz II
- 4) Pause >6 seconds
- 5) Bradycardia <40 bpm and sustained for >30 seconds
- 6) Atrial fibrillation/atrial flutter with average heart rate <40 bpm or >180 bpm and sustained for 60 seconds
- 7) Narrow QRS tachycardia >180bpm and sustained for 60 seconds

EPICARE may in some instances report other abnormalities or alert findings if deemed appropriate.

Description of abnormal findings and alerts

Directions: State or list the abnormalities and provide the description. Example: The heart rhythm monitor recorded atrial fibrillation and ventricular ectopy. Atrial fibrillation is an irregular heart rhythm. Ventricular ectopy are heartbeats that come early and originate from the lower chambers of the heart. They may feel like “palpitations” or “skipping a beat”.

Abnormality or alert	Description
Atrial fibrillation	This is an irregular heart rhythm. It may feel like palpitations or “racing heart beats”.
Atrial flutter	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”.
Supraventricular ectopy (SVE) / Premature atrial contractions (PACs) / Supraventricular bigeminy / Supraventricular trigeminy / Supraventricular couplets / Supraventricular triplets	These are heartbeats that come early and originate from the upper chambers of the heart. They may feel like palpitations or “skipping a beat”.

Supraventricular tachycardia	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”.
Ventricular ectopy (VE) / Premature ventricular contractions (PVCs) / Ventricular bigeminy / Ventricular trigeminy / Ventricular couplets / Ventricular triplets	These are heartbeats that come early and originate from the lower chambers of the heart. They may feel like palpitations or “skipping a beat”.
Nonsustained ventricular tachycardia	This is a fast rhythm that originates from the lower chambers of the heart. It may feel like palpitations or “racing heart beats”.
2 nd degree AV block, Mobitz I (AV Wenkebach)	This is an occasional slowing of heart rate due to a drop of a beat in the lower chambers.
Paced beats	These are heart beats that originate from a pacemaker device rather than your heart’s own pacemaker.
Wide QRS tachycardia >120 bpm and sustained for >30 seconds (includes monomorphic ventricular tachycardia, polymorphic ventricular tachycardia, ventricular fibrillation)	This is a fast rhythm that originates from the lower chambers of the heart and may feel like palpitations or “racing heart beats”.
Complete heart block	This is a slow heart beat due to an interruption in the electrical pathway in the heart.
2 nd degree AV Block, Mobitz II	This is a slow heart beat due to an interruption in the electrical pathway in the heart.
Pause >6 seconds	There was no heart beat for 6 seconds or longer.
Bradycardia <40 bpm and sustained for >30 seconds	This is a slower than usual heart rate that lasted more than 30 seconds.
Atrial fibrillation/atrial flutter with average heart rate <40 bpm or >180 bpm and sustained for 60 seconds	This is an irregular heart rhythm. It may feel like palpitations or “racing heart beats”.
Narrow QRS tachycardia >180bpm and sustained for 60 seconds	This is a fast rhythm that originates from the upper chambers of the heart. It may feel like palpitations or “racing heart beats”.

Lin Y. Chen, MD, MS
Associate Professor,
Principal Investigator, ARIC Heart Patch Monitor Study

Results letter template #2 – Abnormal findings present

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the ARIC Heart Patch Monitor Study at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are detailed in the attached report. The report shows some results may be considered outside of the normal range. In most instances, such results do not mean that a medical problem exists. At your convenience, you may want your physician to review the report and determine whether the results should be studied further.

The findings are: [List below]

Because the ARIC Study does not provide any clinical diagnosis or treatment, we offer to send the attached heart patch monitor report to your physician or provider, when requested. If you do not have a personal physician or do not know where to find one, please call us at [number].

Thank you again for being a member of the ARIC Study.

Sincerely,

[Name]

Professor,

Principal Investigator, [] Field Center

Lin Y. Chen, MD, MS
Associate Professor,
Principal Investigator, ARIC Heart Patch Monitor Study

Results letter template #3 – Alerts present

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the ARIC Heart Patch Monitor Study at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are detailed in the attached report. We have identified some findings which are possibly abnormal. We believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

The findings are: [List below]

Because the ARIC Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. During your ARIC Study visit you indicated that we should send these results to you. We encourage you to consult your physician or usual source of medical care, to alert them to these results that we have highlighted for verification. If you do not have a personal physician or do not know where to find one, please call us at [number].

Thank you again for being a member of the ARIC Study.

Sincerely,

[Name]

Professor,

Principal Investigator, [] Field Center

Lin Y. Chen, MD, MS
Associate Professor,
Principal Investigator, ARIC Heart Patch Monitor Study

Results letter template #4 – Abnormal findings present, including previous Holter findings

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the ARIC Heart Patch Monitor Study at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are detailed in the attached report. The report shows some results may be considered outside of the normal range. In most instances, such results do not mean that a medical problem exists. At your convenience, you may want your physician to review the report and determine whether the results should be studied further.

The findings are: [List below]

We understand that you had previously taken part in the ARIC Heart Monitor (Holter) Study. The following findings were noted in the Holter study: [List below]

Because the ARIC Study does not provide any clinical diagnosis or treatment, we offer to send the attached heart patch monitor report to your physician or provider, when requested. If you do not have a personal physician or do not know where to find one, please call us at [number].

Thank you again for being a member of the ARIC Study.

Sincerely,

[Name]

Professor,

Principal Investigator, [] Field Center

Lin Y. Chen, MD, MS
Associate Professor,
Principal Investigator, ARIC Heart Patch Monitor Study

Results letter template #5 – Alerts present, including previous Holter findings

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the ARIC Heart Patch Monitor Study at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are detailed in the attached report. We have identified some findings which are possibly abnormal. We believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

The findings are: [List below]

We understand that you had previously taken part in the ARIC Heart Monitor (Holter) Study. The following findings were noted in the Holter study: [List below]

Because the ARIC Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. During your ARIC Study visit you indicated that we should send these results to you. We encourage you to consult your physician or usual source of medical care, to alert them to these results that we have highlighted for verification. If you do not have a personal physician or do not know where to find one, please call us at [number].

Thank you again for being a member of the ARIC Study.

Sincerely,

[Name]

Professor,

Principal Investigator, [] Field Center

Lin Y. Chen, MD, MS
Associate Professor,
Principal Investigator, ARIC Heart Patch Monitor Study