Urgent Field Safety Notice

Welch Allyn non-automated blood pressure gauges.
FA-2024-071
Manufacturer: Welch Allyn, Inc (Single Registration Number: US-MF-000013394)
Important Product Information

February 14, 2025

Dear Customer,

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

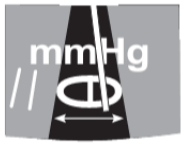
Product Code	Product Description	UDI Number
7670-10	767 MOBILE GAUGE,ADULT,5 LEG BASE	00732094071511

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

1. 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.
2. 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
3. Complete the enclosed customer reply form and return it to Baxter by e-mailing it to device.safety@drugsalesltd.com, even if you don't have any inventory. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.

4. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.

5. If you purchased this product from a distributor, please note that the Baxter customer reply form is not applicable. If a reply form is provided by your distributor or wholesaler, please return it to the supplier according to their instructions.

6. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) that distributed any affected product to other facilities, please notify your customers of this Correction in accordance with your customary procedures.

Further Information and Support

For general questions regarding this communication or any product issue you are experiencing, contact Drugsales Ltd on 21419070/1/2 or email: device.safety@drugsalesltd.com

The Malta Medicines Authority has been notified of this action.

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Adrian Busuttil
RP/Regulatory Affairs Manager Drugsales Ltd
Baxter Healthcare representative and distributor in Malta

Enclosures: Baxter Customer Reply Form