

A13962 - High Priority Medical Device Alert

Medical Device Ongoing Action

Updated: May 11, 2010

UMDNS Terms:

- Defibrillators, External [18499]
- Pacers, Counting, Cardiopulmonary Resuscitation [15771]

Suggested Distribution:

- Clinical/Biomedical Engineering
- Critical Care
- Emergency/Outpatient Services
- Nursing
- OR/Surgery
- EMS/Transport

Geographic Regions:

- Australia
- Canada
- China
- Germany
- Iceland
- India
- Libya
- the Netherlands
- Saudi Arabia
- Spain
- Switzerland
- U.K.
- United Arab Emirates
- U.S.

Philips—CPR Meters Used with HeartStart MRx Monitors/Defibrillators: May Provide Inaccurate CPR Compression Feedback

Product Identifier:

Cardiopulmonary Resuscitation (CPR) Meters used with the following HeartStart MRx Monitors/Defibrillators with Q-CPR options: (1) M3535A, (2) M3536A [[Capital Equipment](#)]
Units distributed between November 30, 2009, and February 3, 2010

Manufacturer: Philips Healthcare Cardiac & Monitoring Systems Div [453548], 3000 Minuteman Rd Mailstop 101, Andover, MA 01810, United States

Problem: In an April 2010 Urgent Medical Device Recall letter, Philips states that the force measurement sensor in the above CPR meters may lose sensitivity with use, potentially leading to inaccurate chest compression release feedback to the user. Philips also states that although the HeartStart MRx is intended only to be used by responders trained in CPR, it is possible that a user might rely solely on the feedback from the device rather than follow the user's training to fully release pressure, potentially reducing CPR effectiveness.

Manufacturer:	Designation:
Philips	Reference No. FSN 86100092

Action Needed: Verify that you have received the April 2010 Urgent Medical Device Recall letter from Philips. Identify any affected CPR meters in your inventory. For an example of affected product, refer to the illustration in the Urgent Medical Device Recall letter. Philips states that a field service engineer will contact your facility to arrange for product replacement with meters containing revised labeling and calibration software at no cost. Philips recommends that users of affected product keep a copy of the Urgent Medical Device Recall letter with the device's instructions for use.

For Further Information:			
Geographic Location:	Contact:	Telephone No.:	Web Site:
U.S.	Philips local representative	(800) 722-9377	Click here
Outside the U.S.	Philips local representative		

Source:

- Letter submitted by manufacturer.

Comment:

- This alert is a [living document](#) and may be updated when ECRI Institute receives additional information. In circumstances in which we determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert.
- This alert is based on information that [may not be independently verified](#) as to its accuracy, completeness, or causal relationship to the product or its supplier.
- The manufacturer has not confirmed the [geographic distribution](#) of affected product. ECRI Institute recommends that you check your inventory for this product regardless of where you are located.

Verification History: Alert Confirmed by Mfr./Dist.[5/7/2010 11:22:32 AM]; Fully verified[5/7/2010 11:22:35 AM]