URGENT MEDICAL DEVICE RECALL

June 20, 2025

Dear Director of Biomedical Engineering or Clinical Engineering:

Baxter Healthcare Corporation has identified that certain **Spectrum** infusion pumps may have an incorrect version of software. A software version intended for **Spectrum V8** pumps may have been installed on the **Spectrum V6** pumps listed below, and a software version intended for **Spectrum V6** pumps may have been installed on the **Spectrum V8** pumps listed below.

Follow the instructions in the 'Actions to be Taken by Customers' section of this letter to confirm if the potentially impacted pumps at your facility have an incorrect software version installed. Baxter will be performing a software update for any pumps with the incorrect version of software.

Affected Product

Product Code	Product Description	Serial Numbers	UDI-DI Number
35700BAX	**Sigma Spectrum** Infusion System (V6 Platform)	Refer to Attachment A	00085412091570
35700BAX2	**Sigma Spectrum** Infusion System (V8 Platform)		00085412498683

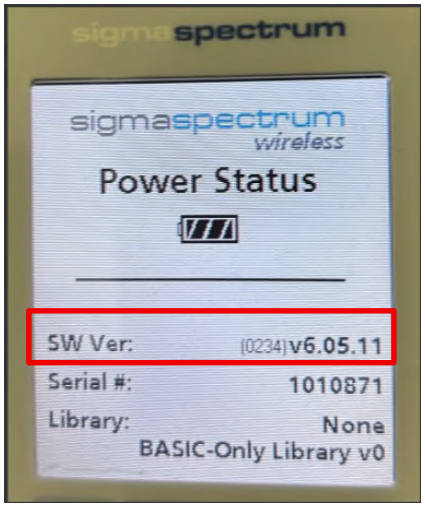
A full list of the affected serial numbers is provided in the enclosed Attachment A. For a list of serial numbers specific to your account, please refer to the enclosed Baxter Reply Instruction Sheet.

Hazard Involved

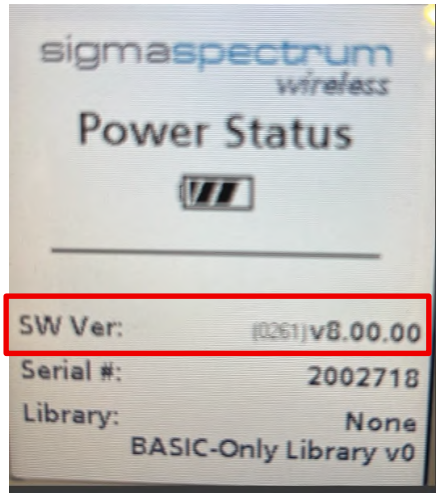
Spectrum software is designed for the pumping mechanism setup specific to each pump platform. The V8 software installed in a **Spectrum V6** pump, or vice versa, may cause an inaccurate flow rate of overinfusion or underinfusion, especially over a long run time. Additionally, the V6 and V8 designs include many differences in the clinical workflow and user interface. The appearance of the menus and the requested inputs from the pump are different between the two platforms. If a user who was trained and experienced on a V6 pump was presented with a V6 pump with V8 software, or vice versa, they may experience confusion and delay during use, or may accidentally mis-program the infusion. This could result in a delay or interruption of therapy, underinfusion, or overinfusion. The hazardous situations described above may lead to serious adverse health consequences, especially in high-risk populations. To date, there have been no reports of serious injury associated with this issue.

Actions to be Taken by Customers

1. Immediately locate **Spectrum** pumps with the affected serial numbers and remove them from service. The product code and serial number can be found on the bottom of the infusion pump.
2. Check and record the software version installed on the pump. The software on a V6 pump should begin with the number 6 and the software on a V8 pump should begin with the number 8. The software version is located on the startup screen upon powering up the pump as pictured on the next page.



Spectrum V6 *infusion pump startup screen*



Spectrum V8 *infusion pump startup screen*

Additionally, the software version is indicated in the pump menu which can be accessed by following the steps.

- For V6: From the Pump Information screen, press the 'sw info' soft key to display the software version screen.
- For V8: From the Select Care Area screen, press the 'options menu' soft key. Select 'User Options' and press OK. Select 'View Information' and press OK. Select 'Pump Information' and press OK to display the Pump Info screen.

3. Contact Baxter to confirm the software version on the affected pumps and to schedule service if required. Baxter Global Technical Services can be reached at 800-843-7867 (select option 1, then option 2), Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.
4. If you received this communication directly from Baxter, acknowledge receipt of this notification by following the instructions on the enclosed reply instruction sheet, even if you have no remaining inventory. Acknowledging receipt will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
5. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
6. Please forward a copy of this communication to the Chief Medical Officer, Medical Director, Director of Nursing, Director of Pharmacy, Facility Risk Manager, Director of Purchasing/Central Supply, and any other departments within your institution who use the affected product.
7. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Recall in accordance with your customary procedures and check the associated box on the customer portal.

Further Information and Support

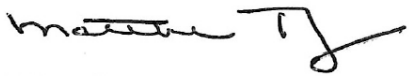
For general questions regarding this communication, or if you experience quality problems, please contact your Baxter sales representative, or Baxter Global Technical Services at 800-843-7867 (select option 1, then option 2) Monday through Friday, between 7:00 am and 7:00 pm Eastern Time.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse events experienced with the use of these products may be reported using one of the following options:

- Contacting Baxter Product Surveillance at the Baxter product feedback portal at https://productfeedback.baxter.com, or emailing Baxter at corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
    - **Online:** By completing and submitting the report at www.accessdata.fda.gov/scripts/medwatch
    - **Regular mail or Fax:** Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

We apologize for any inconvenience this may cause you and your staff.

Sincerely,



Matthew Tanger
Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Reply Instruction Sheet
Attachment A: Full List of Affected Serial Numbers

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Product Code 35700BAX - **Sigma Spectrum** Infusion System (V6 Platform)

765100	772744	789742	841197	867753	920606	1024015
770164	788724	793079	842498	918342	962810	1027523

Product Code 35700BAX2 - **Sigma Spectrum** Infusion System (V8 Platform)

2006307	2052091	2093765	2095360	2104302	2119236	2141815
2025925	2067699	2094483	2095541	2105238	2119436	2143406
2034297	2074097	2094580	2096351	2105769	2135482	2143684
2051591	2090658	2095202	2096856	2118940	2137976	2156201