

HeartStart MRx Defibrillator by Philips Electronics: Class I Recall - Defects in Gas Discharge Tubes May Cause Device Failure

[Posted 02/09/2018]

AUDIENCE: Emergency Medicine, Risk Manager, Nursing

ISSUE: Philips is recalling the HeartStart MRx Defibrillator due to a defect in the device's Gas Discharge Tube (GDT). The GDT has micro cracks which allows internal gasses to escape and causes the tubes to not function as expected. This also permits an electrical current surge to cross the device's designated resistors, which will damage the resistors and prevent the device from working while in automated external defibrillator (AED) mode.

As a result of this GDT defect, the HeartStart MRx may fail at any time, including when delivering repeated shocks in AED mode, or during the periodic Operational Check outlined in the device's Instructions for Use. If the device is used in AED mode after failure, the device will not deliver patient therapy. Continued use of the device in AED mode after failure may lead to serious patient injury or death.

However, the HeartStart MRx will continue to work in "Manual" mode after AED mode failure, though the electrocardiogram (EKG) displayed on the device will be noisy, which may make provider interpretation difficult.

- Model/Item Numbers: M3535A, M3536A
- Lot Numbers: See "**Full List of Affected Devices** (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=159291>)"
- Manufacturing Dates: September 22, 2016 to October 31, 2016
- Distribution Dates: September 26, 2016 to November 2, 2016

BACKGROUND: The HeartStart MRx Monitor/Defibrillator is intended for use by or on the order of a physician, and should only be administered by medical personnel trained in the operation of the device and qualified by training in basic life support, advanced cardiac support, or defibrillation.

RECOMMENDATION: On June 13, 2017, Philips Electronics sent affected customers a "Medical Device Correction Notification" informing them of the device's risks. In the letter, Philips directed customers to:

- Check all inventory for affected models of the HeartStart MRx Defibrillator.
- Contact Philips if the HeartStart MRx Defibrillator fails to function as intended. If the device fails to function, users:
 - Should switch the device to manual mode (if previously operating in AED mode).

- May still use the EKG display and waveforms from other monitoring leads to identify a shockable rhythm and deliver shock therapy while in manual mode.
- May notice the device indicates poor pad placement even though the pads are appropriately positioned.
- Will be contacted by Philips to repair the affected device(s) once replacement parts are available.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report (<http://www.fda.gov/MedWatch/report>)
- [Download form \(/Safety/MedWatch/HowToReport/DownloadForms/default.htm\)](/Safety/MedWatch/HowToReport/DownloadForms/default.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[02/09/2018 - [Recall Notice \(ssLINK/UCM596120\)](#) - FDA]

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