

URGENT MEDICAL DEVICE RECALL

April 8, 2025

Dear Valued McKesson Customer:

Baxter Healthcare Corporation has notified McKesson Medical-Surgical Inc. (MMS) of an Urgent Medical Device Recall regarding their reusable blood pressure cuffs. This notice has been issued 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). Affected product first shipped June 1, 2021.

This Urgent Medical Device Recall is being done with the knowledge of the U.S. Food and Drug Administration. McKesson Medical-Surgical Inc. has taken appropriate action per this notice.

For clinical inquiries, please contact Baxter Technical Support at **(800) 535-6663**.

A review of our records indicates that your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table for a list of affected item(s) distributed by McKesson Medical-Surgical

MMS #	MFG Catalog #	Description	Affected Lot(s)
778038	84MTVEP-B ✓	BLOOD PRESSURE SYS, CONNEX WALL SPO2 PANOPTIC MACR	All Serial Numbers with a manufacture date prior to 2024-06-19
778040	84MTVXC-B ✓	BLOOD PRESSURE SYS, CONNEX WALL SPO2 COAXIAL MACRO	
778041	84MTVXP-B ✓	BLOOD PRESSURE SYS, CONNEX WALL SPO2 PANOPTIC MACR	
778049	84NTVEC-B ✓	BLOOD PRESSURE SYS, CONNEX WALL SPO2 COAXIAL MACRO	
778052	84NTVXC-B ✓	BLOOD PRESSURE SYS, CONNEX WALL SPO2 COAXIAL MACRO	
778064	84XTVXC-B ✓	BLOOD PRESSURE SYS, CONNEX WALL COAXIAL MACROVIEW	
778077	85MTVEP-B ✓	BLOOD PRESSURE SYS, CONNEX WALL PANOPTIC MACROVIEW	
778091	85NTVXC-B ✓	BLOOD PRESSURE SYS, CONNEX WALL COAXIAL MACROVIEW	
778092	85NTVXP-B ✓	BLOOD PRESSURE SYS, CONNEX WALL PANOPTIC MACROVIEW	
807285	77791-2MPX ✓	DIAGNOSTIC SYS, OPHT/OTO/BP/THERM W/ACCESSORIES	
852825	84NXVEC-B ✓	BLOOD PRESSURE SYSTEM, INTERGRATED WALL SYS W/VITALS	
946237	67NXTX-B ✓	MONITOR, BP SPO2 W/ CONTINUOUSPROFILE	
946238	67MXEX-B ✓	MONITOR, BP MASIMO SPO2 THERMOSCAN PRO PULSE RATE	

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MMS #	MFG Catalog #	Description	Affected Lot(s)
946239	68MXTX-B ✓	MONITOR, BP MASIMO SPO2 SURETEMP PLUS NURSE CALL WIRELESS	All Serial Numbers with a manufacture date prior to 2024-06-19
946240	68NXTX-B ✓	MONITOR, BP NELLCOR SPO2 SURETEMP PLUS W/PROFILE W	
946248	74CX-B ✓	MONITOR, BP CONNEX SPO2 UPGRADE TO WIFI	
946249	74CT-B ✓	MONITOR, BP CONNEX SPO2 SURETEMP UPGRADE TO WIFI	
946250	74CE-B ✓	MONITOR, BP CONNEX SPO2 PRO6000 UPGRADE WIFI D/S	
946251	74MX-B ✓	MONITOR, CONNEX MASIMO SPO2 UPGRADE WIFI D/S	
946252	74MT-B ✓	MONITOR, CONNEX MASIMO SPO2 SURETEMP UPGRADE WIFI	
946253	74ME-B ✓	MONITOR, BP CONNEX MASIMO SPO2PRO6000 UPGRADE WIFI	
946257	75CX-B ✓	MONITOR, BP CONNEX SPO2 W/RADIO	
946258	75CT-B ✓	MONITOR, BP CONNEX SPO2 SURETEMP W/RADIO	
946259	75CE-B ✓	MONITOR, BP CONNEX SPO2 THERMOSCAN WIRELESS D/S	
946261	75MT-B ✓	MONITOR, BP CONNEX MASIMO SPO2SURETEMP W/RADIO	
946262	75ME-B ✓	MONITOR, BP CONNEX MASIMO SPO2PRO6000 W/RADIO D/S	
946346	67MXTX-B ✓	MONITOR, BP SURETEMP SPO2 PLUS	
955137	67NXEX-B ✓	MONITOR, BP SPO2 W/MAP/BP AVG NON-INV BP	
959359	73WT-B ✓	MONITOR, BLOOD PRESSURE SPO2 SURE TEMP	
984666	68NCTX-B ✓	MONITOR, CONNEX 6800 VITAL SIGNS	
1010608	67NCTX-B ✓	MONITOR, VITAL SIGNS CONNEX 670	
1047684	67NXXX-B ✓	BP UNIT, SPO2 NELLCOR CONNEX	
1055690	67NXTP-B ✓	MONITOR, PT VITAL SIGNS VSM 6700 BP/SPO2/TEMP/PRINTER	
1070896	67NCTP-B ✓	CONNEX, CVSM 67NCTP-B	
1073635	68MXXX-B ✓	MONITOR, VITAL SIGNS MASIMO BP/SP02 N/NVASV	
1087883	68MXTP-B ✓	MONITOR, VITAL SIGNS CONNEX 6800 SP02 BP PRINTER CONNECT D/S	
1102121	68NXTP-B ✓	MONITOR, PT CONNEX 6800 SPO2/BP/SURE TEMP & PRINTER	
1117522	67MXTP-B ✓	MONITOR, BP CVSM 6700 SPO2 TEMP + PRINTER	
1123490	67MCTP-B ✓	MONITOR, PT CONNEX 6700 W/BP/PULSE/SPO2/CAPNOGRAPY/PRINTER	
1137212	68NCTP-B ✓	MONITOR, BP NELLCOR SPO2 CONNEX 6800	
1148178	67NCTP-B-ECG3A ✓	MONITOR, PT VITAL SIGNS CVSM BP/SPO2/ETC02/TEMP/PRNTR/3LEAD	

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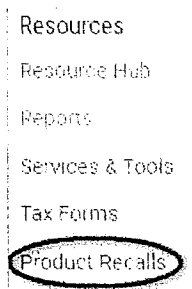
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MMS #	MFG Catalog #	Description	Affected Lot(s)
1148179	67MCTP-B-ECG3A ✓	MONITOR, PT VITAL SIGNS CVSM BP/SPO2/ETC02/TEMP/PRNTR/3LEAD	All Serial Numbers with a manufacture date prior to 2024-06-19
1148180	67NXTP-B-ECG3A ✓	MONITOR, PT VITAL SIGNS CVSM BP/SPO2/TEMP/PRINTER/3LEAD ECG	
1148181	67MXTP-B-ECG3A ✓	MONITOR, PT VITAL SIGNS CVSM BP/SPO2/TEMP/PRINTER/3LEAD ECG	
1154729	44XT-B ✓	MONITOR, BP SPOT 4400 W/ NIBP & SURETEMP PLUG B	
1154730	44WT-B ✓	MONITOR, BP SPOT 4400 W/ NIBP & SURETEMP NONIN PLUG B	
1171103	67MCTX-B ✓	MONITOR, BP MASIMO SPO2 CAPNOGRAPHY TEMP CVSM 6700	
1174631	75RT-B ✓	MONITOR, CONNEX SPOT W/SUREBP SURETEMP SPO2 & RRP	
1180131	74RT-B ✓	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP SURETEMP	
1180152	74RE-B ✓	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP BRAUN PRO6000	
1180154	75RE-B ✓	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP BRAUN 6000 WIFI	
1196567	73WT-B ✓	MONITOR, BLOOD PRESSURE SPO2 SURE TEMP (CANOHEALTH)	
1197766	84MTVE2-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC PLUG B	
1197767	84MTVX2-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB PORTS F-USB PLUG B	
1197768	84NTVE2-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC PLUG B	
1197769	84NTVX2-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC PLUG B	
1197770	85MTVE3-US ✓	MONITOR, PT CONNEX WALL SPO2 A/B/G WIRELESS RADIO IEC PLUG B	
1197771	85MTVX3-US ✓	MONITOR, PT CONNEX WALL SPO2 A/B/G MAP IEC PLUG B	
1197772	85NTVE3-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB A/B/G WIRELESS IEC	
1197773	85NTVX3-US ✓	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC PLUG B	
1221074	68MCTP-B ✓	MONITOR, VITAL SIGNS 6800 SPO2CAPNOGRAPHY SURETEMP	
31910	5082-21 ✓	INFLATION SYSTEM, VELCRO 2TU BG CHILD	All Lot Codes 24-314 or lower
31912	5082-24 ✓	CUFF, VELCRO 2TU BAG CHILD	
44189	5082-02 ✓	CUFF, VELCRO N/C CHILD	
44190	5082-03 ✓	CUFF, VELCRO 1TU BAG INFANT	
44195	5082-08 ✓	CUFF, VELCRO 2TU BAG INFANT	
44197	5082-11 ✓	CUFF, VELCRO N/C THIGH	
44199	5082-16 ✓	CUFF, VELCRO N/C ADULT LARGE	

MMS #	MFG Catalog #	Description	Affected Lot(s)
44244	5098-02 ✓	SPHYG, ANEROID HND MDL VELCRO CUFF	All Lot Codes 24-314 or lower
46596	5082-22 ✓	INFLATION SYSTEM, VELCRO 2TU BG ADULT	
46597	5082-23 ✓	INFLATION SYSTEM, VELCRO 2TU BG ADULT LG	
46788	5082-26 ✓	CUFF, VELCRO 2TU BAG ADULT LARGE	
48886	5082-25 ✓	CUFF, VELCRO 2TU BAG ADULT	
115989	5082-01H ✓	CUFF, VELCRO N/C ADULT	
145420	5082-22H ✓	INFLATION SYSTEM, VELCRO 2TU BG ADULT	
151592	5082-43 ✓	CUFF, VELCRO 1TU BAG ADULT	
153432	5090-41 ✓	SPHYG, ANEROID POCKET W/CUFF & CASE LG ADLT	
159465	5082-07 ✓	CUFF, VELCRO 1TU BAG NEWBORN	
170353	5082-45 ✓	INFLATION SYSTEM, VELCRO 2TU BG THIGH	
173323	5082-44 ✓	CUFF, VELCRO 1TU BAG/BLADDER LG ADLT	
174086	5082-42 ✓	CUFF, VELCRO 1TU BAG CHILD	
198886	5082-23H ✓	INFLATION SYSTEM, VELCRO 2TU BG ADULT LG	
228273	5082-01 ✓	CUFF, VELCRO N/C ADLT	
264023	5098-30 ✓	ANEROID KIT, MULTI CUFF	
264266	5098-27 ✓	SPHYG, ANEROID HAND W/CUFF ADLT	
264307	5098-28 ✓	SPHYG, ANEROID HAND W/CUFF LG ADLT	
264308	5098-29 ✓	SPHYG, ANEROID HAND W/CUFF CHLD	
327200	5200-02 ✓	CUFF, ADLT LG	
387059	5200-01 ✓	CUFF ASSEMBLY, BLOOD PRESSURE ADLT	
436395	DS44-11 ✓	SPHYG, DURASHOCK ADLT	
449507	DS45-12 ✓	SPHYG, DURASHOCK LG ADLT	
459252	5082-77 ✓	CUFF, VELCRO 1TU BAG/BLADDER THIGH	
461152	DS45-11 ✓	SPHYG, DURASHOCK ADLT	
476977	7670-10 ✓	SPHYG, ANEROID MOBILE W/STAND F/765	
479269	5082-78 ✓	CUFF & BLADDER, 2PC THIGH	
486110	DS44-09 ✓	SPHYG, DURASHOCK CHLD	
527921	5098-42 ✓	BLOOD PRESSURE KIT, DS66 W/CUFF	
527922	DS44-11C ✓	CUFF, ANEROID DURASHOCK ADLT	
534525	4500-02 ✓	CUFF & BLADDER, ADLT W/2TUBES	
534526	4500-03 ✓	CUFF & BLADDER, LG ADLT W/2TUBES	
537978	DS58-11 ✓	ANEROID, HAND W/ADLT CUFF NYLON CASE	
537979	DS58-MC ✓	ANEROID, FAMILY PRACTICE KIT 4CUFF SIZES	
537980	DS58-PD ✓	ANEROID, FAMILY PRACTICE KIT CHILD PRINT SM	
709804	DS58-ST ✓	ANEROID, STUDENT KIT BP	
721932	DS45-MC ✓	SPHYG ANEROID KIT, W/GUAGE TU 4SZ CUFFS	
824479	DS45-11C ✓	SPHYGMOMANOMETER, ANEROID ADLTW/CUFF & CASE BLK	
884445	DS44-MC ✓	SPHYG ANEROID KIT, DURASHOCK CLIP ON GAUGE 4CUFFS FLEX PORT	

**Instructions for the McKesson Medical-Surgical online product ordering system – “SupplyManager”,
to access and download a “fillable” PDF reply form.**

- 1) It is important to download the correct reply form for the specific recall you are responding to.
 - a. Reply forms have a specific designation, example: RC-202X-XXX.
 - “202X” is the recall year, and “XXX” is the 3-digit unique numeric identifier for the recall.
- 2) Go to <https://mms.mckesson.com/> and log in to “SupplyManager”, with your username and password.
- 3) On the home page, under ‘Essential Tasks’ click ‘Your Account.’ Under ‘Resources’ a support link titled “Product Recalls” can be found on the right side.
- 4) Click on the hyperlink “Product Recalls” (this will open a listing of recalls for the last 3 months).



- 5) On the recalls list page, locate the “Find” box.
 - a. From the drop-down options, select one of the following: “Keyword”, “McKesson Item #” or “Manufacturer”.
 - b. Enter a Keyword, McKesson Item #, or Manufacturer name in the Find box and click “Find”.

Find Manufacturer ▼

- c. A list of issued recalls will be made visible for you to select from.
- 6) Click on the blue hyperlink, found under the heading “Recall Notice,” for the notice details you want to access.

Manufacturer	Recall Notice	Issued ▼
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- 7) The PDF customer documents associated with the notice will be displayed, *this includes the reply form to download and complete for your response.*
- 8) Click on the hyperlink(s) to open the Customer Document(s). Save/Download this document to your computer. Once the documents are saved, close out the document window.
- 9) Submit completed reply form to MMSRecalls@McKesson.com.
- 10) If you wish to view additional recalls, return to the home recall page by clicking the blue “View All Recalls” button at the upper right corner of the page above the blue alert banner.

McKesson Customer Instructions:

- 1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed in the item table. If you have no products matching the affected item(s) and lot number(s), no further action is needed.
 - **This recall does not apply to reusable blood pressure cuffs that are currently in use.**
- 2.) A copy of the Urgent Medical Device Recall from Baxter has been included for reference.
- 3.) If you have unopened/unused product affected by this notice, fill out the McKesson Reply Form and return it to our Corporate Customer Service Center via email at MMSRecalls@McKesson.com or fax at **(866) 871-0270**. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.
 - **Please note:** Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected product lot numbers are listed in the item table. Once the product is returned, credit will be issued to you.
 - **Please place a new order for replacement product if there is an immediate need.**
- 4.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this Urgent Medical Device Recall and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this notice may have caused you and your staff. If you have any questions about information provided in this communication, please contact our **McKesson Medical-Surgical Recall Message Center** at MMSRecalls@McKesson.com or call **(800) 688-8840**.

Thank you for your prompt attention,

McKesson Medical-Surgical Inc.

McKesson Medical-Surgical Inc.
Device Recall Reply Form: RC-2025-067
Baxter – Reusable Blood Pressure Cuffs

April 8, 2025

Complete this reply form and return all pages immediately via email to MMSRecalls@McKesson.com or fax at (866) 871-0270 should you have affected product.

To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

Date: _____

Your Name: _____

Email Address: _____

Phone Number: _____

Fax Number: _____

Account: 20033147 District: 22510000
CARELINC MEDICAL EQUIP & SUPPLY
ATTN: RISK MANAGEMENT
89 54TH ST SW STE 1
GRAND RAPIDS, MI 49548-5503

☐ I acknowledge that I DO HAVE product affected by this notification and have followed the instructions for return.

Qty	Unit of Measure	MMS #	MFG Catalog #	Description
		778038	84MTVEP-B	BLOOD PRESSURE SYS, CONNEX WALL SPO2
		778040	84MTVXC-B	BLOOD PRESSURE SYS, CONNEX WALL SPO2
		778041	84MTVXP-B	BLOOD PRESSURE SYS, CONNEX WALL SPO2
		778049	84NTVEC-B	BLOOD PRESSURE SYS, CONNEX WALL SPO2
		778052	84NTVXC-B	BLOOD PRESSURE SYS, CONNEX WALL SPO2
		778064	84XTVXC-B	BLOOD PRESSURE SYS, CONNEX WALL COAXIAL
		778077	85MTVEP-B	BLOOD PRESSURE SYS, CONNEX WALL PANOPTIC
		778091	85NTVXC-B	BLOOD PRESSURE SYS, CONNEX WALL COAXIAL
		778092	85NTVXP-B	BLOOD PRESSURE SYS, CONNEX WALL PANOPTIC
		807285	77791-2MPX	DIAGNOSTIC SYS, OPHT/OTO/BP/THERM
		852825	84NXVEC-B	BLOOD PRESSURE SYSTEM, INTERGRATED WALL
		946237	67NXTX-B	MONITOR, BP SPO2 W/ CONTINUOUSPROFILE
		946238	67MXEX-B	MONITOR, BP MASIMO SPO2 THERMOSCAN PRO
		946239	68MXTX-B	MONITOR, BP MASIMO SPO2 SURETEMP PLUS
		946240	68NXTX-B	MONITOR, BP NELLCOR SPO2 SURETEMP PLUS
		946248	74CX-B	MONITOR, BP CONNEX SPO2 UPGRADE TO WIFI
		946249	74CT-B	MONITOR, BP CONNEX SPO2 SURETEMP
		946250	74CE-B	MONITOR, BP CONNEX SPO2 PRO6000 UPGRADE
		946251	74MX-B	MONITOR, CONNEX MASIMO SPO2 UPGRADE WIFI
		946252	74MT-B	MONITOR, CONNEX MASIMO SPO2 SURETEMP
		946253	74ME-B	MONITOR, BP CONNEX MASIMO SPO2PRO6000
		946257	75CX-B	MONITOR, BP CONNEX SPO2 W/RADIO
		946258	75CT-B	MONITOR, BP CONNEX SPO2 SURETEMP W/RADIO
		946259	75CE-B	MONITOR, BP CONNEX SPO2 THERMOSCAN
		946261	75MT-B	MONITOR, BP CONNEX MASIMO SPO2SURETEMP
		946262	75ME-B	MONITOR, BP CONNEX MASIMO SPO2PRO6000

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Qty	Unit of Measure	MMS #	MFG Catalog #	Description
		946346	67MXTX-B	MONITOR, BP SURETEMP SPO2 PLUS
		955137	67NXEX-B	MONITOR, BP SPO2 W/MAP/BP AVG NON-INV BP
		959359	73WT-B	MONITOR, BLOOD PRESSURE SPO2 SURE TEMP
		984666	68NCTX-B	MONITOR, CONNEX 6800 VITAL SIGNS
		1010608	67NCTX-B	MONITOR, VITAL SIGNS CONNEX 670
		1047684	67NXXX-B	BP UNIT, SPO2 NELLCOR CONNEX
		1055690	67NXTP-B	MONITOR, PT VITAL SIGNS VSM 6700 BP/SPO2/TEMP
		1070896	67NCTP-B	CONNEX, CVSM 67NCTP-B
		1073635	68MXXX-B	MONITOR, VITAL SIGNS MASIMO BP/SP02 N/NVASV
		1087883	68MXTP-B	MONITOR, VITAL SIGNS CONNEX 6800 SPO2 BP
		1102121	68NXTP-B	MONITOR, PT CONNEX 6800 SPO2/BP/SURE TEMP
		1117522	67MXTP-B	MONITOR, BP CVSM 6700 SPO2 TEMP + PRINTER
		1123490	67MCTP-B	MONITOR, PT CONNEX 6700 W/BP/PULSE/SPO2
		1137212	68NCTP-B	MONITOR, BP NELLCOR SPO2 CONNEX 6800
		1148178	67NCTP-B-ECG3A	MONITOR, PT VITAL SIGNS CVSM
		1148179	67MCTP-B-ECG3A	MONITOR, PT VITAL SIGNS CVSM
		1148180	67NXTP-B-ECG3A	MONITOR, PT VITAL SIGNS CVSM
		1148181	67MXTP-B-ECG3A	MONITOR, PT VITAL SIGNS CVSM
		1154729	44XT-B	MONITOR, BP SPOT 4400 W/ NIBP & SURETEMP
		1154730	44WT-B	MONITOR, BP SPOT 4400 W/ NIBP & SURETEMP
		1171103	67MCTX-B	MONITOR, BP MASIMO SPO2 CAPNOGRAPHY TEMP
		1174631	75RT-B	MONITOR, CONNEX SPOT W/SUREBP SURETEMP
		1180131	74RT-B	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP
		1180152	74RE-B	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP
		1180154	75RE-B	MONITOR, SPOT CONNEX BP MASIMOSP02 RRP
		1196567	73WT-B	MONITOR, BLOOD PRESSURE SPO2 SURE TEMP
		1197766	84MTVE2-US	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC
		1197767	84MTVX2-US	MONITOR, PT CONNEX WALL SPO2 4USB PORTS
		1197768	84NTVE2-US	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC
		1197769	84NTVX2-US	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC
		1197770	85MTVE3-US	MONITOR, PT CONNEX WALL SPO2 A/B/G WIRELESS
		1197771	85MTVX3-US	MONITOR, PT CONNEX WALL SPO2 A/B/G MAP IEC
		1197772	85NTVE3-US	MONITOR, PT CONNEX WALL SPO2 4USB A/B/G
		1197773	85NTVX3-US	MONITOR, PT CONNEX WALL SPO2 4USB PORTS IEC
		1221074	68MCTP-B	MONITOR, VITAL SIGNS 6800 SPO2CAPNOGRAPHY
		31910	5082-21	INFLATION SYSTEM, VELCRO 2TU BG CHILD
		31912	5082-24	CUFF, VELCRO 2TU BAG CHILD
		44189	5082-02	CUFF, VELCRO N/C CHILD
		44190	5082-03	CUFF, VELCRO 1TU BAG INFANT
		44195	5082-08	CUFF, VELCRO 2TU BAG INFANT
		44197	5082-11	CUFF, VELCRO N/C THIGH
		44199	5082-16	CUFF, VELCRO N/C ADULT LARGE
		44244	5098-02	SPHYG, ANEROID HND MDL VELCRO CUFF
		46596	5082-22	INFLATION SYSTEM, VELCRO 2TU BG ADULT
		46597	5082-23	INFLATION SYSTEM, VELCRO 2TU BG ADULT LG

Qty	Unit of Measure	MMS #	MFG Catalog #	Description
		46788	5082-26	CUFF, VELCRO 2TU BAG ADULT LARGE
		48886	5082-25	CUFF, VELCRO 2TU BAG ADULT
		115989	5082-01H	CUFF, VELCRO N/C ADULT
		145420	5082-22H	INFLATION SYSTEM, VELCRO 2TU BG ADULT
		151592	5082-43	CUFF, VELCRO 1TU BAG ADULT
		153432	5090-41	SPHYG, ANEROID POCKET W/CUFF & CASE LG ADLT
		159465	5082-07	CUFF, VELCRO 1TU BAG NEWBORN
		170353	5082-45	INFLATION SYSTEM, VELCRO 2TU BG THIGH
		173323	5082-44	CUFF, VELCRO 1TU BAG/BLADDER LG ADLT
		174086	5082-42	CUFF, VELCRO 1TU BAG CHILD
		198886	5082-23H	INFLATION SYSTEM, VELCRO 2TU BG ADULT LG
		228273	5082-01	CUFF, VELCRO N/C ADLT
		264023	5098-30	ANEROID KIT, MULTI CUFF
		264266	5098-27	SPHYG, ANEROID HAND W/CUFF ADLT
		264307	5098-28	SPHYG, ANEROID HAND W/CUFF LG ADLT
		264308	5098-29	SPHYG, ANEROID HAND W/CUFF CHLD
		327200	5200-02	CUFF, ADLT LG
		387059	5200-01	CUFF ASSEMBLY, BLOOD PRESSURE ADLT
		436395	DS44-11	SPHYG, DURASHOCK ADLT
		449507	DS45-12	SPHYG, DURASHOCK LG ADLT
		459252	5082-77	CUFF, VELCRO 1TU BAG/BLADDER THIGH
		461152	DS45-11	SPHYG, DURASHOCK ADLT
		476977	7670-10	SPHYG, ANEROID MOBILE W/STAND F/765
		479269	5082-78	CUFF & BLADDER, 2PC THIGH
		486110	DS44-09	SPHYG, DURASHOCK CHLD
		527921	5098-42	BLOOD PRESSURE KIT, DS66 W/CUFF
		527922	DS44-11C	CUFF, ANEROID DURASHOCK ADLT
		534525	4500-02	CUFF & BLADDER, ADLT W/2TUBES
		534526	4500-03	CUFF & BLADDER, LG ADLT W/2TUBES
		537978	DS58-11	ANEROID, HAND W/ADLT CUFF NYLON CASE
		537979	DS58-MC	ANEROID, FAMILY PRACTICE KIT 4CUFF SIZES
		537980	DS58-PD	ANEROID, FAMILY PRACTICE KIT CHILD PRINT SM
		709804	DS58-ST	ANEROID, STUDENT KIT BP
		721932	DS45-MC	SPHYG ANEROID KIT, W/GUAGE TU 4SZ CUFFS
		824479	DS45-11C	SPHYGMOMANOMETER, ANEROID ADLTW/CUFF &
		884445	DS44-MC	SPHYG ANEROID KIT, DURASHOCK CLIP ON GAUGE

*Return unused/unopened Affected lot numbers only

* Any product returned in addition to or in lieu of affected product will be destroyed, without issuance of a credit. The affected lot numbers are listed on the McKesson customer letter.

McKESSON

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If you are on a McKesson truck route, a delivery professional will pick up the affected products, otherwise you will receive UPS return label(s) via email or fax.

- ☐ I am on a McKesson truck route, please schedule a delivery professional pick up.
- ☐ Please send my UPS/Return label by ☐ Fax or ☐ Email. Number of UPS Parcels to be returned: _____

If you have any questions about information provided in this communication, please contact the McKesson Recall Message Center at MMSRecalls@McKesson.com or call (800) 688-8840.

See instructions on the reverse side of this form to access
McKesson Medical-Surgical's online product ordering system, "SupplyManager", for a fillable form.

McKesson Medical-Surgical Inc.

www.mckesson.com

RC-2025-067

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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

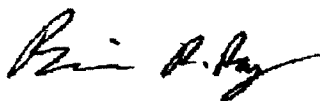
For general questions regarding this communication, please contact Baxter Technical Support between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday at 800-535-6663. Press option 2, then select option 1 or 2 for language preference, then press option 2.

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

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

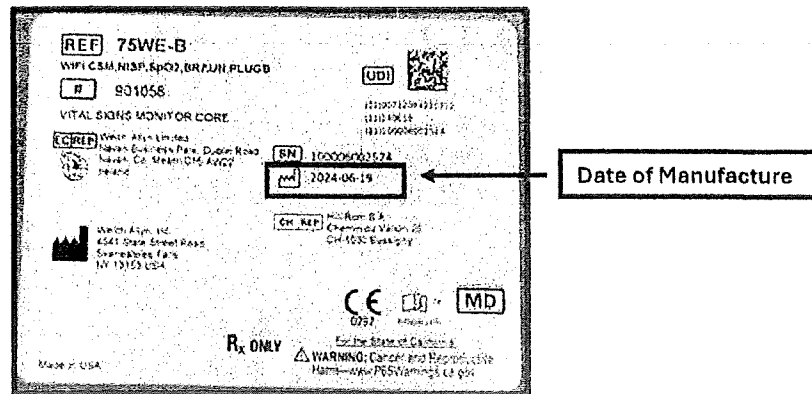


Figure 1 Location of manufacturing date for patient monitoring devices and wall systems

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.

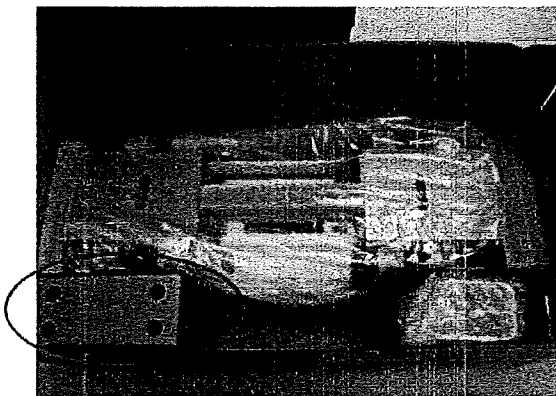


Figure 2 **Welch Allyn Connex Integrated Wall Systems - First Level Packaging**



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

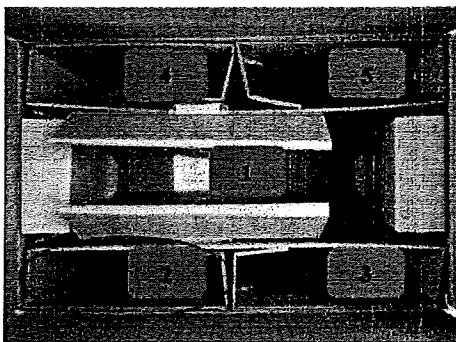


Figure 4 **Welch Allyn Connex Spot Monitor Packaging**

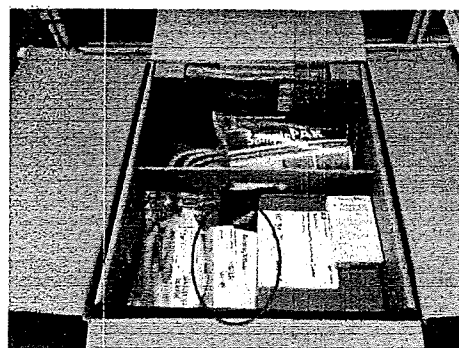


Figure 5 **Welch Allyn Connex Vital Signs Monitor Packaging**

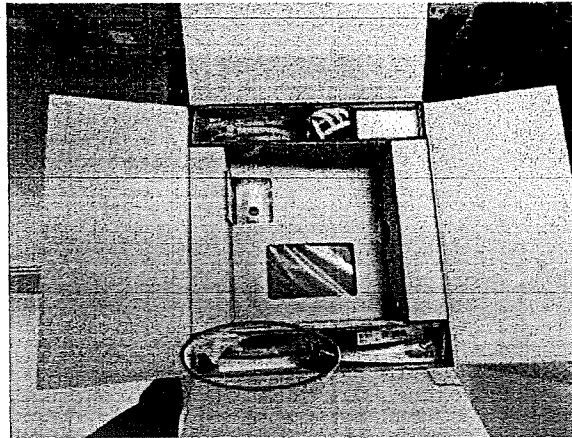
ATTACHMENT A: Affected Product - Welch Allyn Blood Pressure Cuffs

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.

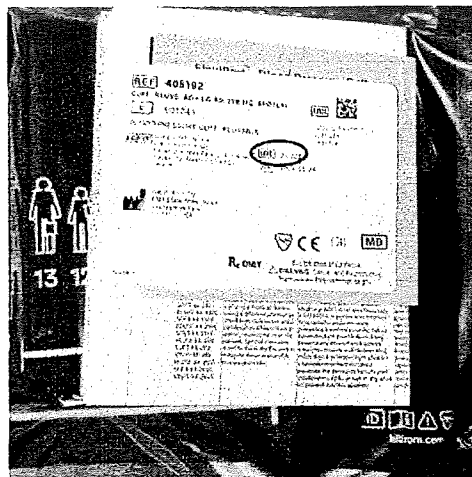


Figure 7 Blood Pressure Cuff Kit Packaging

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

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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

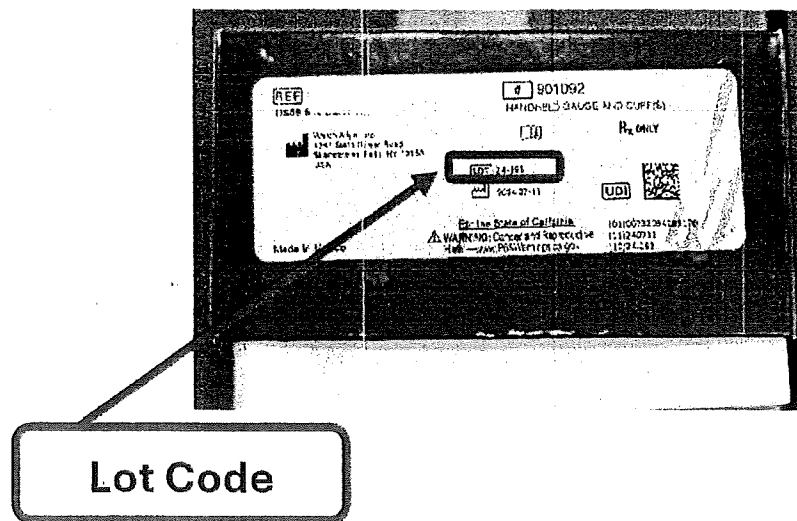


Figure 8 Welch Allyn DuraShock Aneroid Gauge Set with a Reusable Blood Pressure Cuff

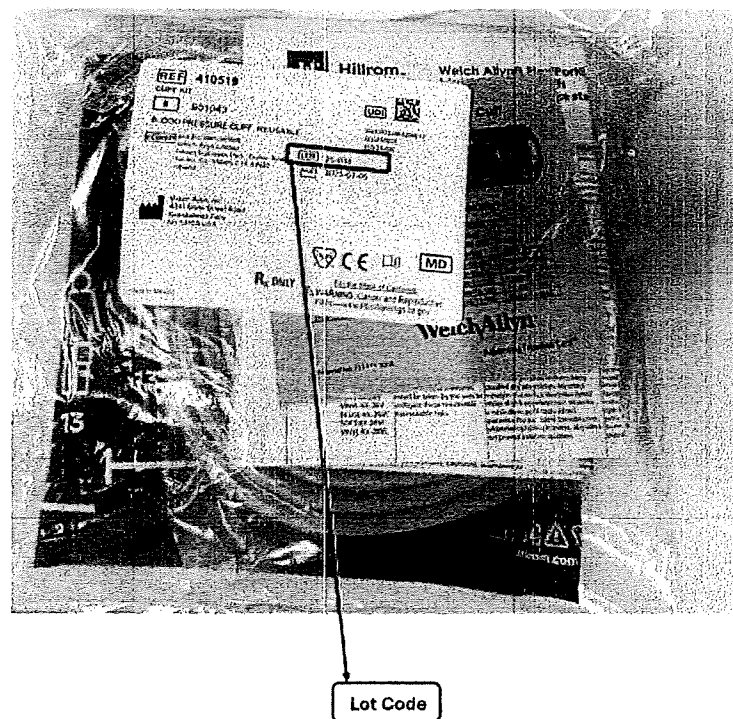


Figure 9 Welch Allyn 2-Piece Reusable Blood Pressure Cuff Kits Packaging

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.