

FDA warns of problems with Philips heart devices (Update)

December 3 2013

Federal health regulators are warning the public that certain cardiac defibrillators recalled by Philips Healthcare may fail to deliver a needed shock in an emergency.

Defibrillators are used by emergency responders and others to restore normal heart function in people suffering a heart attack. The FDA says an electrical problem with recalled Philips' HeartStart devices could cause them to fail to deliver a life-saving shock.

Philips recalled three models of its HeartStart devices in September 2012 due to an internal electrical malfunction. The recall affects about 700,000 defibrillators sold between 2005 and 2012. The recalled HeartStart FRx and HS1 (OnSite and Home) devices include an electrical part called a resistor that could fail when high voltage is applied, and that could prevent the device from delivering the necessary shock. If the resistor fails, the device will emit an audible triple-chirp alert.

Customers who have received the affected devices should contact Philips at 1-800-263-3342 to receive a replacement. Until a replacement is received, the agency does recommend keeping the recalled defibrillators in service because it considers the benefits of attempting to use the device in a cardiac arrest emergency greater than the risk of not attempting to use the defibrillator, said Steve Silverman, director of the Office of Compliance in the FDA's Center for Devices and Radiological Health, in a statement Tuesday.

In March the FDA proposed new requirements for companies that manufacture external defibrillators, which are found everywhere from hospitals to schools to airports. The proposed rules would require an FDA review of devices before their launch and are intended to curb years of recalls caused by design and manufacturing flaws.

Philips said Tuesday that it has not received any reports of patient harm due to this recall and has been working closely with regulatory authorities and with customers to address this issue.

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Citation: FDA warns of problems with Philips heart devices (Update) (2013, December 3) retrieved 10 April 2024 from

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