Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

DATE: October 17, 2013

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

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

SUBJECT: Dräger Inc. [Medical Device]

AFFECTED PRODUCT(S): **Fabius Anesthesia Machines (99 Fabius GS Premium, 9 Fabius OS, 43 Fabius Tiro, and 1 Fabius Tiro D-M)**

SUMMARY: **Voluntary Recall; Dräger issued a statement regarding its voluntary recall on specific Fabius anesthesia machines. Dräger initiated this voluntary action in August of 2013 as a result of an internal investigation into devices that did not pass the high voltage test portion of the final production test. Affected devices were distributed nationally.**

SUGGESTED ACTION: **Recommend notification of affected parties via phone, fax, or e-mail. A recall notification, including affected serial numbers by model, has been sent to all current users of the recalled Fabius anesthesia machines, and is available on the Dräger website at www.draeger.com. Users are being contacted by a DrägerService representative to schedule the replacement of the affected power supply free of charge. Over half of the affected power supplies have already been replaced. For questions regarding the operation and/or servicing of affected Dräger anesthesia machines in the United States, call Dräger Service Technical Support at 1-800-543-5047 between the hours of 8AM to 8PM EST Monday through Friday, or contact Dräger by e-mail at info.usa@draeger.com.**

The US Food and Drug Administration has been advised of this action. Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA: http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm Online (form available to fax or mail), or call FDA 1-800-FDA-1088

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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.

Dräger issues an update on its voluntary recall of Fabius anesthesia machines
Potential failure of automatic ventilation accompanied by an alarm

Contact:
Consumer:
1-800-543-5047
info.usa@draeger.com
www.draeger.com

FOR IMMEDIATE RELEASE - October 7, 2013 - **Today Dräger issued a statement regarding its voluntary recall on specific Fabius anesthesia machines. Dräger initiated this voluntary action in August of 2013 as a result of an internal investigation into devices that did not pass the high voltage test portion of the final production test.**

This recall affected 99 Fabius GS Premium, 9 Fabius OS, 43 Fabius Tiro, and 1 Fabius Tiro D-M anesthesia machines manufactured between February 2013 and May 2013 and distributed in the United States between March 2013 and June 2013. Affected devices were distributed nationally.

Investigations determined that on some power supply units from a particular batch, the required minimum clearance between an electrical component and the unit housing was not maintained.

In extreme cases, the influence of mechanical forces – such as movement of the device, for example – may cause a failure of the automatic ventilation function of the device. If such a fault occurs, an audible and visual alarm is generated. Manual ventilation using the device is still possible and all other device functions remained unaffected.

To date, there have been no reported injuries or reported failures due to this issue.

If users of the Fabius anesthesia machines experience such a failure of the automatic ventilation function, they should switch over to the manual ventilation mode by pressing the "Man/Spont" key, confirm with the rotary knob, and start manual ventilation. Additional details concerning switching to manual ventilation in case of a fault are provided in the Instructions for Use in the Fault-Cause-Remedy and Ventilator Fail Safe sections. Hospitals are urged to notify their personnel accordingly.

A recall notification, including affected serial numbers by model, has been sent to all current users of the recalled Fabius anesthesia machines and is available on the Dräger website at www.draeger.com. Users are being contacted by a DrägerService representative to schedule the replacement of the affected power supply free of charge. Over half of the affected power supplies have already been replaced.

For questions regarding the operation and/or servicing of affected Dräger anesthesia machines in the United States, call DrägerService Technical Support at 1-800-543-5047 (press 4 at the prompt) between the hours of 8AM to 8PM EST Monday through Friday, or contact Dräger by e-mail at info.usa@draeger.com.

The US Food and Drug Administration has been advised of this action. 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[5] (form available to fax or email), or
- Call FDA 1-800-FDA-1088

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