PHILIPS

PH18022R/FSN86100191A

URGENT – Medical Device Recall

Product: Philips HeartStart M5072A Infant/Child SMART Pads Cartridge
Date: August 16, 2018

Dear HeartStart HS1/OnSite/Home AED Owner,

Our records show that you purchased one or more Philips HeartStart Infant/Child SMART Pads Cartridges (M5072A) between August 10, 2015 and August 1, 2018. Philips is issuing this recall due to a printing error on the foil pouch in which the cartridges are supplied. These cartridges fit the Philips HeartStart HS1, OnSite and Home Automated External Defibrillators (AEDs), but the AEDs themselves are not part of this action.

This recall does not involve the replacement of pad cartridges as the cartridges themselves meet all specifications and misprinted information is correctly stated more prominently elsewhere on the pouch and the cartridge itself, but is being undertaken to ensure that users are notified of the printing error.

Please review the following information with your program manager or other person responsible for managing your Philips AED. ***It is important to respond to this notification by completing the attached Customer Reply form.***

Your Philips HeartStart HS1, OnSite or Home AED is used to treat ventricular fibrillation, a common cause of sudden cardiac arrest, and certain ventricular tachycardias in patients of all ages. Philips markets two SMART Pads Cartridges for these AEDs, an Adult Cartridge and an Infant/Child Cartridge for patients under 25 kg (55 lb) or 8 years old or younger. The Infant/Child Cartridge is supplied in a single-unit box, and is sealed in a foil pouch. The cartridge is removed from the pouch and installed in the AED prior to use.

1. Reason for This Recall Notification:

One side of the foil pouch containing the HeartStart Infant/Child SMART Pads Cartridge (M5072A) contains text incorrectly stating “8+ Years.” Elsewhere, larger type “0-8” with “Pink Teddy Bear” icon, and a picture of a small child are correctly printed on both sides of the pouch. See Figures 1 and 2, which show the printing on both sides of the pouch. Importantly, the labeling on the cartridge itself and on the box in which the cartridge is supplied is accurate.

If users read the small printed text on the pouch, they could be confused about the age range for which the Infant/Child cartridge is intended. An Infant/Child pads cartridge should not be used on an adult because it delivers lower energy (50 J vs 150 J) than the Adult pads cartridge and may therefore not be effective on an adult. To date, however, Philips has not received any reports of any harm or confusion due to this printing error. Philips is conducting a voluntary recall of Infant/Child cartridges in the misprinted pouches.

If an Infant/Child cartridge has already been removed from its pouch and installed in an AED, it is not subject to this recall. Because the defibrillation pads are heat-sealed within the cartridge, they have the same expiration date whether or not they have been removed from the pouch. There is no safety issue with the Infant/Child cartridge, so if you need to use an Infant/Child cartridge subject to this recall, you may safely remove the cartridge from its foil pouch and install it in your AED for use in accordance with the AED Instructions for Use.

Philips Canada
281 Hillmount Road, Markham, Ontario, Canada, L6C 2S3,Tel 1-877-744-5633, Fax 1-800-418-4285, www.philips.com

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2. Actions To Be Taken By the Customer/User

Customers should provide the requested information in the attached reply form, and send the form back by fax to the Canada Regulatory Dept at 905-201-4323 or email at Regulatory.Canada@philips.com by September 16, 2018. No further action is required on your part.

Philips apologizes for any inconveniences this recall may cause. Your satisfaction with Philips products and with our response to this situation is very important to us.

Sincerely,

Melissa Lake
Sr. Manager, Quality & Regulatory Affairs
Philips Canada

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Figure 1:
Front side of pouch.
No printing issue.

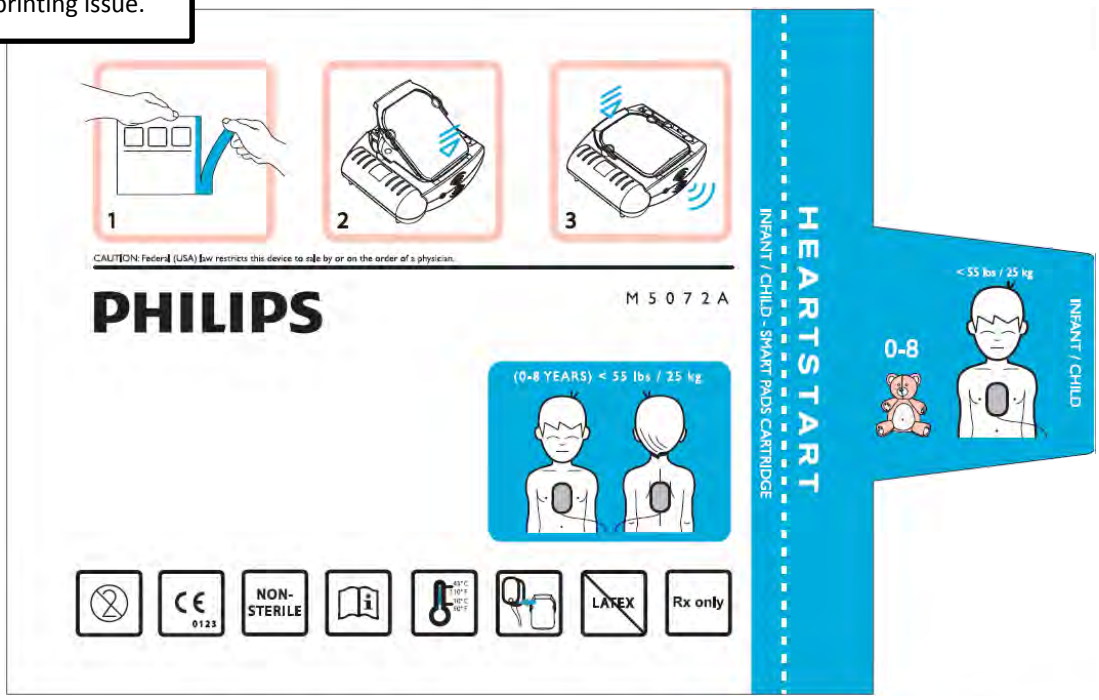

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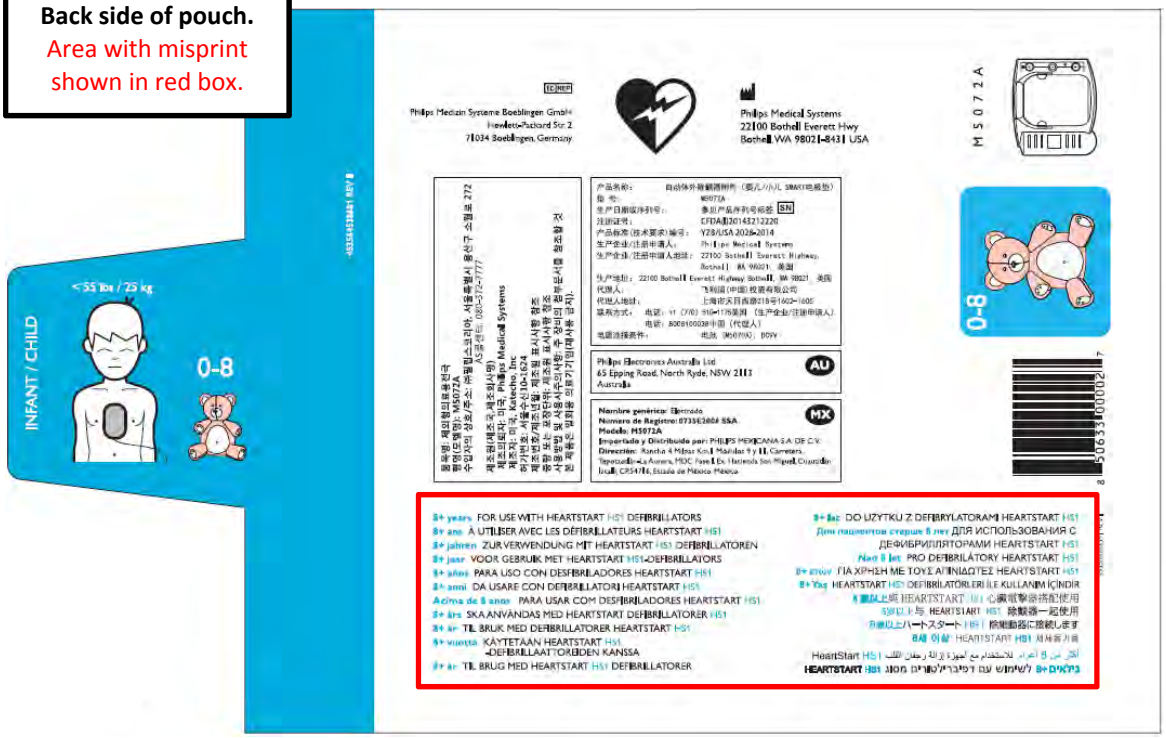
Figure 2:
Back side of pouch.
Area with misprint shown in red box.



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Facilities/Locations Responding For:

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MEDICAL DEVICE RECALL CONFIRMATION FORM

Product: *Philips HeartStart M5072A Infant/Child SMART Pads Cartridge*

Please complete this form and fax or email to:
Philips Healthcare
Attn: Canada Regulatory Dept
Fax: 905-201-4323
E-mail: Regulatory.Canada@philips.com

This will ***confirm receipt of the Medical Device Recall letter*** dated **August 16, 2018**. We have read, understand, and will follow the prescribed instructions.

Signed: _____ **Date:** _____

Name: _____
(Please Print or Type)

Title: _____
(Please Print or Type)

Telephone: _____ **Ext.** _____

E-mail: _____

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