

M5071A Adult SMART Pad Cartridge Replacement Procedure Form for HS1

(Brand name: SMART Pad Cartridge, Notification No.: 13B1X00221000048)

Please use the following procedure to replace your pads.

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.

You can also use the QR code on the right to check the procedure.



1. Make sure you have the following items close at hand: Recall Confirmation Form, List of Affected Pad Lot Numbers, Updated Pad dispatch details (M5071A Adult Pads), and your HS1 HeartStart AED (referred to as the AED). The AED is stored inside a red carrying case.



2. Remove the AED from its carrying case and check the serial number. The alphanumeric serial number is printed on the bottom of the AED. In the photo below, it is indicated by a red arrow.



3. Confirm that the serial number on the AED that you checked in Step 2 is shown on the enclosed Updated Pad Dispatch details (M5071A Adult Pads).
4. If you have a spare SMART pad cartridge, keep it close at hand. SMART pad cartridges are enclosed in red packaging with an illustration of an adult on the front, as shown in the photo below. A spare SMART pad cartridge can often be found in the top compartment of the carrying case. A spare might be stored in a different location, so please check with the person in charge of managing AED units at your facility. Please note that a spare might not be available if it has already been used.



5. Confirm that the SMART pad cartridge mounted on the AED and the spare SMART pad cartridge are affected products. The alphanumeric lot number of a SMART pad cartridge is printed on the back of the product. In the photo below, the lot number starting with Y is indicated by a red arrow. Lot numbers of affected products are listed on the enclosed List of Affected Pad Lot Numbers.

IMPORTANT

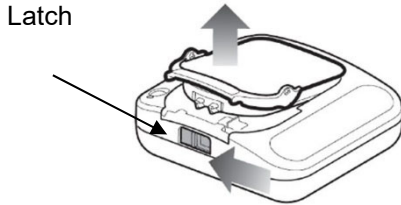
Please only return products whose lot numbers are listed on the List of Affected Pad Lot Numbers. If an ineligible product is returned to us, we will be unable to return the product because we cannot guarantee product quality. Please note that we will take the appropriate steps to dispose of such products.

* Note: M5071A Adult Pads for which the expiration date has passed are not covered by this recall. New replacements should be ordered from a retailer.

[Location of Lot Number] Lot numbers of affected products start with a Y.



6. Remove the SMART pad cartridge that is mounted on the AED. Slide the latch on the top of the AED to release the SMART pad cartridge, and then lift the cartridge to remove it.



Use the QR code below to check the replacement procedure.



Slide the latch on the top of the AED.

7. Make sure the SMART pad cartridge that you received is close at hand. Install the SMART pad cartridge you received in the AED whose serial number you checked in Step 2. Alternatively, you can store it as a spare cartridge for that AED. Remove the new SMART pad cartridge from its packaging, and insert the cartridge into the slot on the front of the AED. You will be able to feel when the cartridge fits securely in place. Make sure the green PULL handle is down (not pulled up).



8. Perform the above steps for all AED that are shown on the Updated Pad Dispatch details (M5071A Adult Pads). After all replacements are complete, check the quantity of SMART pad cartridges for recall. If changes have been made to the locations of pads in accordance with operations at your facility, make replacements as necessary.
9. Refer to the example shown on the Recall Confirmation Form, and then fill in the quantity of cartridges to be returned that you checked in Step 8, as well as all other required fields.
10. Follow the procedure described on the Return Procedure Form to return all SMART pad cartridges to us for recall as confirmed in Step 9, along with the Recall Confirmation Form.

If you have any questions about this product, please call the **Philips AED (HS1) Pad Recall Office at 0120-143-079 (weekdays 9:00 a.m. to 5:30 p.m.)**.