Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: January 2, 2014

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

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

SUBJECT: Vital Signs Devices, a GE Healthcare Company [Medical Device]

AFFECTED PRODUCT: **Disposable Multi Absorber Original**

SUMMARY: **Field Corrective Action; this device has a potential safety issue due to air leakage. The Multi Absorber Original may have a thin wall condition which may lead to small holes in the water (drain tube). This may result in a loss of anesthetic gases, ventilation and oxygenation.**

The affected product number is M1173310 containing lot numbers 12001 through 13031.

SUGGESTED ACTION: **For consumer inquiry only. Customer Service (domestic) at 800-345-2700 (option 2 followed by option 2) if you have any questions or concerns. You may also contact International Customer Service at +1-800-932-0760 (option 2). Hours of Operation: Monday to Friday from 8:00 am EST to 5:00 pm EST.**

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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.

Voluntary Field Corrective Action Initiated for Vital Signs Device's CO2 Multi Absorber Due to a Health Risk

Contact
Consumer:
Customer Service (domestic)
800-345-2700 (option 2 followed by option 2)

Media:
Annette Busateri
GE Healthcare
1-414-362-3605
annette.busateri@ge.com

FOR IMMEDIATE RELEASE – December 30, 2013 – Vital Signs Devices, a GE Healthcare Company, has initiated a voluntary field corrective action of the disposable Multi Absorber Original after becoming aware of a potential safety issue due to air leakage associated with the CO2 Multi Absorber. The Multi Absorber Original may have a thin wall condition which may lead to small holes in the water (drain tube). This may result in a loss of anesthetic gases, ventilation and oxygenation.

The voluntary corrective action was issued after receiving customer complaints and product returns; upon further inspection the returned absorbers were found to leak due to a hole in the drain tube. The affected product number is M1173310 containing lot numbers 12001 through 13031. Not affected are products with lot numbers 13032 and higher.

Vital Signs has notified all customers with affected units through an Urgent Medical Device Correction letter, which alerts users of the concern and safety instructions. Vital Signs is also following up with all customers and will replace all affected units at no cost to customers. You can access the original customer letter by visiting here. To date, no patient injuries have been reported with regards to this issue.

For additional information regarding this corrective action, please contact Customer Service (domestic) at 800-345-2700 (option 2 followed by option 2) if you have any questions or concerns. You may also contact International Customer Service at +1-800-932-0760 (option 2). Hours of Operation: Monday to Friday from 8:00 am EST to 5:00 pm EST.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or email), or
- Call FDA 1-800-FDA-1088.

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