

Accutron, Inc. Ultra PC% Cabinet Mount Flowmeters for Nitrous Oxide-Oxygen Sedation Systems: Class I Recall - Flowmeter May Continue To Release Nitrous Oxide Gas When The Oxygen Is Turned Off

AUDIENCE: Anesthesiology, Dentistry, Risk Manager

ISSUE: Accutron voluntarily recalled the product after learning through two customer complaints that the flowmeter was flowing nitrous oxide gas without any oxygen gas flow. When not mixed with oxygen, inhaling nitrous oxide can lead to temporary and permanent brain damage and death.

BACKGROUND: 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. The company has reported that two complaints have been received for this flowmeter defect, however, no injuries have been reported to date.

RECOMMENDATION: 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report Online: www.fda.gov/MedWatch/report.htm¹

[Download form](#)² or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[10/16/2012 - [Recall Notice](#)³ - FDA]