Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Wednesday, February 10, 2016 4:12 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Oxylog 2000 Plus, 3000, and 3000 Plus Emergency Transport Ventilators by Dräger Medical: Class I Recall - System Error May Lead to a Halt in Ventilation Therapy

Dräger is recalling the Oxylog Emergency Transport Ventilators because an electrical issue may cause the device to stop working if the control knobs (adjustment potentiometers) are not regularly used. See the Recall Notice for affected devices and catalog numbers.

If the device operator does not intervene, the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death.

BACKGROUND: The Dräger Oxylog Emergency Transport Ventilators provide constant breathing support for adults and children. These ventilators are used in hospitals or during patient transport.

RECOMMENDATION: Dräger sent a letter to all customers with affected devices on December 21, 2015, informing them of this issue. The letter provides the following instructions to release the electrical contact resistance in the control knobs:

- Turn the device off
- Rotate all control knobs at least 10 times to the left and right stop (minimum and maximum value)

Customers with questions about this recall may call Drager at 1-800-543-5047 (press 1 at the prompt, then 2, then 32349).

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

[02/10/2016 - Recall Notice - FDA]