URGENT MEDICAL DEVICE RECALL

April 07, 2025

Dear Healthcare Providers, Biomedical Engineering Department and Distributors:

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
Manual Blood Pressure Gauges and Cuffs	**Welch Allyn DuraShock** Aneroid Gauge Sets with a Reusable Blood Pressure Cuff	00732094071511	7670-10
	Welch Allyn 2-Piece Reusable Blood Pressure Cuff Kits	00732094111842	5082-43
Patient monitoring devices and wall systems	**Welch Allyn Spot** Vital Signs 4400 Device	00732094309447	44WT-4

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 mentioned in the above table. 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.

   If you received this communication directly from Baxter, acknowledge receipt by following the instructions on the enclosed Reply Instruction Sheet, even if you have no remaining inventory. Acknowledging receipt of this notification will prevent you from receiving repeated notices. If you do not complete the acknowledgement, you will receive a phone call or email from Baxter Representative to confirm receipt of this notification.
2. If you purchased this product from a distributor or wholesaler, please contact your supplier to arrange for the return and exchange of the affected product. Please note that responding to 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.

3. Please forward a copy of this communication to the Director of Nursing, and any other departments within your institution who unpack the affected product.

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 Technical Support by sending email to TSC-Asia Tech Support - FLC ap_techserv_flc_tech_support_asia@baxter.com

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 and check the associated box on the customer portal.

Further Information and Support

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of this product may be reported via Malaysia_productcomplaint@baxter.com.

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

Sincerely,

Signature: Anju Shear

Electronically signed by: Anju Shear
Reason: I approve this document
Date: Apr 8, 2025 14:16 GMT+5.5

Email: anju_shear@baxter.com

Anju Shear
QA Manager
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Instruction Sheet
Attachment A: Instructions for Welch Allyn Blood pressure cuffs

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Patient Monitoring Devices and Wall Systems	Product Code	UDI-DI Number
Welch Allyn Spot Vital Signs 4400 Device	44WT-4	00732094309447

Instructions for Patient Monitoring Devices and Wall Systems

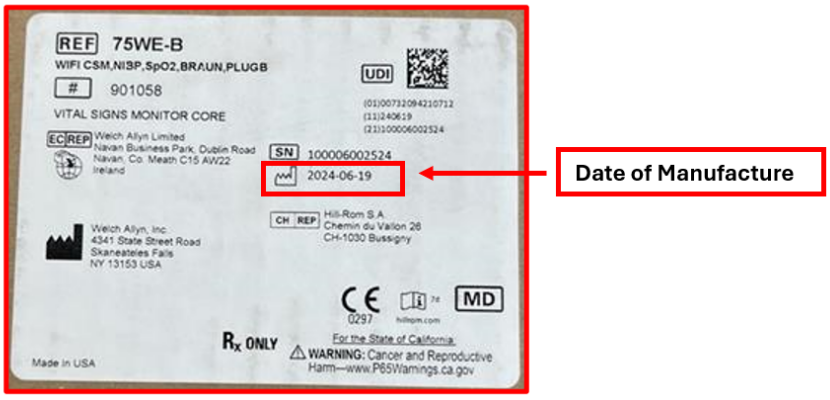

Figure 1 Location of manufacturing date for patient monitoring devices and wall systems

Step 1 - All above patient monitoring devices and wall systems are packaged with a blood pressure cuff kit. If the date of manufacture on the device box label is before the date indicated in the table above, open the device box and locate the blood pressure cuff kit. It will be in a clear plastic bag, including the cuff and IFU bound by a rubber band. Remove the **unopened** plastic bag from the device box, while keeping the cuff kit sealed in the plastic bag. See Figures 2-6 below for location of the blood pressure cuff kit for each product type.

Note: There is no picture below of the **Welch Allyn** Green Series 777 Wall System because the location of the cuff kit in the box may vary.

*Figure 2 **Welch Allyn Connex** Integrated Wall Systems - First Level Packaging*

*Figure 3 **Welch Allyn Connex** Integrated Wall System - Second Level Packaging*

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Figure 4 ***Welch Allyn Connex*** *Spot Monitor Packaging*

Figure 5 ***Welch Allyn Connex*** *Vital Signs Monitor Packaging*

Figure 6 ***Welch Allyn Spot*** *Vital Signs 4400 Device Packaging*

Step 2 - Blood pressure cuff kit: Once the cuff kit is removed from the box, check the lot code on the label of the unopened cuff kit plastic bag (see Figure 7). If the lot code is 24-314 or lower, contact Baxter Technical Support to arrange for return and exchange at 800-535-6663 between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Figure 7 Blood Pressure Cuff Kit Packaging

If the lot code is greater than 24-314, or the cuff kit has been opened and the cuff is in use, no further action is required

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Manual Blood Pressure Gauges and Cuffs	Product Code	UDI-DI Number
Welch Allyn DuraShock Aneroid Gauge Sets with a Reusable Blood Pressure Cuff	7670-10	00732094071511
Welch Allyn 2-Piece Reusable Blood Pressure Cuff Kits	5082-43	00732094111842

Instructions for Manual Blood Pressure Gauges and Blood Pressure Cuffs

Step 1 DuraShock Aneroid Gauge Sets and **Welch Allyn** 2-Piece Reusable Blood Pressure Cuff Kits**:** Check the lot code on the product identification label (see Figure 8 and 9 below).

If you have an aneroid gauge set or a blood pressure cuff where the lot code is 24-314 or lower, do not open the gauge set or cuff package contact Baxter Technical Support to arrange for return and exchange at 800-535-6663 between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday. Please have your Baxter 8-digit ship-to account number, product code, lot number, and quantity of product to be returned ready when calling .

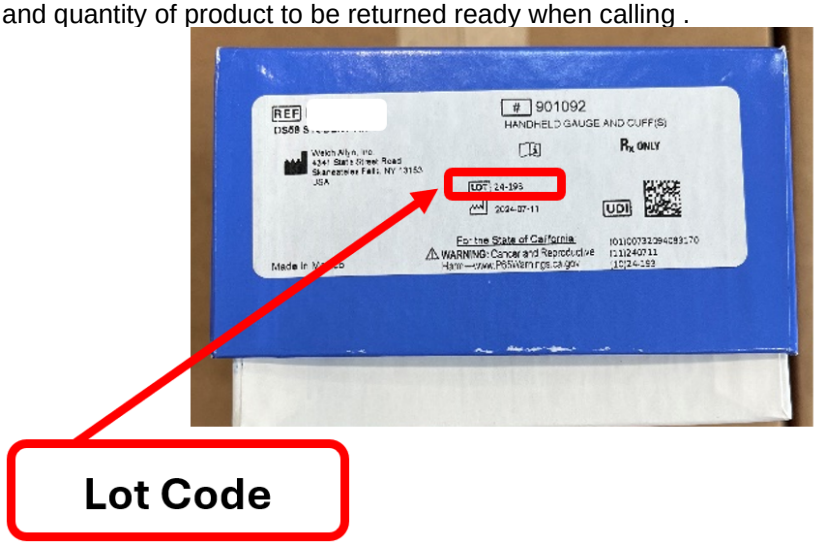

Figure 8 ***Welch Allyn DuraShock*** *Aneroid Gauge Set* with a Reusable Blood Pressure Cuff

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

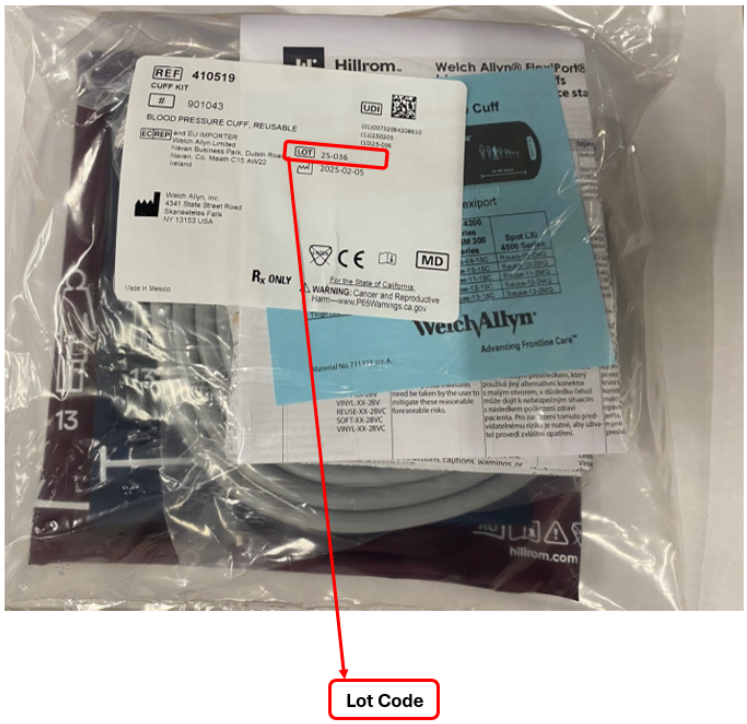

Figure 9 ***Welch Allyn*** *2-Piece Reusable Blood Pressure Cuff Kits Packaging*

If the lot code is greater than 24-314, or if the device has been opened and is in use, no further action is required.

REPLY INSTRUCTION SHEET

URGENT MEDICAL DEVICE RECALL

FlexiPort Reusable Blood Pressure Cuffs, and Two-Piece Reusable Blood Pressure Cuffs

April 07, 2025

CUSTOMER ACCOUNT NUMBER: XXX 1ST
ATTENTION
NAME
ADDRESS
CITY, STATE ZIP

Product Category	Product Description	UDI- DI Number	Product Code
Manual Blood Pressure Gauges and Cuffs	**Welch Allyn DuraShock** Aneroid Gauge Sets with a Reusable Blood Pressure Cuff	00732094071511	7670-10
	Welch Allyn 2-Piece Reusable Blood Pressure Cuff Kits	00732094111842	5082-43
Patient monitoring devices and wall systems	**Welch Allyn Spot** Vital Signs 4400 Device	00732094309447	44WT-4

Please complete this reply form even if there is no remaining inventory at your facility. Completion of the information below indicates that you (1) understand the contents of the attached letter, (2) performed the actions outlined, and (3) disseminated this information, if applicable.

☐ ***For Dealers, Wholesaler, Distributor/Reseller, or Original Equipment Manufacturer (OEM) Only*** - Check this box to indicate that your company has disseminated this communication to your direct customers.

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____

Signature: _____ **Date:** _____/_____/_____

Email a completed copy to Baxter Representative who would be sending this communication to you as a confirmation that you have received this notification.