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Class 2 Device Recall PURE OXYGEN CONCENTRATOR, CHAD Drive

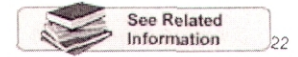


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Class 2 Device Recall PURE OXYGEN CONCENTRATOR, CHAD Drive



Date Initiated by Firm	October 09, 2017
Create Date	January 24, 2018
Recall Status¹	Open ³ , Classified
Recall Number	Z-0407-2018
Recall Event ID	<u>78883</u> ²³
510(K)Number	<u>K080391</u> ²⁴
Product Classification	Generator, oxygen, portable ²⁵ - Product Code CAW ²⁶
Product	PURE OXYGEN CONCENTRATOR, CHAD Drive, Models CH5000 and CH5000S
Code Information	UDI #(s): 00814470020013 (model CHSOOO) and 00814470020006 (model CHSOOOS); All serial numbers
Recalling Firm/ Manufacturer	Inovo, Inc 401 Leonard Blvd N Lehigh Acres FL 33971-6302
Manufacturer Reason for Recall	Post-market surveillance for Pure Stationary Oxygen Concentrators model CHSOOO and CHSOOOS demonstrate an aggregate complaint/service rate greater than 35% for low oxygen purity (output oxygen below the published specification).
FDA Determined Cause²	<i>Under Investigation by firm</i>
Action	The firm initiated their recall by letter on 10/09/2017. The letter stated the following: "Actions to be Taken: Based on our distribution records, your firm has received one or more Pure Stationary Oxygen Concentrators. We respectfully request that you take the following actions: 1. Contact all patients and customers that currently have Pure Stationary Oxygen Concentrators in their homes or facilities and inform them of this recall. Retrieve the oxygen concentrators from their homes or facilities. 2. Destroy all Pure Stationary Oxygen Concentrator(s) in accordance with the following steps: a. Assure that the unit is not plugged into an electrical outlet. b. Cut the power cord of each oxygen concentrator. c. Take a digital photo of each oxygen concentrator that depicts both the power cord and the serial number of the depicted unit. Note that the serial number is located on a label on the back of the unit. d. Dispose of the oxygen concentrator in accordance with local ordinances. e. Record the serial number of each unit that is destroyed, sign and date the enclosed Recall Return Response Card. 3. Email or fax the completed response form and photos documenting destruction to: Email: Inovo4209@stericycle.com Fax: 1-877-497-2559 4. Sales of the Pure Stationary Oxygen Concentrator have been discontinued. Pure Stationary Oxygen Concentrators which have been destroyed will be replaced with a DeVilbiss 525DS Oxygen Concentrator in order to minimize any interruption in patient's supplemental oxygen therapy. 5. Pure Concentrators that have been returned to Inovo for repair will not be returned and will be replaced with a DeVilbiss 525DS Oxygen Concentrator. Other Information: Should you require any additional information about this recall action, please call 1-888-679-5132, Monday-Friday 8am-Spm Eastern."
Quantity in Commerce	13,140 units

Distribution worldwide

Total Product Life Cycle [TPLC Device Report](#)²⁷

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.

Learn more about [medical device recalls](#)²⁸.

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

³ The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database [510\(K\)s with Product Code = CAW and Original Applicant = MEDICAL DEPOT](#)²⁹

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