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URGENT Medical Device Correction

M5071A Adult and M5072A Infant/child pads cartridges for use with HS1/OnSite/Home AEDs may experience gel separation and reduction of gel surface area

24-MAY-2023

This document contains important information for the continued safe and proper use of your equipment

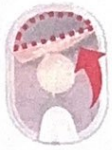
Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.
Please retain a copy with the equipment Instructions for Use.

Dear Customer,

On March 4, 2022, Philips voluntarily initiated an "Urgent Medical Device Correction" for the M5071A Adult and M5072A Infant/child pads cartridges for use with HS1/OnSite/Home AEDs. ***Please respond, even if you no longer own the AED.*** This notice has been reported to the appropriate Regulatory Agencies. The FDA has classified this correction as a Class II recall under the following recall numbers: Z-0881-2022 and Z-0882-2022. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, or by regular mail, or by fax. This letter is intended to inform you about:

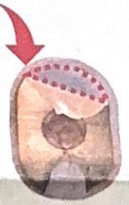
1. **What the problem is and under what circumstances it can occur**

Some electrode pads used with the HS1/OnSite/Home AED 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. A pad in this condition could cause the HS1/OnSite/Home to deliver less effective or ineffective therapy to the patient due to the reduced surface contact area with the skin.



Areas of missing gel

Separated, folded gel may also have a discolored or melted appearance. While the gel may also have a discolored 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 if the gel has separated from the pad.



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 HS1/OnSite/Home 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.

Gel almost completely missing

2. **Hazard/harm associated with the issue:** An electrode pad that experiences gel separation could result in less effective therapy for a patient, delay of therapy for a patient, or cause the HS1/OnSite/Home AED to be unable to deliver any shock through the pads.

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3. **Affected products and how to identify them:** M5071A Adult and M5072A Infant/child pads cartridges with a LOT number that begins with "Y" may experience the issue.

4. **Actions that should be taken by the customer/user in order to prevent risks for patients or users**

Keep your HS1/OnSite/Home AED in service until you receive updated pads. If you need to use your HS1/OnSite/Home AED before an updated pads cartridge has been installed, ensure the majority of the pad surface is covered with gel and apply the pads to the patient. If you notice the gel beginning to separate from the white foam backing as you peel, try if possible to prevent the gel from folding onto itself. Do not hesitate to apply the pads to the patient unless the gel has almost completely separated from the backing. In case of trouble, install a spare pads cartridge if available and continue the rescue. No matter the state of the pads, follow the voice prompts because the HS1/OnSite/Home AED will guide you through the necessary actions. If the problem continues and you do not have a spare pads cartridge, attend to the patient, providing CPR if needed, until Emergency Medical Services Personnel arrive. Philips recommends that you store a spare pads cartridge with your HS1/OnSite/Home AED. A short video showing how to replace the pads cartridge can be found at: www.philips.com/replace-aed-pads

Please pass this notice to all those who need to be aware within your organization or to any organization where HS1/OnSite/Home AED devices or pads cartridges have been transferred. Please keep a copy of this letter with the Instructions for Use/Owner's Manual. **Please respond to this notice because your response is necessary to ensure effectiveness of the recall notification.** Even if you transferred your device to someone, or if your device is no longer in service, please respond.

5. **Actions planned by Philips to correct the problem**

Philips will provide to customers who respond one updated Adult pads cartridge, free-of-charge, per HS1/OnSite/Home AED in service. Unexpired M5071A spare pads cartridges with a LOT number that begins with "Y" will be replaced, free-of-charge. You must respond to receive any free-of-charge updated Adult pads cartridges.

Infant/child pads cartridge updates will be handled separately. If you own an M5072A Infant/child pads cartridge, Philips will provide, free-of-charge, updated M5072A Infant/child pads cartridges when available to replace unexpired Infant/child pads cartridges.

If you need any further information or support concerning this issue, please contact your Philips representative.
Philips regrets any inconvenience caused by this problem.

Sincerely,

Tanya DeSchmidt
Director of Quality

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Customer Code: ADSAR2310

Reply Instructions for FSN C&R 2021-CC-EC-012 (SAR)

Please respond to this notice using the instructions on this page. Your response is necessary to ensure effectiveness of the recall notification.

Instructions: Whether your HS1/OnSite/Home AED remains in service or not, please respond within the next 30 days by scanning the QR code or visiting the URL below.

https://philips.efmfeedback.com/se/705E3ED86F40D003

You will be asked for the serial numbers of your AEDs and LOT numbers of your Adult Pads Cartridges. The images below show where to locate the needed information.