



QSR22-051
January 16, 2023

Dear customer,

Philips Japan, Ltd.
2-13-37 Konan, Minato-ku, Tokyo
108-8507

Notification Regarding the Voluntary Recall of Adult SMART Pad Cartridges for the Philips HeartStart HS1 AED

Thank you very much for your continued support.

As announced in Field Safety Notice (QSR22-023/2021-CC-EC-012), it has been confirmed that the gel on SMART pad cartridges that are used in the Philips HeartStart HS1 can peel away from the pad in some cases. Therefore, we would like to inform you that we will implement a recall of M5071A Adult Pads (Brand name: SMART Pad Cartridge, Notification No.: 13B1X00221000048). We will provide genuine Philips updated SMART pad cartridge (that have passed Philips evaluation testing) for products that are listed in the attached List of Lot Numbers for Recall. When you receive the updated SMART pad cartridge, please replace the pads currently installed in your AED. Please return the affected pad and Recall Confirmation Form to us according to the attached Return Procedure Form within 4 weeks after receiving the updated SMART pad cartridge.

Recall procedures for the M5072A Infant/Child Pads will be announced at a later date.

Philips Healthcare, a foreign manufacturer, places the highest priority on ensuring the safety of patients and users of our products.

We sincerely apologize for the concern and inconvenience that this issue has caused for our customers. We appreciate your understanding and cooperation.

If you have questions regarding the quantity of updated SMART pad cartridge that were sent or any other concerns, please call the **Philips AED (HS1) Pad Recall Office (TEL 0120-143-079, Weekdays 9:00 a.m. to 5:30 p.m.)**.

* The expiration date for M5071A Adult Pads is 30 months from the date of manufacture. Please check the expiration date printed on the product before use.

* For more information on how to replace your pads and how to return affected pads to us, refer to the enclosed Replacement Procedure / Return Procedure Form or use the QR code on the right.

