CareFusion AVEA Ventilator: Recall - Failure May Lead to Lack of Ventilation

U.S. Food & Drug Administration

ISSUE: FDA notified healthcare professionals of a class I recall of CareFusion AVEA Ventilators. The AVEA ventilator can develop a failure where the ventilator activates a false extended high peak alarm, opens the safety valve and stops ventilating. Without health care professional intervention, patients may suffer life-threatening injury or death.

BACKGROUND: The AVEA ventilator is intended for continuous breathing support for the care of neonatal through adult patients who require mechanical ventilation. These ventilators are used in hospitals and other health care institutions. The recalled ventilators were manufactured between March 1, 2009 and June 30, 2011.

RECOMMENDATION: CareFusion's Recall Support Center is contacting customers to arrange for onsite remediation of the affected devices.

Customers were instructed to follow these steps if any AVEA ventilator in their facility exhibits a sustained extended high peak alarm followed by the opening of the safety valve:

1. Remove the ventilator from service
2. Provide alternate ventilation
3. Contact CareFusion Technical Support at 1-800-231-2466 to report the issue

[12/23/2011 - Recall Notice [1] - FDA]

Related MedWatch Alert

[11/04/2011 [2]]

SOURCE [3]

Source URL (retrieved on *03/09/2014 - 5:43pm*):
http://www.mdtmag.com/news/2011/12/carefusion-avea-ventilator-recall-failure-may-lead-lack-ventilation?qt-video_of_the_day=0

Links:
[1] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm285038.htm
[2] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm278677.htm
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanM

edicalProducts/ucm285063.htm