Phillips Healthcare recalls HeartStart MRx Monitor/Defibrillator due to electrical issues that may prevent the device from operating properly

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- HeartStart MRx Monitor/Defibrillator
- Model numbers: M3535A (M3535ATZ) M3536A (M3536ATZ), M3536M, M3536MC, M3536M2, M3536M4, M3536M5, M3536M6, M3536M7, M3536M8, M3536M9
- Manufacturing dates: February 11, 2004 to November 4, 2016
- Distribution dates: February 12, 2004 to November 4, 2016
- Devices Recalled in the U.S.: 47,362 units nationwide

Device Use

The HeartStart MRx Monitor/Defibrillator is used to pace people with a slow heart beat or to deliver lifesaving electrical shocks to people with sudden cardiac arrest, a medical condition in which the heart suddenly and unexpectedly stops beating. Electrodes are attached to the patient and then connected to the device to help it analyze a patient's heart rhythm. The electrodes deliver an electrical shock to restore a normal heart rhythm during sudden cardiac arrest, or to pace the heart at a normal rate when it slows down. The HeartStart MRx Monitor/Defibrillator is intended for use by medical professionals who are trained in CPR.

HeartStart MRx Monitor/Defibrillator

Reason for Recall
Phillips is recalling the HeartStart MRx Monitor/Defibrillator due to electrical and battery connection issues that may prevent the device from powering up, charging, and delivering an electrical shock therapy. The device may also unexpectedly stop pacing. A delay in delivering therapy could result in serious patient injury such as permanent organ damage, brain injury, or death.

Who May be Affected

- Health care providers and first responders using this defibrillator
- Patients who may need defibrillation or pacing to restore normal heart rhythm

What to Do
On February, 2017, Phillips Healthcare sent an "Urgent Medical Device Correction" notice to its customers. The cause of the issue can be easily verified by:

- Identifying affected devices in their possession using the model number information;
- Inspecting that the battery connector pins are clean, fully extended, and free of residue;
- Following the rest of the instructions enclosed in the notice, including:
- Reviewing the information with other staff trained in the use of the defibrillator;
- Filling out and return the 'Confirmation Response' included with the notice; and
- Contacting Phillips Healthcare for further information or support at 1-800-722-9377.

Contact Information
Health care professionals and consumers with questions related to this recall can contact Phillips Healthcare at 1-800-722-9377.

Date Recall Initiated
February 24, 2017

How do I report a problem?
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

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