

URGENT Field Safety Notice

Philips M5072A Infant/Child SMART Pads Cartridge
for use with the Philips HeartStart OnSite and HeartStart Home AEDs

The graphic on the cover for the pads cartridge incorrectly shows application to an adult instead of a child.

19-AUG-2021

This notification updates the replacement instructions provided in the original notification dated 26-JUL-2021

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.

Dear Customer,

A problem has been identified in certain Philips M5072A HeartStart Infant/Child SMART Pads Cartridges which are used with the Philips HeartStart OnSite and HeartStart Home Automated External Defibrillators (AEDs). The problem could pose a risk for patients. This notification is intended to inform you about:

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

Some M5072A Infant/Child SMART Pads Cartridges contain an incorrect image on the protective cover seen underneath the PULL handle. The image on the protective cover should show a drawing of pads placement for a child's chest and back (Figure 1). However, some M5072A Infant/Child SMART Pads Cartridges from LOT Number Y111220-01 incorrectly show the pads placement for an adult's chest on the inner layer protective cover (Figure 2). However, the image is correct on the outer pouch that contains the infant/child pads cartridge (Figure 3). To date, from over 19,000 pads cartridges from this LOT Number, Philips has received customer complaints for 11 cartridges for the incorrect image. No patient harm was reported for these 11 instances.



Figure 1: Correct Image



If Lot Number is Y111220-01,
then Do Not Use

Figure 2: Incorrect Image

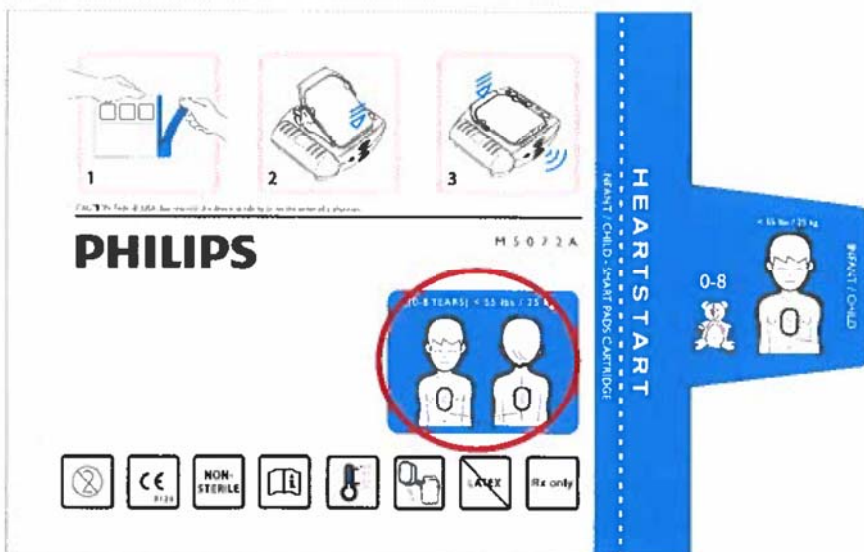


Figure 3: Outer Pouch has the Correct Image

2. Describe the hazard/harm associated with the issue

There are two main hazards associated with Infant/Child SMART Pads Cartridges from Lot Y111220-01 that contain an incorrectly printed protective cover.

- 1) The first hazard is delay of therapy delivery.
 - i. During a rescue of an **infant/child patient**, the user may become unsure upon seeing the drawing of pads placement for an adult's chest. Once the user has removed the protective cover, they would see white adhesive pads correctly printed with pads placement for an infant/child. The user could then proceed normally with the rescue. The initial confusion, however, could lead to delay of therapy which would decrease the chance of a successful resuscitation.
 - ii. During a rescue of an **adult patient** the user may mistake the Infant/Child SMART Pads Cartridge for an adult AED pads cartridge. The time needed to install a correct Adult SMART Pads Cartridge could lead to delay of therapy which would decrease the chance of a successful resuscitation.
- 2) The second hazard is delivery of lower energy than indicated for an adult patient. During the rescue of an **adult patient**, the user may mistake the Infant/Child SMART Pads Cartridge for an Adult SMART Pads Cartridge. If the user were to place the infant/child pads onto the adult patient, and if a shock were advised by the AED, then lower energy than indicated for an adult patient would be delivered which would decrease the chance of a successful resuscitation.

3. Affected products and how to identify them

The affected products are Philips M5072A Infant/Child SMART Pads Cartridges with Lot Number Y111220-01 which were distributed beginning in December 2020. The Lot Number can be found on the bottom of the shipping box (Figure 4) and on the front of the outer pouch (Figure 5). If the Infant/Child SMART Pads Cartridge has been removed from the outer pouch, the Lot Number can be found on the protective cover of the pads cartridge (Figure 6).

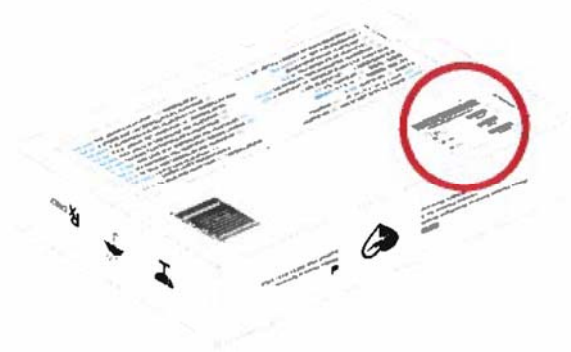


Figure 4: Bottom of AED Pads Shipping Box with Location of Lot Number Circled in Red



Figure 5: Outer Pads Pouch with Location of Lot Number Circled in Red



Figure 6: AED Pads Cartridge with Location of Lot Number Circled in Red

Product Name	Catalog Number	Lot Number
Philips Infant/Child SMART Pads Cartridge	M5072A	Y111220-01

4. Actions to be taken by the customer/user

Action 1: If needed, contact your distributor to request a replacement

Customers who purchased their pads cartridges directly from Philips will receive their replacements without any further action on their part. Customers who purchased their pads cartridges from a distributor should contact that distributor to request replacement. Replacement pads cartridges may not be available immediately, therefore, refer to Action 2, below.

Action 2: Determine if the Infant/Child SMART Pads may remain in service until replaced

Philips, or your Philips Distributor, will supply a replacement of all M5072A Infant/Child SMART Pads Cartridges from Lot Number Y111220-01.

If the Infant/Child SMART Pads Cartridge is still inside the outer pouch, then it can remain in service **until replaced**. While waiting to receive the replacement, customers should keep the Infant/Child SMART Pads Cartridge inside the outer pouch until the cartridge is replaced, or until it is needed for therapy. The reason is that the outer pouch correctly identifies the cartridge as intended for infant/child patients. (Figure 7).



Figure 7: An Infant/Child SMART Pads Cartridge that is still inside the pouch, which may remain in service **until replaced**.

If the Infant/Child SMART Pads Cartridge has been removed from the outer pouch, and if the protective cover shows the correct drawing of pads placement for a child's chest and back, then it can remain in service **until replaced**. The reason is because the protective cover has the correct image with the image of a child's chest and back. (Figure 8).



Figure 8: An Infant/Child SMART Pads Cartridge that has been removed from the pouch, and that shows a drawing of pads placement for a child's chest and back, which may remain in service **until replaced**.

If the Infant/Child SMART Pads Cartridge has been removed from the outer pouch, and if the protective cover shows a drawing of an adult's chest, **then the cartridge should be taken out of service immediately and discarded**. The reason is because the protective cover has an incorrect image and could be mistakenly used for therapy on an adult patient, which would deliver lower energy than indicated for an adult and/or delay of therapy. (Figure 9).



If Lot Number is Y111220-01, then Do Not Use

Figure 9: An Infant/Child SMART Pads Cartridge that has been removed from the pouch, and that shows a drawing of pads placement for an adult's chest. **This pads cartridge should be discarded immediately.**

Action 3: Discard the affected pads cartridge, after replacement has been received

To reduce the chance that the products would be used inadvertently after you have discarded them, please use scissors to cut the 4 corners off the outer pouch of the old pads cartridges, and then discard it all (Figure 10). If the cartridge was already removed from the pouch, then please discard the cartridge after receiving a replacement.

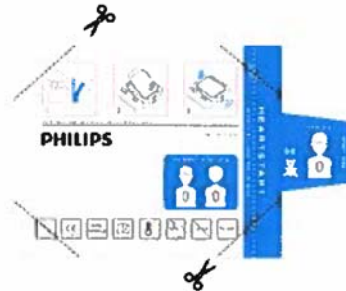


Figure 10: After receiving a replacement pads cartridge, customers should cut the corners from the pads pouch being replaced, and discard the cartridge and pouch.

Action 4: Pass this notice to those who need to be aware

This notice needs to be passed on to all those who need to be aware of its contents within your organization or to any organization where the potentially affected devices have been transferred. Until all the Infant/Child SMART Pads Cartridges are replaced, please ensure that your staff remains aware of the contents of this notice.

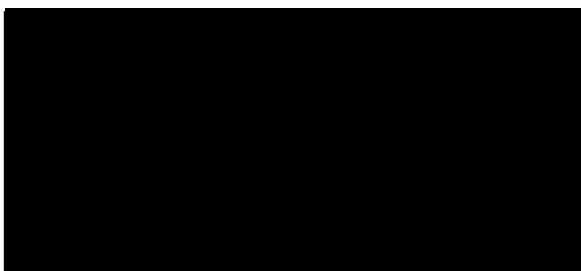
Action 5: Complete and return the Response Form found at the end of this letter

Please complete and return the Response Form to Philips promptly upon receipt and no later than 30 days from receipt. The Reply form can be found at the end of this letter.

5. Actions planned by Philips Emergency Care and Resuscitation to correct the problem

Philips will provide replacement M5072A Infant/Child SMART Pads Cartridges. Replacement pads cartridges may not be available immediately. If you need any further information or support concerning this issue, please contact your local Philips Representative. This action has been reported to the appropriate Regulatory Agencies. 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.

Philips regrets any inconvenience caused by this problem.





MEDICAL DEVICE RECALL RESPONSE FORM

Reference: 2021-CC-EC-011 : Philips M5072A Infant/Child SMART Pads Cartridge for use with the Philips HeartStart OnSite and HeartStart Home AEDs. Cartridge pads cover incorrectly includes a graphic for applying pads to an adult instead of to a child.

Instructions: Please complete and return this form to Philips promptly upon receipt and no later than 30 days from receipt. Completing this form confirms receipt of the Medical Device Removal Notification referenced above, understanding of the issue, and required actions.

Customer / Consignee / Facility Name: _____

Street Address: _____

City / State / Zip / Country: _____

Customer Actions as described more fully in the Medical Device Removal Notification:

- *If your pads cartridges were purchased from a distributor, you should contact that distributor to request replacement.*
- *Determine if Infant/Child SMART Pads Cartridges may remain in service until replaced*
- *Once the replacements have been received, use scissors to cut the 4 corners off the outer pouch of the old cartridges being replaced, and discard both the old cartridges and the old pouches*
- *Pass the notice to those who need to be aware of its contents*

We acknowledge receipt and understanding of the accompanying Medical Device Removal Notification and confirm that the information from this Notification has been properly distributed to all users that handle the M5072A Infant/Child SMART Pads for use with the Philips HeartStart OnSite and HeartStart Home AEDs.

Name of person acknowledging receipt and understanding:

Signature: _____

Printed Name: _____

Title: _____

Telephone Number: _____

Email Address: _____

Date (DD-MMM-YYYY): _____

Please choose one of the following options to return the form to Philips.

1. Email completed and signed form to **< Key Market to provide email address >**
2. Fax completed and signed form to **< Key Market to provide FAX number >**