

IMPORTANT PRODUCT INFORMATION

February 14, 2025

Dear Office Manager and/or Biomedical Engineering Department:

Baxter Healthcare Corporation is issuing this Important Product Information letter to inform customers that **Welch Allyn** non-automated blood pressure gauges may not meet leak and accuracy specifications following exposure to high temperature storage. Baxter recommends storing the devices at a temperature not exceeding the operating temperature of 40°C/104°F.

Affected Product


Product Code	Product Description	UDI Number
See Attachment A	Welch Allyn non-automated blood pressure gauges. See Attachment A for detailed, individual product descriptions.	See Attachment A

Hazard Involved

There is a remote risk that blood pressure gauges exposed to high-temperature storage could lead to inaccurate measurement of blood pressure or the inability to inflate the blood pressure cuff.

Actions to be Taken by Customers

- Customers may continue to use **Welch Allyn** non-automated blood pressure gauges if the device is calibrated. To check that the device is calibrated, please perform the following quick check of calibration as described in the product Instructions for Use.

At zero pressure, make certain the pointer is within the oval surrounding the zero-pressure gradation on the dial. If the pointer is fully outside of the tolerant zone (the darkly shaded area in the illustration) the device may need calibration. Although an unpressurized reading of zero does not guarantee accuracy at all scale points, failure of the pointer to indicate zero (± 3 mm Hg) is an obvious sign of error.
- For further information related to this product, visit the following link to the Instructions for Use: www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf
- If you received this communication directly from Baxter, acknowledge receipt by following the instructions on the enclosed reply form instruction sheet, even if you have no remaining inventory. Acknowledging receipt of this notification will prevent you from receiving repeat 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.
- If you purchased this product from a distributor or wholesaler, 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.
- Please forward a copy of this communication to the Director of Nursing and Facility Risk Manager/Patient Safety and any other departments within your institution who use the affected product.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please distribute this notification to them 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 #1 or #2 to select language preference, then press option #1, and then option #3.

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 #1 or #2 to select language preference, then press option #1, and then option #3
- 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 Form Instruction Sheet
Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges

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PRODUCT CODE	PRODUCT DESCRIPTION	UNIQUE DEVICE IDENTIFIER
2254	PSS-45CB WITH LARGE ADULT CUFF	20612479204120
105622	DS WALL UNIT GAUGE	00732094236569
400270	HANDHELD GAUGE, SHOCK RESISTANT CLASSIC	00732094055184
400271	INTEGRATED POCKET GAUGE, SHOCK RESISTANT CLASSIC	00732094055177
400272	POCKET GAUGE, CLIP, SHOCK RESISTANT CLASSIC	00732094055160
402297	DS45 PSS LOGO	00732094052763
407637	MOBILE ANEROID WITH ONE PIECE CUFF	00732094046755
407639	MOBILE ANEROID WITH TWO PIECE CUFF	00732094046748
407671	MOBILE ANEROID WITH NO CUFF	00732094046717
700875	GAUGE, DURASHOCK, WELCH ALLYN LOGO	00732094132335
704262	DS66 PURCHASED WITH MALE LUER	00732094128925
401183C	GAUGE, DURASHOCK, TYCOS LOGO IN METRO, CALIBRATED	00732094006773
44S964	GAUGE, DS45, WELCH ALLYN	00732094004533
44S965-1C	GAUGE, DURASHOCK, PSS, LOGO, CALIBRATED	00732094004502
5090-02	POCKET GAUGE WITH ADULT CUFF	00732094110609
5090-02CB	POCKET GAUGE WITH ADULT CUFF	00732094110579
5090-03	PCKT MDL - GAUGE ONLY	00732094110548
5090-41	POCKET GAUGE WITH LARGE ADULT CUFF	00732094110494
5090-41CB	POCKET GAUGE WITH LARGE ADULT CUFF	00732094110463
5098-02	CLASSIC HAND GAUGE, ADULT CUFF	00732094110128
5098-02CB	CLASSIC HAND GAUGE, ADULT TWO-PC CUFF	00732094110104
5098-03	CLASSIC HAND GAUGE, WITHOUT CUFF	00732094110081
5098-20	CLASSIC HAND, FAMILY PRACTICE KIT	00732094109955
5098-23	CLASSIC HAND, FAMILY PRACTICE KIT	00732094109900
5098-27	DS66 TRIGGER ANEROID, ADULT CUFF	00732094109856
5098-27CB	DS66 TRIGGER ANEROID, ADULT TWO-PC CUFF	00732094109825
5098-28	DS66 TRIGGER ANEROID, LG ADULT CUFF	00732094109801
5098-28CB	DS66 TRIGGER ANEROID, LG ADULT TWO-PC CUFF	00732094109788
5098-29	DS66 TRIGGER ANEROID, CHILD CUFF	00732094109764
5098-29CB	DS66 TRIGGER ANEROID, CHILD, TWO-PC CUFF	00732094109740
5098-30	DS66 TRIGGER ANEROID, WITH FOUR-CUFF KIT	00732094109726
5098-30CB	DS66 TRIGGER ANEROID, TWO-PC CUFF KIT	00732094109696
5098-31	DS66 TRIGGER ANEROID ONLY	00732094109672
5098-33	DS66 TRIGGER STUDENT BP CUFF SET	00732094109658
5098-42	DS66 TRIGGER STUDENT BP CUFF	00732094109603
5098-42CB	DS66 TRIGGER STUDENT BP TWO-PC CUFF	00732094109580
700875C	GAUGE, DURASHOCK, WELCH ALLYN LOGO, CALIBRATED	00732094079845
704262C	DS66 PURCHASED WITH MALE LUER, CALIBRATED	00732094079760
7670-01	767 WALL GAUGE, ADULT CUFF	00732094072099
7670-01C	767 WALL GAUGE, CHILD PRINT CUFF	00732094072075

Attachment A: Affected Welch Allyn Non-automated Blood Pressure Gauges

PRODUCT CODE	PRODUCT DESCRIPTION	UNIQUE DEVICE IDENTIFIER
7670-01CB	767 WALL GAUGE, TWO-PC CUFF	00732094072051
7670-01S	767 WALL GAUGE ONLY PLATFORM COLORS	00732094071986
7670-01W	767 INTEGRATED WALL GAUGE, ADULT CUFF	00732094071962
7670-02	767 WALL GAUGE, WITH 8 FT TUBING	00732094071788
7670-03	767 MOBILE GAUGE, ADULT, FOUR LEG BASE	00732094071764
7670-03CB	767 MOBILE GAUGE, ADULT, TWO-PC FOUR LEG BASE	00732094071740
7670-03K	767 MOBILE GAUGE, WITHOUT CUFF, FIVE LEG BASE	00732094071719
7670-10	767 MOBILE GAUGE, ADULT, FIVE LEG BASE	00732094071511
7670-10CB	767 MOBILE GAUGE, ADULT, TWO-PC, FIVE LEG BASE	00732094071399
7670-16	767 DESK GAUGE, ADULT CUFF	00732094071290
DS44	DURASHOCK, GAUGE ONLY	00732094085907
DS44-09	DURASHOCK, CHILD CUFF	00732094085884
DS44-09CB	DURASHOCK, CHILD TWO-PC CUFF	00732094085839
DS44-09P	DURASHOCK, CHILD PRINT CUFF	00732094085815
DS44-10	DURASHOCK, SMALL ADULT CUFF	00732094085662
DS44-11	DURASHOCK, ADULT CUFF	00732094085631
DS44-11BR	DURASHOCK, ADULT CUFF	00732094215779
DS44-11C	DURASHOCK, ADULT CUFF & CASE	00732094085617
DS44-11CB	DURASHOCK, ADULT TWO-PC CUFF	00732094085495
DS44-11CBT	DURASHOCK, ADULT TWO-PC CUFF, TYCOS DIAL	00732094085488
DS44-11CV	DURASHOCK, ADULT & CASE, VARIETY PACK	00732094085457
DS44-11V	DURASHOCK, ADULT CUFF, VARIETY PACKK	00732094085419
DS44-12	DURASHOCK, LARGE ADULT CUFF	00732094085389
DS44-12CB	DURASHOCK, LARGE ADULT TWO-PC CUFF	00732094085365
DS44-13CB	DURASHOCK, THIGH TWO-PC CUFF	00732094085341
DS44A	DURASHOCK, GAUGE ADAPTER	00732094084870
DS44A-001	DURASHOCK, FOR KENZ MEDICO	00732094084856
DS44-MC	DURASHOCK, DS44 MULTI CUFF KIT	00732094084924
DS45	DURASHOCK, GAUGE ONLY	00732094084832
DS45-09	DURASHOCK, CHILD CUFF	00732094084818
DS45-10	DURASHOCK, SMALL ADULT CUFF	00732094084634
DS45-11	DURASHOCK, ADULT CUFF	00732094084610
DS45-11C	DURASHOCK, ADULT CUFF & CASE	00732094084498
DS45-11CB	DURASHOCK, ADULT TWO-PC CUFF	00732094084474
DS45-12	DURASHOCK, LARGE ADULT CUFF	00732094084429
DS45-12CB	DURASHOCK, LARGE ADULT TWO-PC CUFF	00732094084405
DS45-13CB	DURASHOCK, THIGH TWO-PC CUFF	00732094084382
DS45A	DURASHOCK GAUGE ADAPTER	00732094083941
DS45-MC	DURASHOCK, DS45 MULTI CUFF KIT	00732094083965
DS48	DS48 GAUGE ONLY	00732094083927

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PRODUCT CODE	PRODUCT DESCRIPTION	UNIQUE DEVICE IDENTIFIER
DS48-11	DS48 WITH ADULT CUFF & CASE	00732094083903
DS48-11CB	DS48A WITH ADULT TWO-PC CUFF & CASE	00732094083880
DS48A	DS48A GAUGE ONLY	00732094083866
DS-5401-189	DS-54 MANOMETER SINGLE TUBE	00732094087369
DS-5501-300	DS-55 MANOMETER CHROME HIGHLIGHTS	00732094086881
DS5502000	DS55, SCALE SW. RING CHROME TWO TUBE	00732094195675
DS-5541-300	DS-55 MANOMETER RED HIGHLIGHTS	00732094086454
DS58	DS58 GAUGE ONLY	00732094083514
DS58-11	DS58 WITH ADULT CUFF & CASE	00732094083385
DS58-11CB	DS58 WITH ADULT TWO-PC CUFF & CASE	00732094083361
DS58-MC	DS58 FAMILY PRACTICE KIT	00732094083347
DS58-MCCB	DS58 FAMILY PRACTICE KIT WITH TWO-PC CUFFS	00732094083323
DS58-PD	DS58 PEDIATRIC KIT	00732094083309
DS58-PDCB	DS58 PEDIATRIC KIT WITH TWO-PC CUFFS	00732094083194
DS58-ST	DS58 STUDENT KIT	00732094083170
DS58-STCB	DS58 STUDENT KIT WITH TWO-PC CUFFS	00732094083149
DS-6501-189	DS-65 TRIGGER MODEL SILVER DURASHOCK	00732094086140
DS-6501-300	DS-65 TRIGGER MODEL SILVER-MAN	00732094086102
DS-6601-000	DS-66 TRIGGER MODEL PREMIUM	00732094195736
DS-6601-300	DS-66 TRIGGER MODEL PREMIUM	00732094085938