

State of North Carolina  
Department of Environment,  
Health and Natural Resources

Division of Radiation Protection

James B. Hunt, Jr., Governor  
Jonathan B. Howes, Secretary  
Dayne H. Brown, Director



MEMORANDUM

TO: All Accelerator Licensees

FROM: Wendy B. Tingle, Health Physicist *WBT*  
Radioactive Materials Section

SUBJECT: Siemens Accelerator Recall

DATE: January 25, 1995

Siemens Medical Systems, Inc. has issued a recall on the following linear accelerators:

- 1) Digital Mevatron Linear Accelerators with Therapy Data Management System (TDMS);
- 2) Conventional Mevatron Linear Accelerator with TVS System

This recall is for ALL serial numbers and ALL models having TDMS Digital Model TVS for conventional models. The recall number to reference is Z-236/237-5. Should you have questions about this recall, please contact Mr. Brian Carter at 1-800-876-9086 ext. 352 or FAX: (610) 497-0255.

This is an informational bulletin and no response to our office is required.

rbd

January 27, 1994. Firm-initiated recall complete.  
 DISTRIBUTION Nationwide.  
 QUANTITY 3.5 million were distributed.  
 REASON Product may exhibit air leakage at the female luer lock connection to the male luer of the hemodialysis machine under normal operating conditions.

PRODUCT DiaPure Dissolution System, used in hemodialysis treatment. Recall #Z-235-5.  
 MANUFACTURER Fresenius USA, Inc., Walnut Creek, California.  
 RECALLED BY Manufacturer, by retrofitting with new valves between June 20, 1994 and September 15, 1994. Firm-initiated field correction complete.  
 DISTRIBUTION California, Louisiana, Maryland, New Jersey, Oklahoma.  
 QUANTITY 66 units.  
 REASON Product does not have an approved application for pre-market approval or an investigational device exemption in effect. The device is further adulterated in that the pinch valve may fail causing the device to report "bag not filling."

PRODUCT Siemens Linear Accelerators: (a) Digital Mevatron Linear Accelerators with Therapy Data Management System (TDMS); (b) Conventional Mevatron Linear Accelerator with TVS System. Recall #Z-236/237-5.  
 CODE All serial numbers. All models having TDMS Distal Model TVS for conventional models.  
 MANUFACTURER Siemens Medical Systems, Inc., Oncology Care Systems, (1-800-241-7660) Concord, California. 94524  
 RECALLED BY Manufacturer, by letter September 15, 1994. Firm-initiated field correction ongoing.  
 DISTRIBUTION Nationwide and international.  
 QUANTITY 110 units were distributed.  
 REASON The TDMS software and hardware versions 3.3 and 3.5 were not adequately validated before release.

PRODUCT Aequitron Ventilators: (a) Model LP6 V Volume Ventilators; (b) LP10 Volume Ventilators; (d) Drager Model EV 801 Electronic Ventilators, used to provide continuous respiratory support for patients with respiratory insufficiencies: Recall #Z-264/266-5.  
 CODE Serial numbers: (a) 131104, 131106-131111, 131113, 131115-131126, 131128, 131131, 131134-131141, 131143, 131154, 131155, 131160-131169, 131171-131174, 131179-131195, 131197, 131198, 131219, 131223-131236, and 131242-131245. (b) 102344, 102348, 102355, 102356, 102359, 102360, 102361, 102364, 102365, 102367-102377, 102381, 102390, 102393-102407, 102409, 102410, 102414, 102417-102439, 102442-102445, 102448-102469, 102471-102481, 102503-102506, 102508-102527, 102529-102531, 102534-102539, 102543, 102547-102550, 102609-102651, 102653-102663, 102702-102711, 102714, 102716, 102718, 102719, 102740, and 102743. (c) ARHC-0001 through ARHC-0041, ARHC-0044 through ARHC-0060, ARHE-0001 through ARHE-0020, ARHE-0042 through