IMPORTANT PRODUCT INFORMATION

Mar 13, 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.

Product code	Product name
DS-6501-189	DS-65 TRIGGER MODEL SILVER DUR
7670-10	DS-65 TRIGGER MODEL SILVER DUR
7670-16	767 MOBILE GAGE,ADULT,5 LEG BASE
7670-01	767 DESK GAGE, ADULT CUFF
5098-27	DURASHOCK, ADULT CUFF & CASE

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 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.

4 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.

5.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.

.

Further Information and Support

The Medical Device Authority (MDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of this product may be reported via Malaysia_productcomplaint@baxter.com.

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

Sincerely,

Signature: Anju Shear *Electronically signed by: Anju Shear*
Reason: I approve this document
Date: Mar 13, 2025 13:17 GMT+5.5

Email: anju_shear@baxter.com

Anju Shear
QA Manager
Baxter Healthcare Corporation