Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: December 5, 2012

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: Bunnell Incorporated Recall

SUGGESTED ACTION: **Unclassified Recall; Life Pulse High-Frequency Ventilator Patient Circuits. The product has been found to have heater wire insulation that can melt, causing sparking and smoke close to the humidifier cartridge; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled product was distributed in the State of Indiana. The product was distributed in the USA to wholesalers and retailers. Detail store information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-351-7190.

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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.

Bunnell Incorporated Issues Nationwide Recall Notification of Life Pulse High-Frequency Ventilator Patient Circuits

Contact:
Consumer:
1-800-800-4358 ext. 6
plattdr@bunl.com

FOR IMMEDIATE RELEASE -December 5 , 2012 - On December 12, 2012 Bunnell Incorporated will voluntarily initiate a nationwide recall notification of Life Pulse High-Frequency Ventilator Patient Circuits. A complete list of Lot numbers affected by the recall is identified in the recall notice and on Bunnell's website, www.bunl.com[1].

The product has been found to have heater wire insulation that can melt, causing sparking and smoke close to the humidifier cartridge. There have been 12 reported failures out of 5,771 Patient Circuits distributed. There have been no reports of patient injury or death. However, out of an abundance of caution Bunnell wants clinicians to be aware of the potential that a Patient Circuit failure could result in patient injury or death.

Bunnell is working with the U.S. Food and Drug Administration to resolve this issue.

Bunnell will notify customers via certified mail and will post the recall notification and other important information at www.bunl.com[2].

- Customers with questions should contact Bunnell at 800-800-4358 ext. 6 between 8:00 AM and 4:00 PM (MST) Monday through Friday or via e-mail at plattdr@bunl.com.

Adverse reactions or quality problems experienced with the use of this product should be reported to Bunnell Inc. or the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Online at http://www.fda.gov/MedWatch/report.htm [3]
- Regular Mail: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[4]. Mail to address on the pre-addressed form
- Call FDA 1-800-FDA-0178

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