Baxter

PRODUCT

RECALL

Urgent Field Safety Notice

Control-A-Flo Solution Administration Set with Needle Y-site
FA-2024-076
Manufacturer: Baxter Healthcare SA (BHSA) (Single Registration Number: CH-MF-000026124)
Type of Action: Recall

January, 2025

Dear Sir/Madam,

Baxter Healthcare Corporation is issuing an Urgent Medical Device Recall for the **Control-A-Flo** solution administration sets listed below due to customer reports of separation at the junction between the drip chamber and tubing. The affected lot numbers were distributed from 14/9/2023 to 25/4/2024.

Affected Product

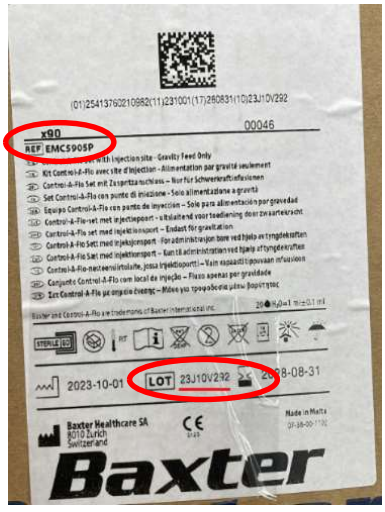
Product Code	Product Description	Lot Number	Expiration Date
EMC5905P	**Control-A-Flo** Solution Administration Set with Needle Y-site	23H21V586	30-Jun-2028
		23H23V587	30-Jun-2028
		23J10V292	31-Aug-2028

Hazard Involved

Separation of the administration set between the drip chamber and tubing may lead to delay, interruption or insufficient therapy, and exposure to air or microbial contamination. Depending on the type of patient access (peripheral vs. central), as well as numerous patient- and therapy-related factors, this may lead to serious or critical adverse health consequences, such as blood loss, air embolism, or bloodstream infection. To date, Baxter has received one report of serious injury related to this issue.

Actions to be Taken by Customers

1. Locate and remove all affected products from your facility. The product code and lot number can be found on the individual product package and shipping carton (pictured below).



2. Contact Baxter Healthcare Center for Service to arrange for return and credit. The Center for Service can be reached. Please have your ship-to account number ready when calling.
3. Complete the enclosed customer reply form and return it to Baxter by either faxing it or scanning and e-mailing or sending it by post, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
4. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.
5. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. 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 Correction in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Baxter.

The local Ministry of Health (MOH) has been notified of this action.

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

Sincerely,

Baxter Healthcare Corporation

Attachment 1: Customer Reply Form

Baxter

Quarantine product / Do not sell or distribute

(Customer communication)

CUSTOMER REPLY FORM related to Product Recall letter dated January 2025

PRODUCT NAME: Control-A-Flo Solution Administration Set with Needle Y-site

Product code: EMC5905P

Batch Number: 23H21V586, 23H23V587 and 23J10V292

Please complete and return one copy of this form per facility either by fax or by e-mail as confirmation that you have received this notification. A fax cover sheet is not required.

Facility Name and Address:	
Reply Confirmation Completed By *(Please Print)*:	
Title *(Please print)*:	
Email and/or Telephone Number (including Area Code):	

Please check boxes as appropriate:

☐ We do not have any of the affected lots in our inventory.

☐ We do have the affected lots in our inventory and products have been quarantined.

Please list the quantity of the specific lot(s) to be returned below*:

Product Code	Lot number	Quantity in units to be returned

*You may attach an additional sheet if required.

☐ I would like Baxter to contact my patients and will provide support as needed

☐ I will contact my home patients directly and will provide information to Baxter as it becomes available.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date: REQUIRED FIELD	_____