

March 24, 2022

Dear Costco Member,

Costco records indicate that you, or one of your add-on members, have purchased the Philips M5068A Home AED, item # 359854, between 2012 and 2018.

The electrode pads used with your Home AED (Philips PNs: M5071A Adult pads, M5072A Infant/Child pads) have been observed to experience gel separation from the foam/tin backing when peeled from the yellow plastic liner. The gel may fold onto itself resulting in reduced surface area of gel on the pad, or it may separate almost completely leaving only a small amount of gel on the pad. When a pad with separated, folded gel is placed on the patient's bare skin, the Home AED could deliver less effective or ineffective therapy to the patient due to the reduced surface contact area with the skin.

Separated, folded gel may also have a discolored and/or melted appearance. While the gel may also have a discolored and/or melted appearance, the appearance does not have any impact on the delivery of therapy; however, there may be a delay in therapy if the user hesitates to apply the pad due to its appearance, and the AED may deliver less effective or ineffective therapy to the patient due to the reduced contact area with the skin.

It is also possible that the gel could separate almost completely from the foam/tin backing when peeled. Due to a small amount of gel surface contact area with the skin, electrical arcing could occur when a shock is delivered leading to burns to the patient's skin, or the AED could be unable to deliver any shock through the pads. A delay in therapy will result while the user installs a replacement pads cartridge (if available) or performs CPR while waiting for Emergency Medical Services Personnel to arrive.

Costco Member Actions:

- 1. Continue to use the Home AED and pads as-is. In case of trouble, install spare pads if available. If you notice the gel beginning to separate from the foam backing as you peel, try to prevent the gel from folding onto itself if possible. Do not hesitate to apply the pads to the patient unless the gel has almost completely separated from the backing. No matter the state of the pads, follow the AED voice prompts because the AED will step you through the necessary actions.
- 2. Keep a copy of this letter with the Owner's Manual of your Home AED.

At a later date, Philips will provide, free of charge, one updated M5071A Adult Pads cartridge to the owner of every Home AED sold in the past 10 years. Costco Members will receive a second communication when the updated pads are available. For more information about this URGENT Medical Device Correction, please visit <u>www.philips.com/pads-notice</u>, or <u>click here</u> for a document that further explains this important medical device correction.

Please call Philips at (800) 263-3342, Monday - Friday, 8:00AM – 8:00PM Eastern if you have any issues or concerns.

Thank you,

Tanya DeSchmidt Director of Quality Philips Emergency Care and Resuscitation





