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Fresenius Kabi Initiates Voluntary U.S. Recall of Volumat MC Agilia™ Infusion System and Vigilant Drug'Lib™ due to Software Anomalies, End of Infusion Alarm

FOR IMMEDIATE RELEASE

LAKE ZURICH, Ill., June 28, 2019 – Fresenius Kabi USA is voluntarily recalling the Volumat MC Agilia Volumetric Infusion Pump and Vigilant Drug'Lib to address software anomalies and to upgrade a "Keep Vein Open (KVO), End of Infusion" alarm.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

The affected units are the Volumat MC Agilia™ Volumetric Infusion Pump with software versions 1.7 and 1.9a (**Product Code: Z021135**) and the Vigilant Drug'Lib™ versions 1.0 and 1.1 (**Product Code: Z073476**).

Fresenius Kabi will upgrade the software applications and alarm affected by this recall on site at customer locations or at the company's service center. Fresenius Kabi USA is notifying its customers by letter which includes directions to immediately implement corrective measures to help prevent patient harm and will schedule training with each customer on these instructions. The company is also issuing this notification out of an abundance of caution. Customers will be contacted by a Fresenius Kabi USA representative or distributor to schedule a service appointment for the upgrades and also to schedule training on the supplemental user instructions.

The Volumat MC Agilia Volumetric Infusion Pump is a small, lightweight, portable device designed for use in multiple care settings. The Vigilant Drug'Lib is a dose-error reduction software application used to build site-specific drug libraries and pump configurations.

The recall is designed to solve four software anomalies that have the potential to cause over- or under-infusion of fluids or medications, which in rare circumstance, could lead to serious patient injury or death.

To date, Fresenius Kabi has not received any reports of adverse events related to these software anomalies. The company has received 14 related complaints.

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As part of the recall, Fresenius Kabi also will upgrade the pumps' "Keep Vein Open (KVO), End of Infusion" alarm to a high-priority alarm from a low-priority alarm. Fresenius Kabi has determined that a high-priority alarm is better suited to inform clinicians that the Volume to Be Infused (VTBI) is complete. If infusion must continue, the alarm can help prevent serious injury or death.

If enabled, the "Keep Vein Open (KVO), End of Infusion" alarm informs users that the infusion has transitioned to a user-defined "Keep Vein Open (KVO)" rate, which is not intended to be a therapeutic rate.

There have been no injuries or deaths reported in the U.S. related to this alarm. There has been one death reported outside of the U.S. related to a norepinephrine infusion when a clinician did not adjust the "Volume To Be Infused" after changing the drug bag infusion and also did not notice the pump's alarms. No other injuries have been reported related to the "Keep Vein Open (KVO), End of Infusion" alarm.

If customers have not heard from Fresenius Kabi USA within three business days of receiving their recall notification, please contact Fresenius Kabi USA at 1-800-333-6925, prompt 3.

U.S. customers with questions regarding this recall can contact Fresenius Kabi USA at 1-800-333-6925, prompt 3, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Standard Time.

Adverse reactions or quality problems experienced with the use of this product may be reported to Fresenius Kabi USA at 800-333-6925, prompt 3 or by email at mdpmqa.usa@fresenius-kabi.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

About Fresenius Kabi

Fresenius Kabi (www.fresenius-kabi.com/us) is a global health care company that specializes in medicines and technologies for infusion, transfusion and clinical nutrition. The company's products and services are used to help care for critically and chronically ill patients. The company's U.S. headquarters is in Lake Zurich, Illinois. The company's global headquarters is in Bad Homburg, Germany. For more information about Fresenius Kabi worldwide, please visit www.fresenius-kabi.com.

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