Nidek Medical Products Mark 5 Nuvo, Nuvo 8, and Nuvo Lite Oxygen Concentrators: Class I Recall - Risk of Fire, Loss of Supplemental Oxygen

U.S. Food & Drug Administration

AUDIENCE: Consumer

ISSUE: Capacitor failure may result in a fire hazard and loss of supplemental oxygen. These products may cause serious adverse health consequences, including death.

Affected products include serial numbers from 042-10000 through 102-09335. These oxygen concentrators were manufactured from January 1, 2004 to May 15, 2010.

BACKGROUND: Oxygen concentrators are used to supply supplemental oxygen to patients within a home setting.

RECOMMENDATION: The firm sent its distributors a Field Correction notice May 1, 2012, asking distributors to contact customers and/or patients who brought these products. Consumers should notify your equipment provider if you have an affected product in your home or place of business. According to the firm, patients may continue to use the device while waiting for a replacement for the corrected component.
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.htm [1]
- 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

[06/21/2012 - Recall Notice [3] - FDA]

SOURCE [4]

Source URL (retrieved on *04/25/2015 - 9:59pm*):

http://www.mdtmag.com/news/2012/06/nidek-medical-products-mark-5-nuvo-nuvo-8-and-nuvo-lite-oxygen-concentrators-class-i-recall-risk-fire-loss-supplemental-oxygen?qt-video_of_the_day=0&qt-most_popular=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm309420.htm
[4] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm309426.htm