From: General Board of Pharmacy Subscriber List on behalf of Board of Pharmacy
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Medical Device Recall - G5 Ventilator by Hamilton
Date: Tuesday, November 17, 2015 10:41:19 AM

G5 Ventilator by Hamilton: Class I Recall - Ventilation and Alarm Failure

Includes V2.00 and V2.31

AUDIENCE: Risk Manager, Nursing, Pharmacy

ISSUE: The ventilator may stop working without sounding an alarm when the device operator presses the oxygen enrichment key to attach the ventilator mask to the patient (suctioning maneuver). This problem can occur during the following conditions:

- When pressing the oxygen enrichment key a second time within 50 milliseconds after the disconnection is detected, or,
- When disconnection is detected immediately before the oxygen enrichment period automatically ends, so that detection of disconnection and termination of O2-enrichment occur within 50 milliseconds of each other.

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.

See the Recall notice for a listing of affected catalog numbers and

Serial Numbers.

BACKGROUND: Recalled Device is the G5 Ventilator V2.00 and V2.31, distribution dates March 2007 to March 2014. The firm has received a total of 1 report of device malfunction. No injuries or deaths were reported.

RECOMMENDATIONS: For Device operators:

- After a suctioning maneuver is finished, the operator must verify that the ventilation continues.
- If the ventilation does not continue, use one of the following options to re-establish ventilation:
  - Pressing the "Manual Breath" key on the ventilator's front side.
  - Change of the ventilation mode.
  - Switch to the "Standby Mode" and return to the previously used ventilation mode.
- Keep this information with the G5 Operator's Manual.

For Distributors:

- Distribute the Medical Device Safety Alert immediately to all operators of G5 ventilators.
- Permanently disable the automated suctioning maneuver functionality on all G5 ventilators by using a software key provided by the manufacturer.
- Update the G5 Operator's Manual with the disabled automated suctioning functionality as soon as possible upon its availability.

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

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm471725.htm

Please immediately check your inventory, quarantine, discontinue distribution of the affected product, and contact your wholesaler for directions.