

## Urgent Field Safety Notice

### Patient Monitoring Devices and Wall Systems; Manual Blood Pressure Gauges and Cuffs

FA-2025-007

Manufacturer: Welch Allyn, Inc (Single Registration Number: US-MF-000013394)

Type of Action: Recall

April 2025

Dear Sir/Madam

Baxter Healthcare Corporation is issuing a voluntary product recall for reusable blood pressure cuffs because the product is labeled “not made with natural rubber latex,” however, there is a latex-containing rubber band located around the product instructions for use (IFU). Baxter is requesting the return of **unopened** affected blood pressure cuffs in their packaging.

- Please note that some of the products listed below are patient monitoring devices and wall systems that contain a blood pressure cuff kit. Baxter is requesting the return of **unopened blood pressure cuff kits** included with patient monitoring devices, and the IFU and rubber band, *not the entire device*.
- Regarding manual blood pressure gauges and stand-alone cuffs, Baxter is requesting the return of the entire device.
- This recall does not apply to reusable blood pressure cuffs that are currently in use.

### Affected Product

Product Category	Product Description	UDI- DI Number	Product Code
Patient Monitoring Devices and Wall Systems	<b>Welch Allyn Connex</b> Integrated Wall System	See Attachment A	See Attachment A
	<b>Welch Allyn Connex</b> Spot Monitor		
	<b>Welch Allyn Connex</b> Vital Signs Monitor		
	<b>Welch Allyn Spot</b> Vital Signs 4400 Device		
	<b>Welch Allyn Green Series 777</b> Wall System		
Manual Blood Pressure Gauges and Cuffs	<b>Welch Allyn DuraShock</b> Aneroid Gauge Sets with a Reusable Blood Pressure Cuff		
	<b>Welch Allyn 2 Piece</b> Reusable Blood Pressure Cuff Kits		

### Hazard Involved

If the person opening the package has an allergy to latex, they may experience symptoms that include rash, itching, swelling, sneezing, etc. Certain people with a latex allergy are at remote risk for a critical, systemic reaction such as anaphylaxis. Additionally, exposure of a patient or caregiver to residual latex protein, transferred to the cuff from the rubber band, cannot be ruled out. Baxter has not received any reports of injury associated with this issue.

### Actions to be Taken by Customers

1. The list of impacted product codes and UDI-DI numbers is in Attachment A enclosed. Immediately locate the impacted products at your facility that are **unopened**. Follow the instructions in Attachment A to determine if your **unopened** products are affected and how to arrange for return as appropriate.



2. Complete the enclosed customer reply form and return it to Baxter by either faxing 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.
3. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
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.

**Actions to be Taken by Dealers, Wholesalers, Distributors/Resellers, or Original Equipment Manufacturers (OEM)**

1. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) and you have an affected product, please do not distribute. Contact Baxter for additional instructions.
2. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please conduct a consumer-level recall of the affected product that you distributed to customers.

**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

Enclosure: Baxter Customer Reply Form  
Attachment A: Affected Product - **Welch Allyn** Blood Pressure Cuffs