Urgent Field Safety Notice

Welch Allyn Connex Vital Signs Monitor (CVSM), CP150 Electrocardiograph & Connex Spot Monitor Accessory Power Management Stand (APM)

Field Action Reference: FA-2025-009
Manufacturer: Welch Allyn, Inc. (Single Registration Number: US-MF-000013394)
Type of Action: Correction

February 28, 2025 (to be adapted locally)

Dear Sir/Madam, (to be adapted locally)

Baxter Healthcare Corporation is issuing this Urgent Field Safety Correction Notice for the products listed below due to customer reports of devices which experienced battery-related fires. The investigation found that the devices in question were utilizing third-party, after-market batteries that are not approved by Baxter. Consistent with Baxter product labeling (Refer to Attachment A), the products should only be used with the approved Baxter / **Welch Allyn** battery (product code BATT99).

THE USE OF AN UNAPPROVED BATTERY MAY LEAD TO COMBUSTION, FIRE OR DEVICE PERFORMANCE ISSUES.

The impacted product was distributed in the United States beginning 8/16/2010. (to be adapted locally) Baxter will update the IFUs and service manuals to include instructions to only use a Baxter approved battery for replacement and highlight the risks associated with using an unapproved battery.

Affected Product (to be adapted locally)

<table>
<tr><th>Product Code</th><th>Product Description</th><th>Serial Number</th><th>UDI-DI Number</th></tr>
<tr><td rowspan="2">Refer to attachment B</td><td>Welch Allyn Connex Vital Signs Monitor (CVSM)</td><td rowspan="4">All</td><td rowspan="2">Refer to attachment B</td></tr>
<tr><td>Welch Allyn CP150 Electrocardiograph</td></tr>
<tr><td>75-HCA-CTB</td><td rowspan="3">Welch Allyn Connex Spot Monitor Accessory Power Management Stand (APM)</td><td>00732094240597</td></tr>
<tr><td>7000-APM</td><td>00732094210613</td></tr>
<tr><td>75-HCA-MTB</td><td>00732094240603</td></tr>
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Hazard Involved

The use of unapproved batteries may lead to various issues including inoperability of the device and thermal runaway, which may cause overheating, with the battery cell(s) catching on fire, or in extreme cases, a combustion reaction. Most patients will have minor to no injuries as a result, but patients at higher risk (those who are on oxygen, elderly, immobile, etc.) may have serious or critical consequences due to burns, smoke inhalation, or musculoskeletal injury. To date, Baxter received eight complaints related to this issue, however, there were no injuries reported.

Actions to be Taken by Customers

1. DO NOT USE UNAPPROVED BATTERIES. Baxter asks customers to only use the approved Baxter / **Welch Allyn** BATT99 battery, consistent with product labeling due to their safety and performance testing.
2. INSPECT ALL DEVICES. If you have a device identified in the affected product table above, check the device for the correct battery type. See Figure 1 below for examples of labels from approved batteries labelled with the BATT99 product code, “Welch Allyn”, and the Skaneateles Falls manufacturing facility address.

Figure 1: Examples of Label for Approved Batteries

3. STOP USING THE DEVICE if an unapproved battery is found.
4. IMMEDIATELY REPLACE THE UNAPPROVED BATTERY with an approved battery. Please contact your local Baxter sales representative to order the approved Baxter / Welch Allyn BATT99 batteries.
5. Complete the enclosed customer reply form and return it to Baxter by either scanning and e-mailing it to (insert local contact information) or sending it by post to (insert local contact information), 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 distribute this product to other facilities or departments within your institution, please forward a copy of this communication to them.
7. 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.
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 (insert local contact information), between the hours of (insert local information).

The local Ministry of Health (MOH) has been notified of this action. (to be adapted locally)

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

Sincerely,

Name (to be adapted locally)
Title (to be adapted locally)
Baxter Healthcare Corporation (to be adapted locally)

Enclosures: Attachment A: IFU Warning Statements Regarding Use of Approved Accessories
Attachment B: List of Affected Product Codes (to be adapted locally)
Baxter Customer Reply Form (to be adapted locally)