Draeger issues an update on its voluntary recall of Fabius anesthesia machines

PR Newswire

Today Draeger issued a statement regarding its voluntary recall on specific Fabius anesthesia machines. Draeger 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 [1], including affected serial numbers by model, has been sent to all current users of the recalled Fabius anesthesia machines and is available on the Draeger website at www.draeger.com [2]. Users are being contacted by a DraegerService 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 Draeger anesthesia machines in the United States, call DraegerService 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 Draeger by email at info.usa@draeger.com [3].

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 (form available to fax or email), or
- Call FDA 1-800-FDA-1088

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