Product Defect Correction

CHIEF EXECUTIVE OFFICER
CC: Biomedical Engineering Dept
SURF LIFE SAVING SVCS PVT LTD
3 NARABANG WAY
BELROSE NSW 2085

Philips Healthcare
Locked Bag 30
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NSW 1670
Australia

FSN-2021-CC-EC-012

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TGA Reference #:	RC-2022-RN-00499-1
Product / Device Name / Model #	Philips M5071A (adult) and M5072A (infant/child) for use specifically with the HeartStart HS1 AEDs/OnSite/Home AED
ARTG Ref #	337264, 374814
Short Problem Description	Adult SMART Pads Cartridge and the Infant/Child SMART Pads Cartridge 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 a 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. 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 our **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 Product Defect Correction.

Sincerely,

Lailah Cheng
Quality Assurance and Regulatory Affairs Specialist
Philips Healthcare Australia and New Zealand