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: August 2, 2011

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 Recall

SUGGESTED ACTION: **Class I Recall; Vital Signs Hygroscopic Condenser Humidifier (HCH)/Anesthesia Breathing Circuit; Information provided in case of consumer inquiry.**

From the information provided by FDA, the products being recalled may have been distributed in the State of Indiana. The Vital Signs Devices Passive Humidification Device (Hygroscopic Condenser Humidifier or "HCH") may have an occlusion that can prevent proper flow of the medical gases or oxygen, possibly resulting in insufficient oxygen delivered to the patient (hypoxia or hypoxemia). Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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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 Worldwide Field Corrective Action of the Vital Signs Hygroscopic Condenser Humidifier (HCH) / Anesthesia Breathing Circuit

Contact:
Consumer:
1-800-932-0760

Media:
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GE Healthcare
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FOR IMMEDIATE RELEASE - July 29, 2011 - In April 2011, Vital Signs Devices, a GE Healthcare Company, initiated a voluntary worldwide field correction of the Vital Signs Hygroscopic Condenser Humidifier (HCH)/Anesthesia Breathing Circuit. This device is sold under various part numbers - see list below.

The Vital Signs Devices Passive Humidification Device (Hygroscopic Condenser Humidifier or "HCH") may have an occlusion that can prevent proper flow of the medical gases or oxygen, possibly resulting in insufficient oxygen delivered to the patient (hypoxia or hypoxemia). This device may be included in Vital Signs anesthesia circuits or sold separately. The affected units were manufactured between January 2011 and April 2011.

GE Healthcare initiated the field correction in April 2011, and began notifying customers with affected units through an Urgent Medical Device Correction Letter and a follow-up call to confirm receipt of the letter. Through these efforts, all customers were informed of the issue and provided with safety instructions. Customers have been directed to **NOT** use the anesthesia circuits containing the Vital Signs Devices Passive Humidification Device (Hygroscopic Condenser Humidifier, or "HCH"), or the stand alone HCH device with the product item numbers and lot numbers listed below, isolate all affected product, contact Vital Signs Customer Service at 1-800-932-0760 to arrange for the return and replacement of product. All affected Hygroscopic Condenser Humidifier and Anesthesia Breathing Circuits with affected Hygroscopic Condenser Humidifiers are being replaced.

The U.S. Food and Drug Administration (FDA) has classified this recall as a Class I recall. FDA defines Class I recalls as "a situation in which there is a reasonable probability that the use of or exposure to the volatile product will cause serious adverse health consequences or death."

For additional information regarding this field correction, please contact Vital Signs Customer Service at 1-800-932-0760.Hours of Operation: 8:00 am EST to 5:00 pm EST, Monday through Friday.

Product	Lot #	Product	Lot #	Product	Lot #	Product	Lot #
5020AEHM	11087A	A5632X15	11070A	A5U5201XX1	11076B	ADU12914	11074A
	11098B		11095A		11083A		11074B
5701	5301C	A565192X	11094A		11088A		11075A
	5344E		11095A		11090A		11087A
	5348V		11095B		11101A		11090B
	5353K		11096A	A5W32014	11077A		11094B
	5366T		11097A		11090B		11098B
5701E	5346Z	A5U32020	11070A	A5Z51914	11069B		11101A
5702	5301D		11070B		11070A		11101B

A0F52014	11091A		11074B		11084A	ADU52914	11073A
	11098B		11077B		11097B		11074A
A4112X14	11070A		11081A	A8T52914	11082B		11075A
A415112A	11098B		11081B	A8U52015	11069A		11077A
A41X2X24	11092A		11083A		11075A	ADW32014	11073A
A4612X2C	11077A		11087A		11075B		11083A
	11081B		11087B		11083B		11087A
	11095B		11090A		11091A		11094A
	11098A		11092A		11101B		11098A
A4F12014	11075A		11094B	A8U5211X	11094A		11098B
	11084B		11097A	A8U52X14	11075A		11101A
	11090B		11098A		11077A	AFN52024	11074A
	11091A		11101A		11083A		11083B
	11094A		11102A		11090B		11084A
	11101B		11102B	A8W52914	11069A		11091B
	11091A	A5U32414	11077B		11083A		11096A
	11101A		11080A		11088A		11098B
A4F52X10	11075B		11082A	A9U5211X	11094A	AFN5291C	11069B
	11077B		11082B		11080A		11070B
	11082A		11090A		11090B		11083A
	11090A		11094A		11094A		11090A
A4F52X14	11074B		11094B	AD132X14	11073A		11098A
A4U12214	11080B		11097A		11074A	AFN52X1X	11070B
	11092A		11097B		11075A		11088A
	11097A		11098A		11088A	AFR5191X	11069B
	11098A	A5U32X14	11076B		11095B	AFR58014	11069B
	11101A		11083B		11096B		11076A

	11083A		11084A	AD152914	11074B		11098B
A4U52X1X	11087A		11070A		11070A		11101A
	11090A		11077A		11073A		11101B
	11077B		11080A		11074A		11073B
A5152914				AD632X11		AFR5XX20	
	11080A	A5U32X24	11083B		11081A		11101A
	11081A		11087B		11083A		11070A
A52X2314	11091A		11098B	ADA52014	11076A	AGN1QX1C	11070B
	11096B		11101A	ADG5291X	11101B		

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