Urgent Product Defect Correction – TGA Copy

PHILIPS

CHIEF EXECUTIVE OFFICER

CC: Biomedical Engineering Dept

<Customer Name & Company Details>

Philips Healthcare
Locked Bag 30
North Ryde
NSW 1670
Australia

January 2023

FSN-2022-CC-EC-011

TGA Reference #:	RC-2022-RN-01534-1
Product / Device Name / Model #	M5071A Adult and M5072A Infant/child pads cartridges for use with HS1/OnSite/Home AEDs
ARTG Ref #	337264, 374814
Short Problem Description	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

Dear Customer,

Philips following consultation with the Therapeutic Goods Administration (TGA), is conducting an Urgent Product Defect Correction of Philips M5071A (adult) and M5072A (infant/child) AED pads that could pose a risk for patients or users. We are contacting you as the potentially affected product has been supplied to your organisation.

On April 2022, Philips initiated a Product Defect Correction (RC-2022-RN-00499-1) for the M5071A Adult and M5072A Infant/child pads cartridges for use with HS1/OnSite/Home AEDs. Due to customer feedback, we have decided to notify customers who received an HS1/OnSite/Home AED more than 10 years ago. Please respond, even if you no longer own the AED.

A similar notice was previously sent to customers who purchased HS1/OnSite/Home AEDs less than 10 years ago. If you received that notification, please respond to both notifications.

This letter is intended to inform you about:

- what the problem is and under what circumstances it can occur
- the actions that should be taken by the customer / user in order to prevent risks for patients or users
- the actions planned by Philips to correct the problem

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 Instruction for Use.

If you need any further information or support concerning this issue, please contact **Philips Service Delivery Team on 1800 251 400.**

Philips apologises for any inconveniences caused by this problem. Thank you for your assistance in helping us to manage this Urgent Product Defect Correction.

Sincerely,

Princess Nochefranca
Quality Specialist
Philips Healthcare Australia and New Zealand

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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 AED 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 HS1/OnSite/Home 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 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. As of 31 August 2022, there have been a total of 151 complaints reported to Philips.
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. **LOT Number of affected pads begins with "Y"** 
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

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	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 If your HS1/OnSite/Home AED is in service and installed with an unexpired M5071A Adult pads cartridge with a LOT number that begins with "Y", then you are eligible to receive an updated Adult pads cartridge, free-of-charge. 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. 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 that is installed with an unexpired M5071A Adult pads cartridge with a LOT number that begins with "Y". 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. Corrected M5071A Adult pads are expected to release for shipping to Australia this month (January 2023). 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. Philips anticipates beginning to ship corrected Infant/Child pads in Q1 2023. A similar notice was previously sent to customers who purchased HS1/OnSite/Home AEDs less than 10 years ago. **If you received that notification, please respond to both notifications.**
FURTHER INFORMATION AND SUPPORT	If you need any further information or support concerning this issue, please contact **Philips Service Delivery Team on 1800 251 400.**

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Customer Acknowledgement Form

Please complete this form within 3 business days, *Whether your HS1/OnSite/Home AED remains in service or not.*

Return via email: qr_anz@philips.com or fax: 02 99470240 Attn. - Q&R Department.

I acknowledge receipt and understanding of this Urgent Product Defect Correction Notice and confirm that the information from this notification has been properly distributed to all who handle the HS1/OnSite/Home AED. The contact information below will be used to provide the replacement pads cartridge(s). The information below will not be used for marketing purposes. Acknowledging this notice will not reduce your coverage or rights under any Philips AED Warranty or Indemnification.

Site / Hospital Name:			
Your Name & Position			
Your Contact details: Phone Fax Email address			
Signature		**Date**	

What is the **status** of your HS1/OnSite/Home AED?

Please check the box and use the space on the right to provide additional info. If different status for multiple AEDs please provide information for all AEDs and make the status of each clear in your response.

☐ My HS1/OnSite/Home AED remains in service, and my M5071A Adult pads cartridge is unexpired and has a LOT number that begins with "Y". The **Serial Number** of my HS1/OnSite/Home AED and the **LOT number(s)** of my M5071A Adult pads cartridge, and spare cartridge(s) if applicable, are listed to the right. (If multiple HS1/OnSite/Home AEDs and Adult pads, please include all. **Add a separate page if needed.)** Therefore, please send me the replacement Adult pads cartridge(s). I understand I need to provide both the serial number of the device and LOT number(s) of the unexpired Adult pads cartridge(s) to receive the replacement(s) free-of-charge. (Note: M5072A Infant/child pads cartridge updates will be handled separately, so please do not include Infant/child pads cartridge information.)

Use this space to provide additional information

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☐ My HS1/OnSite/Home AED is no longer in service (discarded, lost, permanently retired or destroyed). If the Serial Number is known to me, I have listed it to the right. (If multiple, please include all serial numbers.)

Use this space to provide additional information.

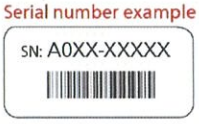
☐ Ownership of my HS1/OnSite/Home AED was transferred to someone else. If available, I have listed the Serial Number of the AED to the right. (If multiple, please include all serial numbers. **Add a separate page if needed**.) I will share this notice with the new owner(s).

Use this space to provide additional information.

☐ My HS1/OnSite/Home AED is installed with an Adult pads cartridge that is past its expiration date. I have listed the AED Serial Number(s) in the space provided, but I understand that because my pads are expired, I will not receive a free-of-charge replacement Adult pads cartridge.

Use this space to provide additional information.

Serial number example



LOT # example

Other organisations

Has your organisation supplied potentially affected product to any other organisation?

☐ **No**	☐ **Yes** I/we will forward all the recall information to the suppliers/distributors/customers	☐ **Yes** (please supply names and contact information of the organisations)