



Urgent Field Safety Notice – Follow up Communication

ProBP 3400, Spot Vision Screener and Power Cords
FA-2024-017
Welch Allyn Inc (US-MF-000013394)
Type of Action: Correction

**Urgent Field
Safety Notice
Correction**

19 November, 2024

Dear Sir/Madam

On 24 April 2024 Baxter issued a Correction letter for the power cords used with the **Welch Allyn Connex** ProBP 3400 Digital Blood Pressure Device and **Welch Allyn Spot** Vision Screener. The issue was related to the power cord's insulation not meeting country-specific requirements and international electrical standards.

Baxter improved the power cord's insulation and is asking customers to submit a request for replacement power cords. See the Actions to be taken by Customers section for instructions on requesting replacement power cords.

Affected Product

Product Code	Description
106366	SPOT VS POWER SUPPLY SET/PLUG4/UK
34BFST-4	PROBP 3400, SUREBP, BLUETOOTH, MOBILE,UK
34BXST-4	PROBP 3400, BLUETOOTH, MOBILE, UK
34XFST-4	PROBP 3400, SUREBP, MOBILE, UK
34XXST-4	PROBP 3400, MOBILE, UK
4500-404	LINE CORD (UK)
PWCD-5WT-4	PROBP MOBILE STAND CORD ASSY UK
PWCD-6WT-4	PROBP MOBILE STAND CORD ASSY UK
VS100-4	SPOT VISION SCREENER,W/O CASE,PLUG4/UK
VS100S-4	SPOT VISION SCREENER,W/CASE,PLUG4/UK

Hazard Involved

Non-compliant power cords have a minimal increase in risk compared to compliant cords. Compliant cords are less susceptible to physical damage incurred over time due to the insulation being slightly thicker relative to the non-compliant cords. If a user is exposed to a visibly damaged power cord, the injury incurred would most likely be minor to moderate, such as discomfort, tingling, or a minor burn; more serious adverse health consequences may occur in rare situations and higher-risk populations. Baxter has not received any reports of patient injury associated with this potential safety issue.

Actions to be Taken by Customers

1. Please submit your request for replacement power cords by contacting Baxter customer support at HRC_ordersUK@baxter.com. Please have the following information ready when calling, if available: product name, product codes, quantity needed, facility contact details (contact name, phone number, and shipping address).
2. Healthcare providers may continue using the affected power cords while waiting for replacement power cords. If fraying or damage is observed, users should avoid contact with the cord and should discard the power cord immediately.



3. Healthcare providers should continue to regularly inspect the non-compliant power cords for fraying or other damage.
4. Once you receive replacement power cords, discard any non-compliant power cords.
5. Complete the enclosed customer reply form and return it to Baxter by scanning and e-mailing it to uk_shs_fca@baxter.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.
6. If you purchased this product from a distributor, please return their reply form as per their instructions.
7. If you distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
8. 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 Baxter at uk_shs_fca@baxter.com

The local Ministry of Health (MOH) has been notified of this action.

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

Sincerely,

Petra Bascones
Business Unit Head
Healthcare Systems and Technologies UKI & Nordics
Baxter Healthcare Limited

Enclosure A: Customer Reply Form



Enclosure A: Customer Reply Form

CUSTOMER REPLY FORM related to Product Correction letter FA-2024-017 updated 19 NOVEMBER 2024

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Please complete and return one copy of this form per facility by e-mail (uk_shs_fca@baxter.com) as confirmation that you have received this notification.

Facility Name	
Shipping Address	
Reply Confirmation Completed By <i>(Please Print):</i>	
Title <i>(Please print):</i>	
Email and/or Telephone Number <i>(including Area Code):</i>	

Please list the specific products and quantity of power cords required for your facility below*:

Product Description	Quantity power cords needed

*You may attach an additional sheet if required.

Your signature below indicates that you have received the attached letter; performed the actions as outlined in the letter as needed; and disseminated this information to staff and other services or facilities as applicable.

Signature/Date:	
REQUIRED FIELD	