Baxter

URGENT MEDICAL DEVICE RECALL

March 21, 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
Patient Monitoring Devices and Wall Systems	**Welch Allyn Connex** Integrated Wall System	See Attachment A	See Attachment A
	Welch Allyn Connex Spot Monitor		
	Welch Allyn Connex Vital Signs Monitor		
	Welch Allyn Spot Vital Signs 4400 Device		
	Welch Allyn Green Series 777 Wall System		
Manual Blood Pressure Gauges and Cuffs	**Welch Allyn DuraShock** Aneroid Gauge Sets with a Reusable Blood Pressure Cuff		
	Welch Allyn 2 Piece 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. 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 from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.

3. 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 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.
4. 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 at the phone number below 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 and check the associated box on the customer portal.

Further Information and Support

For general questions regarding this communication, please contact Baxter Technical Support between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday at 800-535-6663. Press option 2, then select option 1 or 2 for language preference, then press option 2.

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

- Contacting Baxter Technical Support between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday at 800-535-6663 (press option 2, then select option 1 or 2 for language preference, then press option 2)
- 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,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

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

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ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Patient Monitoring Devices and Wall Systems	Product Code	UDI-DI Number	Product Code	UDI-DI Number
Welch Allyn Connex Integrated Wall System (manufactured on or before December 18, 2024)	84MTVE2-4	00732094350548	84XTVXC-B	00732094057065
	84MTVE2-6	00732094350463	85MTVE3-2	00732094350586
	84MTVE2-B	00732094349856	85MTVE3-4	00732094350500
	84MTVE2-US	00732094350388	85MTVE3-B	00732094349818
	84MTVEC-6	00732094058741	85MTVE3-US	00732094350340
	84MTVEC-B	00732094058734	85MTVEC-4	00732094197808
	84MTVEP-B	00732094119442	85MTVEC-B	00732094118964
	84MTVEX-4	00732094198638	85MTVEP-2	00732094056211
	84MTVX2-4	00732094350531	85MTVEP-B	00732094056174
	84MTVX2-6	00732094350456	85MTVX3-4	00732094350494
	84MTVX2-B	00732094349849	85MTVX3-B	00732094349801
	84MTVX2-US	00732094350371	85MTVX3-US	00732094350333
	84MTVXC-4	00732094058550	85MTVXC-6	00732094196221
	84MTVXC-B	00732094058512	85MTVXC-B	00732094056075
	84MTVXP-2	00732094198607	85MTVXX-6	00732094196245
	84MTVXP-4	00732094058390	85MXVEC-2	00732094197693
	84MTVXP-B	00732094058352	85MXVEC-4	00732094197686
	84MTVXX-2	00732094198584	85MXVEC-B	00732094118940
	84MXVEC-4	00732094198553	85MXVEP-4	00732094055887
	84MXVEC-B	00732094058277	85NTVE3-4	00732094350487
	84MXVEP-4	00732094058260	85NTVE3-6	00732094350401
	84MXVEP-B	00732094058222	85NTVE3-B	00732094349795
	84NTVE2-6	00732094350449	85NTVE3-US	00732094350326
	84NTVE2-B	00732094349832	85NTVEC-B	00732094055740
	84NTVE2-US	00732094350364	85NTVEP-2	00732094197532
	84NTVEC-B	00732094058048	85NTVEP-6	00732094196320
	84NTVX2-6	00732094350432	85NTVEP-B	00732094055597
	84NTVX2-B	00732094349825	85NTVX3-6	00732094350395
	84NTVX2-US	00732094350357	85NTVX3-B	00732094349788
	84NTVXC-4	00732094198362	85NTVX3-US	00732094350319
	84NTVXC-B	00732094057775	85NTVXC-B	00732094055467
	84NTVXP-B	00732094057713	85NTVXP-2	00732094055443
	84NXVEC-4	00732094057652	85NTVXP-B	00732094055412
	84NXVEC-6	00732094057638	85NXVEC-4	00732094055252
	84NXVEC-B	00732094057485	85NXVEC-B	00732094055207
	84XTVXC-2	00732094198096	85NXVEP-6	00732094196375
Welch Allyn Connex Spot Monitor (manufactured on or before November 9, 2024)	73WT-B	00732094210033	75CX-B	00732094209464
	74CE-B	00732094209921	75-HCA-CTB	00732094240597
	74CT-B	00732094209860	75-HCA-MTB	00732094240603
	74CX-B	00732094209792	75ME-B	00732094209419
	74ME-B	00732094209716	75MT-B	00732094209372
	74MT-B	00732094209679	75MT-BR	00732094322477

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Patient Monitoring Devices and Wall Systems	Product Code	UDI-DI Number	Product Code	UDI-DI Number
Welch Allyn Connex Spot Monitor (manufactured on or before November 9, 2024)	74MX-B	00732094209624	75MX-B	00732094209334
	74RE-B	00732094335781	75RE-B	00732094335606
	74RT-B	00732094335712	75RT-B	00732094335538
	75CE-B	00732094209570	75WE-B	00732094210712
	75CT-B	00732094209518	75WT-B	00732094209167
	75CT-BR	00732094322491		
Welch Allyn Connex Vital Signs Monitor (manufactured on or before November 9, 2024)	67MCTP-B	00732094151374	68MXDX-B	00732094249187
	67MCTP-B-ECG3A	00732094323795	68MXEP-B	00732094150964
	67MCTX-B	00732094151367	68MXEX-B	00732094150957
	67MXEX-B	00732094151268	68MXTP-B	00732094150940
	67MXTP-B	00732094151251	68MXTP-B-ECG3A	00732094345902
	67MXTP-B-ECG3A	00732094323788	68MXTX-B	00732094150933
	67MXTX-B	00732094151244	68MXTX-BR	00732094322613
	67MXXP-B	00732094151237	68MXXX-B	00732094150919
	67MXXX-B	00732094151220	68NCEP-B	00732094150902
	67NCTP-B	00732094151190	68NCTP-B	00732094150889
	67NCTP-B-ECG3A	00732094323771	68NCTP-B-ECG3A	00732094345896
	67NCTX-B	00732094151183	68NCTX-B	00732094150872
	67NXEX-B	00732094151145	68NCXP-B	00732094150865
	67NXTP-B	00732094151138	68NXEP-B	00732094150841
	67NXTP-B-ECG3A	00732094323764	68NXEX-B	00732094150834
	67NXTX-B	00732094151121	68NXTP-B	00732094150827
	67NXXX-B	00732094151107	68NXTP-B-ECG3A	00732094345889
	68MCTP-B	00732094151060	68NXTX-B	00732094150810
	68MCTP-B-ECG3A	00732094345919	68NXTX-BR	00732094322590
	68MCTX-B	00732094151053	68NXXX-B	00732094150797
	68MCXX-B	00732094151039		
Welch Allyn Spot Vital Signs 4400 Device (manufactured on or before November 9, 2024)	44WT-2	00732094309461	44XT-2	00732094309386
	44WT-3	00732094309454	44XT-4	00732094309362
	44WT-4	00732094309447	44XT-6	00732094309348
	44WT-6	00732094309423	44XT-B	00732094309324
	44WT-B	00732094309409		
Welch Allyn Green Series 777 Wall System (manufactured on or before November 9, 2024)	77791-2MP2X	00732094066890	77791-2MPXL	00732094201826
	77791-2MP2XL	00732094201833	77796-2MPX	00732094066289
	77791-2MPX	00732094066876	77796-2MPXL	00732094184013
	77791-2MPX-HS	00732094231045		

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

Instructions for Patient Monitoring Devices and Wall Systems

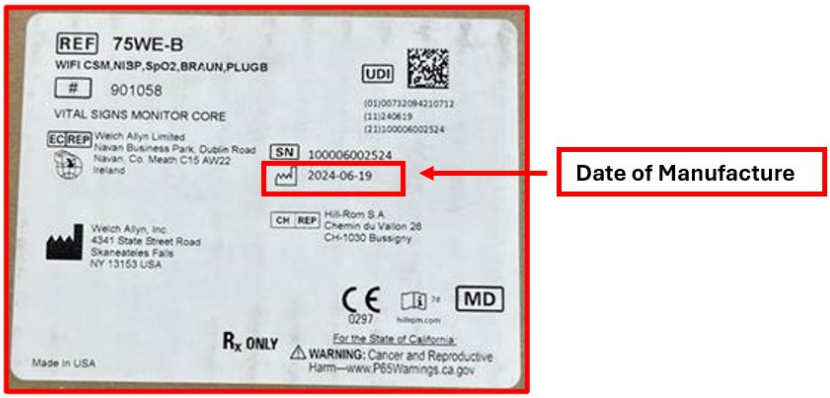

Figure 1 Location of manufacturing date for patient monitoring devices and wall systems

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*

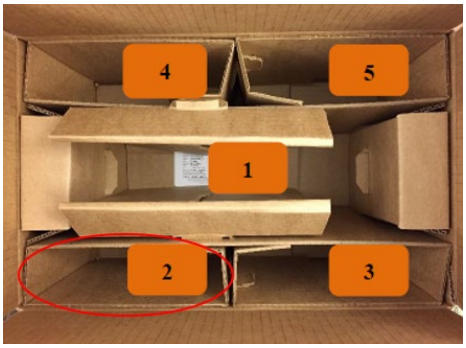

*Figure 4 **Welch Allyn Connex** Spot Monitor Packaging*

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

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

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.

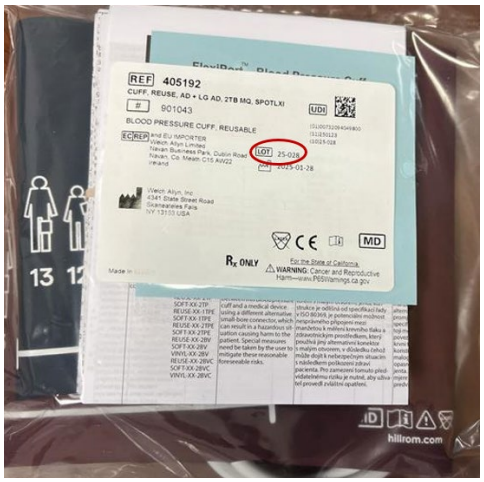

Figure 7 Blood Pressure Cuff Kit Packaging

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	Product Code	UDI-DI Number
Welch Allyn DuraShock Aneroid Gauge Sets with a Reusable Blood Pressure Cuff	407637	00732094046755	DS44-11	00732094085631
	5098-02	00732094110128	DS44-11C	00732094085617
	5098-23	00732094109900	DS44-MC	00732094084924
	5098-27	00732094109856	DS45-11	00732094084610
	5098-28	00732094109801	DS45-11C	00732094084498
	5098-29	00732094109764	DS45-12	00732094084429
	5098-30	00732094109726	DS45-MC	00732094083965
	5098-33	00732094109658	DS58-11	00732094083385
	5098-42	00732094109603	DS58-MC	00732094083347
	7670-10	00732094071511	DS58-PD	00732094083309
	DS44-09	00732094085884	DS58-ST	00732094083170
Welch Allyn 2-Piece Reusable Blood Pressure Cuff Kits	410519	00732094208610	5082-22	00732094112290
	4500-02	00732094004199	5082-22H	00732094112276
	4500-03	00732094004182	5082-23	00732094112245
	45-15-389	00732094004472	5082-23H	00732094112221
	45-22-189	00732094004397	5082-24	00732094112207
	45-23-189	00732094004380	5082-25	00732094111996
	47-15-389	00732094002423	5082-26	00732094111897
	47-22-189	00732094002379	5082-42	00732094111873
	47-23-189	00732094002362	5082-43	00732094111842
	5082-01	00732094113723	5082-44	00732094111811
	5082-01H	00732094113693	5082-45	00732094111798
	5082-02	00732094113679	5082-77	00732094111644
	5082-03	00732094113648	5082-78	00732094111613
	5082-07	00732094113631	5090-41	00732094110494
	5082-08	00732094113600	5098-20	00732094109955
	5082-11	00732094113327	5200-01	00732094108583
	5082-16	00732094113105	5200-02	00732094108569
	5082-21	00732094112344		

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.

ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

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

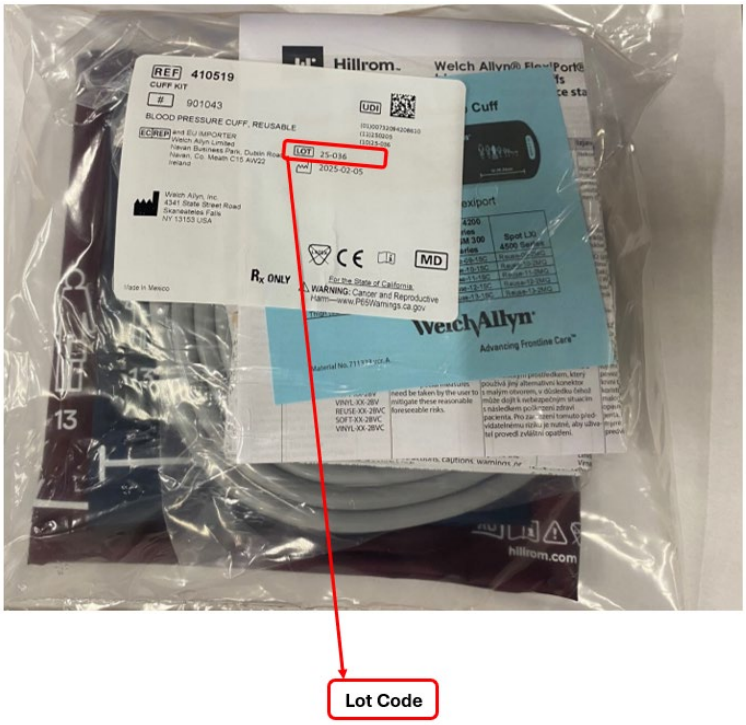

Figure 9 ***Welch Allyn*** *2-Piece Reusable Blood Pressure Cuff Kits Packaging*

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.

