PHILIPS

Philips Healthcare

2nd October 2018

Clarification on FCO 86100186A and FDA Recall Event 79343

Dear Sir/Madam,

Thank you for your interest in Philips HeartStart Automated External Defibrillators. At Philips, we take the quality and reliability of our products very seriously and would like to explain the recent FDA Recall Event 79343.

Philips has issued a recall/notification that updates the company's previous 2012 and 2013 notifications regarding the HeartStart FRx, HeartStart Home, and HeartStart HS1 Automated External Defibrillator (AED) devices manufactured between 2002 and 2012. This is related to the same FDA recall event 79343.

We would like to clarify that

1. Only defective units made between 2002 and 2012 are affected, units manufactured after 2012, ***especially new units*** are free from the recall.
2. ***Virtually all*** of these resistor-related failures were detected through the device's automatic self-testing, alerting the user by issuing audible chirps (please refer to user manual on triple chirps).
3. Philips is proactively ***recalling and replacing*** all affected units and even extending support to out of warranty units
4. The in-use reliability of these AEDs is ***greater than 99.9%*** when the AED determines a cardiac arrest victim is in need of shock therapy.

For more information, you can refer to our customer letter or contacting your authorized Philips representatives.

Yours sincerely,

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