

Baxter Healthcare Recalls Baxter SIGMA Spectrum Infusion Pumps with Master Drug Library (Versions 6 and 8) and Spectrum IQ Infusion Systems with Dose IQ Safety Software Due to Unplanned Shutdown Issues

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 Products

- Baxter SIGMA Spectrum Infusion Pump with Master Drug Library (Version 6)
 - Product Code: 35700ABB and 35700BAX
- Baxter SIGMA Spectrum Infusion Pump with Master Drug Library (Version 8)
 - Product Code: 35700BAX2
- Spectrum IQ Infusion System with Dose IQ Safety Software
 - Product Code: 357009
- Manufacturing Dates:
 - Product code - 35700BAX and 35700ABB (Version 6): 01/01/2005 - 05/13/2020
 - Product code - 35700BAX2 (Version 8): 07/01/2014-Present
 - Product code - 3570009- (Version 9): 04/12/2018-Present
- Distribution Dates: July 1, 2008 to July 14, 2020
- Devices Recalled in the U.S.: 553,443
- Date Initiated by Firm: April 1, 2020

Device Use

The Baxter Healthcare Sigma Spectrum Infusion pumps with Master Drug Library (V6, V8) and the Baxter Spectrum IQ Infusion with Dose IQ Safety Software (V9) are software-controlled infusion pumps that deliver controlled amounts of fluids such as pharmaceutical drugs, blood, and blood products and other required patient therapies. The fluids are provided through an infusion tubing set into a patient's vein or through other cleared routes of administration. The devices are used in hospitals and other healthcare facilities.

Reason for Recall

Baxter Healthcare is recalling the Baxter Healthcare Sigma Spectrum Infusion Pumps with Master Drug Library (V6, V8) and the Baxter Spectrum IQ Infusion Systems with Dose IQ Safety Software (V9) because improper cleaning of the devices may lead to residue build-up or corrosion on the device. If the device is running only on battery power, this may lead to an unplanned shutdown without alarming or alerting the user. This may cause an infusion delay or an interruption in treatment.

Use of the affected product may cause serious adverse events, including death.




There have been 17,493 complaints about this device issue and 16 reports of serious injuries. There have been no reported deaths.

Who May be Affected

- Health care providers using the affected Baxter Healthcare systems
- Patients who receive fluids or medications delivered by the affected Baxter Healthcare systems

What to Do

On August 28, 2020, Baxter Healthcare sent an Urgent Device Correction to all affected customers. They stated this was a follow-up communication to the Safety Alert Baxter previously issued on April 1, 2020. The letter provided the following instructions for customers:



- Follow the instructions for cleaning provided in the Operator's Manual
 - See an electronic copy of the Operator's Manual at <https://service.baxter.com> (<https://service.baxter.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
 - See a full list of approved cleaning agents at www.spectrumIQ.com/resources.html (<http://www.spectrumIQ.com/resources.html>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
- Inspect all pumps at the facility to check the electrical pins on the pump rear case and the battery electrical contacts for residue buildup or corrosion.
 - If corrosion or residue buildup is found, contact Baxter to service the device.
- Access the updated Instructions for Use online at the Baxter Global Technical E-Service Center at <https://service.baxter.com> (<https://service.baxter.com>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) when Baxter communicates they are available
- Clinicians should ensure backup devices are readily available when infusing critical medications where interruptions could cause serious injury or death

- Maintain the battery properly by plugging the pumps into AC power when possible to prevent battery depletion
- Complete the customer reply form enclosed with the device and return it to Baxter by emailing the address indicated in the Urgent Device Correction letter, if the product was purchased directly from Baxter
 - If the product was purchased from a distributor, return the customer reply form provided by the supplier according to their instructions
- Forward a copy of the Urgent Device Correction to any facilities or end users who may have the affected product

Contact Information

Consumers with questions about this recall may contact their Baxter sales representative or Baxter Technical Assistance at 800-356-3454 (choose option 1), Monday through Friday between 7:00 a.m. and 7:00 p.m. Eastern Time or by emailing corporate_product_complaints_round_lake@baxter.com (mailto:corporate_product_complaints_round_lake@baxter.com).

Additional Resources

- Medical Device Recall Database Entry (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=182588>)
- Urgent Device Correction Customer Letter (<https://www.baxter.com/sites/g/files/ebysai746/files/2020-10/FA-2020-012%20Urgent%20Device%20Correction%20dated%20August%2028%202020.pdf>) 
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
- Baxter Press Release (<https://www.baxter.com/baxter-newsroom/baxter-issues-urgent-device-correction-reinforce-important-safety-information>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.