

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

Urgent Field Correction

24 April 2024

Dear Sir/Madam

Problem Description

Baxter is issuing a Correction for the power cords used with the Welch Allyn Connex ProBP 3400 Digital Blood Pressure Device and Welch Allyn Spot Vision Screener. Baxter received reports of an issue related to the construction of the power cord not meeting the insulation rating per country-specific requirements and international electrical standards.

Baxter is currently working on obtaining replacement power cords and these will be provided to all impacted customers once the power cords are available for distribution.

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. Non-compliant cords are more susceptible to physical damage incurred over time due to the insulation being slightly thinner than the 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.



Action to be taken by the user

Baxter is kindly asking that you take the following actions:

1. Inspect the condition of the power cords. If fraying or other damage is observed, users should discard the power cord immediately.
2. Healthcare providers may continue to use the affected power cords after they are inspected for damage.
3. Healthcare providers should regularly inspect the power cords for fraying or other damage.
4. Once Baxter has replacement power cords, a follow-up notification will be sent with additional instructions on how to request replacement 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 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 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,

A handwritten signature in black ink, appearing to read 'PB', is positioned above the typed name.

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

Enclosure A: Customer Reply Form



Enclosure A: CUSTOMER REPLY FORM related to Product Correction letter FA -2024-017 dated 24 April 2024

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VS100-4	SPOT VISION SCREENER, W/O CASE, PLUG4/UK
VS100S-4	SPOT VISION SCREENER, W/CASE, PLUG4/UK

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 and Address:	
Reply Confirmation Completed By (Please Print):	
Title (Please print):	
Email and/or Telephone Number (including Area Code):	

Please list the specific products and lot numbers in your facility below*:

Product Code	Lot number

*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, other services or facilities, and customers as applicable.

Signature/Date:	
REQUIRED FIELD	_____