Class I Medical Device Recall: Accutron, Inc. Ultra PC% Cabinet Mount Flowmeters for Nitrous Oxide-Oxygen Sedation Systems

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: April 29, 2012

Product: Accutron, Inc. Ultra PC% Cabinet Mount Flowmeter

Model Numbers: Affected Model and Serial numbers are available on the FDA's website [1]

Manufacturing and Distribution Dates: The affected product was manufactured from November 2009 to April 2009 and distributed from November 26, 2008, to June 9, 2011.

Intended Use: The Ultra PC% flowmeter is used to control the flow of gases used in nitrous oxide-oxygen sedation systems. Nitrous oxide-oxygen sedation systems are used to sedate patients during certain dental procedures.

Recalling Firm:
Accutron, Inc.
1733 West Parkside Lane
Phoenix, Arizona 85027-1382

Reason for Recall: The flowmeter may continue to release nitrous oxide gas when the oxygen is turned off. When not mixed with oxygen, inhaling nitrous oxide can lead to temporary and permanent brain damage and death.

Public Contact: Consumers with questions may contact Accutron at 1-800-531-2221.

FDA District: Los Angeles

FDA Comments:
Consumers with the affected flowmeters should stop using and return the flowmeters to Accutron for a free replacement. The company notified distributors and customers of this recall by mail and is arranging for return and replacement of all recalled products.

Accutron voluntarily recalled the products after learning through two customer complaints that the flowmeter was flowing nitrous oxide gas without any oxygen gas flow. The company has reported that two complaints have been received for

this flowmeter defect. No injuries have been reported to date.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products at http://www.fda.gov/Safety/MedWatch/ HowToReport/default.htm [2], by regular mail, by telephone, or by FAX.

Additional Information:

- Company Press Release [3]

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http://www.mdtmag.com/news/2012/10/class-i-medical-device-recall-accutron-inc-ultra-pc-cabinet-mount-flowmeters-nitrous-oxide-oxygen-sedation-systems?qt-recent_content=0

Links:
[1] http://www.fda.gov/Safety/Recalls/ucm322808.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm
[3] http://www.fda.gov/Safety/Recalls/ucm322799.htm