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2025-03-04

URGENT MEDICAL DEVICE SAFETY NOTICE
WELCH ALLYN Non-Automated Blood Pressure Gauges

R2504
1st Attempt

Baxter (formerly Welch Allyn) has advised The Stevens Company of a type III advisory for Welch Allyn non-automated blood pressure gauges. For a list of all impacted devices, please see Appendix A: List of Impacted Devices accompanying this notice.

Reason for Advisory

Baxter 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.



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.

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, Welch Allyn is directing users to the Instructions for Use: www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80025/80025959LITPDF.pdf

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Action Required (Due March 14, 2025)

1. Always ensure your non-automated blood pressure gauges are within calibration.
2. Notify all affected users, facilities or customers of the contents of this notice.
3. Complete the attached Acknowledgment and return by email to **regulatory-affairs@stevens.ca** or fax to 604-585-0193.

Even if you have no inventory of this product, please complete the Acknowledgment and check the appropriate box. Your response ensures that this recall is carried out effectively.

Thank you,
Steve Baker, CQIA
Regulatory Affairs & Quality Assurance Manager



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Appendix A

List of Impacted Devices

Product Name	Stevens Catalog #	Manufacturer #
DS66 TRIGGER ANEROID, ADULT CUFF	111#5098-27-SP	5098-27
DS66 TRIGGER ANEROID, W/4-CUFF KIT	111#5098-30-SP	5098-30
DURASHOCK, ADULT CUFF & CASE	111#DS44-11C-SP	DS44-11C
DS58 W/ ADULT CUFF & CASE	111#DS58-11-PROMO	DS58-11
DS58 W/ ADULT CUFF & CASE	111#DS58-11-SP	DS58-11
DS58 FAMILY PRACTICE KIT	111#DS58-MC-PROMO	DS58-MC
DS58 FAMILY PRACTICE KIT	111#DS58-MC-SP	DS58-MC
DS66 TRIGGER ANEROID, ADULT CUFF	111-5098-27	5098-27
DS66 TRIGGER ANEROID, ADULT 2-PC CUFF	111-5098-27CB	5098-27CB
DS66 TRIGGER ANEROID, LG ADULT CUFF	111-5098-28	5098-28
DS66 TRIGGER ANEROID, LG ADULT 2-PC CUFF	111-5098-28CB	5098-28CB
DS66 TRIGGER ANEROID, CHILD CUFF	111-5098-29	5098-29
DS66 TRIGGER ANEROID, W/4-CUFF KIT	111-5098-30	5098-30
DS66 TRIGGER ANEROID, 2-PC CUFF KIT	111-5098-30CB	5098-30CB
DS66 TRIGGER ANEROID ONLY	111-5098-31	5098-31
767 WALL GAGE, CHILD PRINT CUFF	111-7670-01	7670-01C
767 WALL GAGE, CHILD PRINT CUFF	111-7670-01C	7670-01C
767 WALL GAGE, ADULT 2-PC CUFF	111-7670-01CB	7670-01CB
767 WALL GAUGE ONLY PLATFORM COLORS	111-7670-01S	7670-01S
767 WALL GAGE, WITH 8' TUBING	111-7670-02	7670-02
767 MOBILE GAGE, ADULT, 4 LEG BASE	111-7670-03	7670-03
767 MOBILE GAGE, ADULT, 2-PC 4 LEG BASE	111-7670-03CB	7670-03CB
DURASHOCK, GAGE ONLY	111-DS44	DS44
DURASHOCK, CHILD CUFF	111-DS44-09	DS44-09
DURASHOCK, SMALL ADULT CUFF	111-DS44-10	DS44-10
DURASHOCK, ADULT CUFF & CASE	111-DS44-11	DS44-11C
DURASHOCK, ADULT CUFF & CASE	111-DS44-11C	DS44-11C
DURASHOCK, LARGE ADULT CUFF	111-DS44-12	DS44-12
DURASHOCK, THIGH 2-PC CUFF	111-DS44-13CB	DS44-13CB
DURASHOCK, DS44 MULTI CUFF KIT	111-DS44-MC	DS44-MC
DURASHOCK, GAGE ONLY	111-DS45	DS45
DURASHOCK, ADULT CUFF	111-DS45-11	DS45-11
DURASHOCK, ADULT CUFF & CASE	111-DS45-11C	DS45-11C
DURASHOCK, LARGE ADULT CUFF	111-DS45-12	DS45-12
DURASHOCK, THIGH 2-PC CUFF	111-DS45-13CB	DS45-13CB
DS48 GAUGE ONLY	111-DS48	DS48
DS48 W/ ADULT CUFF & CASE	111-DS48-11	DS48-11
DS48A W/ ADULT 2-PC CUFF & CASE	111-DS48-11CB	DS48-11CB
DS48A GAUGE ONLY	111-DS48A	DS48A
DS58 GAUGE ONLY	111-DS58	DS58
DS58 W/ ADULT CUFF & CASE	111-DS58-11	DS58-11
DS58 W/ ADULT 2-PC CUFF & CASE	111-DS58-11CB	DS58-11CB
DS58 FAMILY PRACTICE KIT	111-DS58-MC	DS58-MC
DS58 FAMILY PRACTICE KIT W/ 2-PC CUFFS	111-DS58-MCCB	DS58-MCCB
DS58 PEDIATRIC KIT	111-DS58-PD	DS58-PD
DS58 PEDIATRIC KIT W/ 2-PC CUFFS	111-DS58-PDCB	DS58-PDCB