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February 28, 2025

**Notice: Important Product Information Letter**

We have enclosed an important product information letter from Baxter Healthcare Corporation. They are the manufacturer of Hokanson’s DS400 sphygmomanometer products. Baxter has identified a potential hazard with the product and they are required under the United States and Canadian medical device regulations to notify customers of the issue. To accomplish this, they have issued an Important Product Information letter outlining the potential hazards and actions to address it. See attached.

Hokanson is required to forward this Important Product Information letter to our customers (you), and receive an acknowledgement from you, that you have received and understand the letter’s contents.

**Action:** Please sign and return this letter to Hokanson using one of the contact addresses listed below.

<b>Acknowledged By (Print &amp; Sign)</b>		<b>Date</b>	
<b>Facility Name &amp; Address</b>			
<b>Email &amp; Phone Number</b>			
<b>Comments</b>			

<b>Mail</b>	<b>Email:</b>	<b>Fax:</b>
D. E. Hokanson, Inc. 12840 NE 21 <sup>st</sup> Place Bellevue, WA 98005	<a href="mailto:regulatory@deh-inc.com">regulatory@deh-inc.com</a>	(425) 881-1636

If we do not receive a copy of this completed notice within 90 days from the date it was sent, we will accept that as acknowledgement that you have received and understood the Product Information Notification.

If you identify that your device is out of calibration, discontinue use and contact Hokanson at (425) 882-1689 or email us at [regulatory@deh-inc.com](mailto:regulatory@deh-inc.com) to receive instructions of how to return the device for re-calibration or repair.

If you have any questions or concerns about the Important Product Information letter, you may contact Hokanson at (425) 882-1689 or email us at [regulatory@deh-inc.com](mailto:regulatory@deh-inc.com). In addition, you may contact the manufacturer directly at Baxter Healthcare Corporation Technical Support, Monday through Friday between 8:00 am and 8:00 pm Eastern Time at (800) 535-6663. Please refer to the Baxter Healthcare product model number or product code 5098-31 for the DS400.

We apologize for any inconvenience this may have caused.

Sincerely,

Robert Melloy  
 Quality and Regulatory Manager  
 D. E. Hokanson, Inc.

# 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	<b>Welch Allyn</b> 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 ( $\pm 3$  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](http://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

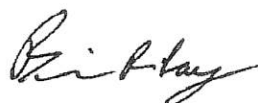
For general questions regarding this communication, please contact Baxter Technical Support between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday at 800-535-6663. Press option #2, then select #1 or #2 to select language preference, then press option #1, and then option #3.

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](http://www.accessdata.fda.gov/scripts/medwatch)
  - **Regular mail or Fax:** Download the form from [www.fda.gov/MedWatch/getforms.htm](http://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