U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

B. Braun Medical Inc. Recalls Dialog+ Hemodialysis Systems Due Defective Conductivity Sensors

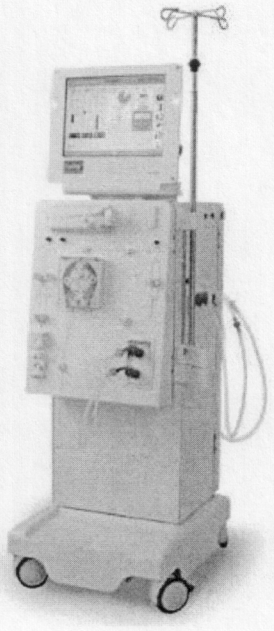
The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Dialog+ Hemodialysis Systems
- Model numbers: 710200L, 710200K, 710200S, 710200U, 710500L, 710500K
- Manufacturing dates: April 1, 2013 to July 3, 2013
- Distribution dates: June 25, 2013 and October 7, 2015
- Devices recalled in the U.S.: 1,033 units in Alabama, Arizona, California, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Iowa, Kansas, Kentucky, Maryland, Missouri, New Jersey, New Mexico, New York, North Dakota, Ohio, Oklahoma, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, Wisconsin, Puerto Rico, and the Virgin Islands

Device Use

The Dialog+ Hemodialysis System is a machine used in the treatment of chronic kidney disease for patients whose own kidneys are no longer healthy enough to filter their blood of wastes and excess fluid. These systems are used in hospitals, health centers, and in outpatient dialysis center settings.



Reason for Recall

B. Braun Medical Inc. is recalling the Dialog+ Hemodialysis System

Dialog+ Hemodialysis System

due to cracks in conductivity sensors that may allow air to enter into the solution (dialysis fluid or dialysate) used to help filter waste and other excess fluids in the blood. The presence of air in dialysis fluid may lead to improper blood filtration, causing serious adverse health consequences, including death.

Who May be Affected

- Patients who are undergoing hemodialysis therapy using this device
- Health care professionals using this device for conduct hemodialysis therapy

What to do

On April 1, 2016, B. Braun Inc. sent an "Urgent Medical Device Correction" letter to affected customers asking them to:

- Inform all other potential users about the issue
- Identify affected units in their inventory
- Have a qualified service technician run a pressure test using the instructions attached with the letter
- Tag the machine and continue its use if no drop in pressure was identified
- Contact B. Braun Inc. customer service at 1-800-848-2066 for part replacement if air leakage was identified
- Return a "Medical Device Correction Acknowledgment" form by email to **PA_QualityAssurance.BBMUS_Service@bbraun.com** or by fax to 610-849-1197

Date Recall Initiated:

April 1, 2016

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 to 1-800-FDA-0178.

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