



FDA Class 2 Recall Communication

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Recall for Over 205,000 Fresenius 2008 Dialysis Machines due to UF Rate Errors

Reason for Recall:

When the UF Rate, Goal or Time is adjusted using the up and down arrow keys, and the change is cancelled by using the esc key, the cancelled UF Rate is actually being executed rather than rate displayed on the machine.

Product Description	<i>Fresenius 2008T Series Hemodialysis System</i>	<i>Fresenius 2008K Series: Hemodialysis System</i>	<i>Fresenius 2008K2 Series: Hemodialysis System</i>	<i>Fresenius 2008K@home Series: Hemodialysis System</i>
Product Quantity	65361 units (US) 249 units (OUS)	78481 (US) 2734 units (OUS)	60,151 units (US) 1773 (OUS)	1400 units (US) 556 units (OUS)
Recall Number	Z-1026-2017	Z-1027-2017	Z-1028-2017	Z-1029-2017
Code Information	All serial numbers	All serial numbers	All serial numbers	All serial numbers

Distribution Pattern

- Nationwide
- Foreign: Canada, Mexico, Jamaica, Germany, Guam

For full recall information:

- [Fresenius 2008T Series Hemodialysis System](#) - 65,361 units (US) 249 units (OUS)
- [Fresenius 2008K Series: Hemodialysis System](#) - 78,481 units (US) 2734 units (OUS)
- [Fresenius 2008K2 Series: Hemodialysis System](#) - 60,151 units (US) 1773 units (OUS)
- [Fresenius 2008K@home Series: Hemodialysis System](#) - 1400 units (US) 556 units (OUS)