

Heartstart Defibrillation Pads (2018-08-10)

Report a Concern
(<http://www.healthycanadians.gc.ca/report-signalez/index-eng.php>)

Starting date:	August 10, 2018
Posting date:	August 31, 2018
Type of communication:	Medical Device Recall
Subcategory:	Medical Device
Hazard classification:	Type II
Source of recall:	Health Canada
Issue:	Medical Devices
Audience:	General Public, Healthcare Professionals, Hospitals
Identification number:	RA-67628

- Reason
- Affected products

Affected products

Heartstart Defibrillation Pads

Reason

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. 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.

Affected products

Heartstart Defibrillation Pads

Lot or serial number

More than 1000 numbers, contact manufacturer.

Model or catalog number

M5072A

Companies

Manufacturer

Philips Medical Systems
 22100 Bothell Everett Highway
 Bothell
 98021
 UNITED STATES

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