Class I Medical Device Recall: Draeger Medical Inc., Infinity Acute Care System Monitoring Solution (M540)

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: October 18, 2011

Product: Infinity Acute Care System Monitoring Solution (M540), Catalog number MS25510

All serial numbers are affected by this recall.

This product was manufactured from March 1, 2011 through September 30, 2011 and distributed only to the Rush University Medical Center (Chicago, Illinois) from July 1, 2011 through September 30, 2011.

Use: This product is a networked solution system used to monitor a patient's vital signs and therapy, control alarms, review Web-based diagnostic images, and access patient records. The number of monitored vital signs can be increased or decreased based on the patient's needs.

Recalling Firm:
Draeger Medical, Inc.
3135 Quarry Rd
Telford, Pennsylvania 18969-1042

Manufacturer:
Draeger Medical GmbH
Moislinger Allee 53-55
23558 Lubeck, Germany

Reason for Recall: The weight-based drug dosage calculation may indicate incorrect recommended values, including a drug dosage up to ten times the indicated dosage. Additionally, there may be a 5-10 second delay between the electrocardiogram and blood pressure curves (waveforms) at the Infinity Central Station.

Public Contact:
Draeger Medical, Inc.
3135 Quarry Road
Telford, Pennsylvania 18969-1042
215-660-2349

FDA District: Philadelphia

FDA Comments:
On October 17, 2011, the company sent the Rush University Medical Center a letter stating that users should enter the patient's weight by way of the admin/demographics screen to ensure the drug dosage is calculated as intended.

Additionally, the company's letter states that users should follow the Instructions for Use of the Infinity Acute Care System Monitoring Solution. The Instructions for Use includes, "For primary monitoring and diagnosis of bedside patients, use the bedside monitor. Use the Infinity Central Station only for remote assessment of a patient's status."

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

SOURCE [2]

Source URL (retrieved on *05/05/2015 - 3:23am*):
http://www.mdtmag.com/news/2011/12/class-i-medical-device-recall-draeger-medical-inc-infinity-acute-care-system-monitoring-solution-m540

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm282461.htm