



Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: April 19, 2013
TO: All Local Health Departments
Attn: Chief Food Inspection Officer
FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program
SUBJECT: Covidien Recall

SUGGESTED

ACTION: Unclassified Recall; Certain Power Pac batteries for the Newport™ HT70 and HT70 Plus ventilators; Recommend notification of affected stores via phone, fax or e-mail.

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Power Pac batteries with Serial Numbers between 2096134110001 and 2292048120050 must be replaced. Affected batteries were distributed within and outside the United States. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-8475.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Covidien Issues Voluntary Recall of Power Pac Batteries for Newport™ HT70 and HT70 Plus Ventilators

Contact

Consumer:
(800) 451-3111, ext. 500 for U.S. customers
(714) 427-5811, ext. 500 for International customers

Media:

Rhonda Luniak
Vice President, Communications
Respiratory & Monitoring Solutions
(303) 305-2263
rhonda.luniak@covidien.com

Bruce Farmer
Vice President
Public Relations
(508) 452-4372
bruce.farmer@covidien.com

FOR IMMEDIATE RELEASE - April 18, 2013 – Covidien announced today that it notified customers on April 4, 2013, of a voluntary recall of certain Power Pac batteries for the Newport™ HT70 and HT70 Plus ventilators.

This action was in response to customer reports of Newport HT70 and HT70 Plus ventilators alarming and going to internal backup battery sooner than expected while the ventilator is being operated on Power Pac battery. These conditions have been reported in two types of situations. In the first situation, the screen on the Newport HT70 or HT70 Plus ventilator may indicate that the Power Pac battery is fully charged when it is not. In the second situation, the unit may switch to the backup battery as soon as it is removed from AC power.

In both situations, the ventilator's alarm sounds and the ventilator will continue to function on the internal backup battery for at least 30 minutes. There is a reasonable likelihood of serious adverse health consequences if these issues occur when the user is away from AC power (including during transport) and an alternate source of power cannot be made available before the charge on the internal battery is depleted. Therefore, although no adverse consequences have been reported in connection with these issues, users should ensure that alternate sources of power, including required power cords, are available nearby until this issue is resolved. As is common standard clinical practice, alternate means of supporting ventilation should always be available.

Power Pac batteries with **Serial Numbers between 2096134110001 and 2292048120050** must be replaced. Affected batteries were distributed within and outside the United States. Anyone who has Power Pac batteries for Newport HT70 and HT70 Plus ventilators, including distributors, healthcare providers and home users, is instructed to immediately check their Newport HT70 and HT70 Plus ventilators and related Power Pac batteries to determine the serial numbers. Customers whose Power Pac serial numbers fall within the above range should contact the Newport Medical Technical Support Department to request replacement batteries, which will be provided at no charge. Contact information for the department can be found below. If you purchased or obtained the Newport HT70 / HT70 Plus ventilator or Power Pac battery from a distributor or healthcare provider, please contact them directly for instructions on obtaining a replacement Power Pac battery.

Covidien alerted its customers of the recall by letter on April 4, 2013, and provided instructions for obtaining replacement Power Pac batteries. The U.S. Food and Drug Administration (FDA)

and other regulatory bodies have been notified of this recall.

To request the replacement Power Pac batteries, please contact the distributor or healthcare provider from whom you obtained the unit. If you obtained the affected unit directly from Newport Medical, please contact the Newport Medical Technical Support Department:

- (800) 451-3111, ext. 500 for U.S. customers
- (714) 427-5811, ext. 500 for international customers.

Adverse events experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by phone or fax.

- **Online:** www.fda.gov/medwatch/report.htm¹
- **Phone:** 1-800-FDA-1088
- **Fax:** 1-800-FDA-0178

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