Zio Patch Instructions

This leaflet will guide you through wearing and removing the Zio Patch monitor. There is also a demonstration video available on the study website (www.amalfitrial.org). Please note that, for this study, you will NOT need to enrol as stated in section 1 ("Plan & Position") of the cardboard leaflet containing the patch.



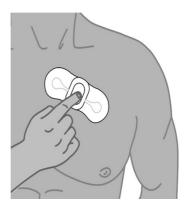
WARNING: Do not use the Zio Patch if you have a known allergic reaction to adhesives or hydrogels or a family history of adhesive skin allergies.

Do not reuse the Zio Patch on anyone else. It is a single patient use device. Reuse will cause incorrect patient data and may cause skin irritation.

1. Application

You may find it easier if someone can help you put the Zio Patch on. It should go in the upper left chest, just below the collar bone. You may need to shave off any hair in this area.

You will need to abrade the skin 10 times vertically, horizontally and diagonally (with the abrader) to remove any loose skin cells. Next, clean the area with the alcohol wipe and allow the area to dry for a minute or two, as this will help the patch to stick better. It is normal for the skin to look more red than usual after abrading and cleaning.



Remove the backing, trying to avoid touching the adhesive area.

Place the patch 1-2 fingers width below the left collar bone. Make sure you avoid the armpit and breast tissue. Press firmly in place for a minute or two.

Peel off the white top-labels marked 1 and 2. Start with label 1 and pull downwards in the direction of the arrow. With your other hand, make sure the clear layer remains stuck down to your chest. Repeat with the other side, pulling label 2 upwards to remove. Smooth the patch firmly all over, pressing the adhesive onto your skin, especially around the edges.

Hold the button down on the Zio Patch until the light flashes green several times. At this point the device is active and will begin recording.

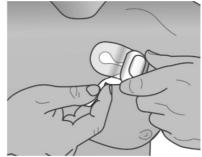
2. During Recording

Wear the Zio Patch during your normal daily activities, even while showering, exercising and sleeping. Do try to be careful it does not come loose during this time. Wearing the patch is different for all subjects, depending on sweating and skin preparation at application.

3. Removing the Zio Patch

After 2 weeks, gently tilt the centre of the patch up. Using the adhesive remover, sweep to the right between your skin and the patch while peeling from the centre out. Repeat for the left side, again peeling from the centre out. Wash skin with mild soap, rinse with water, and dry.

To return, put the Zio Patch in the back of the instruction booklet and send in the original box. A sticker is supplied to seal it. Remember, the results will go back to your GP who may want to discuss the findings with you.



Frequently asked questions:

How long am I supposed to wear the Zio Patch?

Wear the Zio Patch for 14 days if you can. If you have problems before the end of the 14-day period, contact the AMALFI team.

What is the Zio Patch doing?

The Zio Patch is recording every heartbeat. Your GP will use the data from the Zio Patch to look at your heart rhythm and if necessary, determine a proper course of action.

Can I exercise while wearing the Zio Patch?

Yes, but excessive sweating may shorten wear time.

Can I shower with the Zio Patch on?

Yes, but showers should be brief. Try to keep your back to the jet of water and keep soaps and lotions away from the Zio Patch. When towel-drying, press the Zio Patch down against your skin to secure it.

Can I take a bath?

Yes, but keep the Zio Patch above water as the patch is water resistant, not water proof.

Can I go swimming or in a hot tub?

No. The Zio Patch should not be submerged in water.

Is it normal for the Zio Patch wings to become cloudy?

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

What activities should I avoid?

Swimming or any activity that causes excessive sweating. Sweat can cause the Zio Patch to slide, become loose and fall off. This shortens the wear time.

Can I travel with the Zio Patch on?

Yes. If questioned during security screening, show them the study documentation. There is a security statement in the booklet supplied inside the patch box.

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

Yes, the Zio Patch may blink orange after removal.

IT IS OK IF...

- You experience some itching.
- The Zio Patch peels or lifts at the edges. Try
 to press and hold along the edges to re-stick.
 If necessary, use medical tape (such as
 Tegaderm or Micropore) to help.
- The Zio Patch moves slightly from its original position. A blue gel may become visible under the wings of the Zio Patch.

CALL THE AMALFI TEAM IF...

- The Zio Patch falls off.
- You experience severe itching or irritation.
- The Zio Patch flashes orange this means that the patch is not well attached; it does <u>not</u> mean there is a problem with your heart. Press evenly on the Zio Patch for 3 to 5 minutes. If the flashing persists or reoccurs, call the AMALFI team.

Contact the AMALFI research team Call: Freephone 0808 164 5080

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