State of New Hampshire Department of Safety

John J. Barthelmes, Commissioner

Division of Fire Standards and Training and Emergency Medical Services
Office of the EMS Bureau Chief
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CLINICAL BULLETIN

Bulletin #	Title			Date Issued
34	Medical Device Safety/Recall: Drager Emergency Transport Ventilator			February 18, 2016
Superseded	**Released By**	**Approved By**	**Source**	
	K. Doolan	N. Mercuri		

Dräger Medical Inc. Recalls Emergency Transport Ventilators Due to a System Error that may lead to a Halt in Ventilation Therapy

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Devices:

- Dräger Oxylog 2000 plus, Oxylog 3000, and Oxylog 3000 Plus Ventilator
- Catalog numbers: 5705080, 2M86300, 2M86965, 5704813, 5704831
- Distribution Dates: April 1, 2007 to December 12, 2015
- Devices Recalled in the U.S.: 117 distributed in Arkansas, Arizona, California, Connecticut, Florida, Georgia, Iowa, Idaho, Illinois, Indiana, Kansas, Kentucky, Louisiana, Maryland, Maine, Michigan, Minnesota, Missouri, Mississippi, Montana, North Carolina, Nebraska, New Hampshire, New Jersey, New York, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Vermont, Washington, Wisconsin, West Virginia and Wyoming

Device Use:
The Dräger Oxylog Emergency Transport Ventilators provide constant breathing support for adults and children. These ventilators are used in hospitals or during patient transport.

Reason for Recall:
Dräger is recalling the Oxylog Emergency Transport Ventilators because an electrical issue may cause the device to stop working if the control knobs (adjustment potentiometers) are not regularly used.
If the device operator does not intervene, the patient may not receive enough oxygen and could suffer serious adverse health consequences, including injury or death.

Who May be Affected:

- Health care providers using Dräger Oxylog 2000 plus, Oxylog 3000, and Oxylog 3000 Plus Ventilators
- All patient groups who may be given breathing support with these ventilators

What to Do:
Dräger sent a letter to all customers with affected devices on December 21, 2015, informing them of this issue.
The letter provides the following instructions to release the electrical contact resistance in the control knobs:

- Turn the device off
- Rotate all control knobs at least 10 times to the left and right stop (minimum and maximum value)

Contact Information:
Customers with questions about this recall may call Dräger at 1-800-543-5047 (press 1 at the prompt, then 2, then 32349).
Customers with questions regarding the operation and/or servicing of Dräger Oxylog ventilators may contact Dräger Service Technical Support at 1-800-543-5047 (press 4 at the prompt).
Date Recall Initiated: December 22, 2015
How do I report a problem?
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program either online, by regular mail or by FAX.