

URGENT MEDICAL DEVICE CORRECTION

March 19, 2025

**SECOND NOTICE
16 APR 2025**

Dear Office Manager, Biomedical Engineering, Risk Manager and/or Distributor,

Baxter Corporation is issuing this Urgent Medical Device Correction 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 Canada beginning 06-Oct-2010. 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

Product Code	Product Description	Serial Number
Refer to attachment B	Refer to attachment B	All

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. Please forward a copy of this communication to the Medical Director/Office Manager, Director of Biomedical Engineering, Patient Safety Officer, Risk Manager, Surgical Director and any other departments within your institution who use the affected product.
6. If you received this communication directly from Baxter, please complete the enclosed Baxter Customer Reply Form and return it to Baxter by faxing it to 1-888-490-4660 or scanning and e-mailing it to baxter@ptm-health.com. Returning the customer reply form promptly will confirm your receipt of this notification and prevent you from receiving repeat notices.
7. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter Customer Reply Form is not applicable. If a response is requested by your distributor or wholesaler, please respond to them 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 Urgent Medical Device Correction in accordance with your customary procedures and complete the applicable section on the reply form.

Further Information and Support

For general questions regarding this communication, please contact Baxter Technical support team at 1-800-267-2337 (Option 1 for English, Option 2 for French), or at hrc_canadiantechsupport@baxter.com.

Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options: Contacting Baxter Technical Support between the hours of 8:00 am and 8:00 pm Eastern Time, Monday through Friday at 800-535-6663. Press option 2, then select option 1 or 2 to select language preference, then press option 2.

Health Canada has been notified of this action.

We thank you for your attention to this urgent issue. Baxter is committed to providing approved BATT99 for use in your CVSM, APM Stand, and CP150 devices, and appreciates your actions related to the issue.

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

Sincerely,



Brandon Gingrich
Associate Director, Quality and Regulatory
Baxter Corporation - Canada

Enclosures: Attachment A: IFU Warning Statements Regarding Use of Approved Accessories
Attachment B: List of Affected Product Codes
Baxter Customer Reply Form

Attachment A - IFU Warning Statements Regarding Use of Approved Accessories
for CVSM, CSM (APM), and CP150 Devices**Welch Allyn Connex Vital Signs Monitor (CVSM)**

DIR 80029736, Version B



WARNING Use only Welch Allyn approved accessories, and use them according to the manufacturer's instructions for use. Using unapproved accessories with the monitor can affect patient and operator safety and can compromise product performance and accuracy.

Location: 2nd warning on Page 16**Welch Allyn Connex Spot Monitor Accessory Power Management Stand (APM) - Connex Spot Monitor**

DIR 80029757, Version A



WARNING Use only Welch Allyn approved accessories, and use them according to the manufacturer's directions for use. Using unapproved accessories with the monitor can affect patient and operator safety and can compromise product performance and accuracy, and void the product warranty.

Location: 3rd warning on Page 21**Welch Allyn CP150 Electrocardiograph**

DIR 80023839, Version A



WARNING Defective batteries can damage the electrocardiograph. Visually inspect the battery at least monthly, if the battery shows any signs of damage or cracking, it must be replaced immediately and only with a battery approved by Welch Allyn.

Location: 8th warning on Page 10

WARNING Use only parts and accessories, including thermal paper, that were supplied with the device and available through Welch Allyn. The use of accessories other than those specified may result in degraded performance or unsafe use of this device.

Location: 11th warning on Page 10

Material #	Material Description
63MTPX-B	VSM6300/SPM/ST/PR/PLUGB
63MTXX-B	VSM6300/SPM/ST/PLUGB
63MXPE-B	VSM6300/SPM/PR/IR/PLUGB
63MXPX-B	VSM6300/SPM/PR/PLUGB
63MXXE-B	VSM6300/SPM/IR/PLUGB
63MXXX-B	VSM6300/SPM/PLUGB
63NTPX-B	VSM6300/SPN/ST/PR/PLUGB
63NTXX-B	VSM6300/SPN/ST/PLUGB
63NXPE-B	VSM6300/SPN/PR/IR/PLUGB
63NXPX-B	VSM6300/SPN/PR/PLUGB
63NXXE-B	VSM6300/SPN/IR/PLUGB
63NXXX-B	VSM6300/SPN/PLUGB
63XTPX-B	VSM6300/ST/PR/PLUGB
63XTXX-B	VSM6300/ST/PLUGB
63XXPX-B	VSM6300/PR/PLUGB
63XXXE-B	VSM6300/IR/PLUGB
63XXXX-B	VSM6300/PLUGB
64MTPE-B	VSM6400/SPM/ST/PR/IR/PLUGB
64MTPX-B	VSM6400/SPM/ST/PR/PLUGB
64MTXE-B	VSM6400/SPM/ST/IR/PLUGB
64MTXX-B	VSM6400/SPM/ST/PLUGB
64MXPE-B	VSM6400/SPM/PR/IR/PLUGB
64MXPX-B	VSM6400/SPM/PR/PLUGB
64MXXE-B	VSM6400/SPM/IR/PLUGB
64MXXX-B	VSM6400/SPM/PLUGB
64NTPE-B	VSM6400/SPN/ST/PR/IR/PLUGB
64NTPX-B	VSM6400/SPN/ST/PR/PLUGB
64NTXE-B	VSM6400/SPN/ST/IR/PLUGB
64NTXX-B	VSM6400/SPN/ST/PLUGB
64NXPE-B	VSM6400/SPN/PR/IR/PLUGB
64NXPX-B	VSM6400/SPN/PR/PLUGB
64NXXE-B	VSM6400/SPN/IR/PLUGB
64NXXX-B	VSM6400/SPN/PLUGB
64XTPX-B	VSM6400/ST/PR/PLUGB
64XTXX-B	VSM6400/ST/PLUGB
64XXPX-B	VSM6400/PR/PLUGB
64XXXE-B	VSM6400/IR/PLUGB
64XXXX-B	VSM64/PLUGB
65HTXX-B	VSM6500/SPMHb/ST/RADIO/PLUGB
65MTPX-B	VSM6500/SPM/ST/PR/RADIO/PLUGB
65MTXE-B	VSM6500/SPM/ST/IR/PLUGB
65MTXX-B	VSM6500/SPM/ST/RADIO/PLUGB
65MXPX-B	VSM6500/SPM/PR/RADIO/PLUGB

Attachment B - List of impacted products

Material #	Material Description
65MXXE-B	VSM6500/SPM/IR/PLUGB
65MXXX-B	VSM6500/SPM/RADIO/PLUGB
65NTPX-B	VSM6500/SPN/ST/PR/RADIO/PLUGB
65NTXX-B	VSM6500/SPN/ST/RADIO/PLUGB
65NXPE-B	VSM6500/SPN/PR/IR/PLUGB
65NXPX-B	VSM6500/SPN/PR/RADIO/PLUGB
65NXXX-B	VSM6500/SPN/RADIO/PLUGB
65XTXX-B	VSM65/ST/RADIO/PLUGB
65XXXE-B	VSM6500/IR/PLUGB
65XXXX-B	VSM65/RADIO/PLUGB
67MCEP-B	VSM6700/SPM/CO2/IR/PR/PLUGB
67MCTP-B	VSM6700/SPM/CO2/ST/PR/PLUGB
67MCTP-B-ECG3A	VSM6700/SPM/CO2/ST/PR/PLUGB/ECG3A
67MCTX-B	VSM6700/SPM/CO2/ST/PLUGB
67MCXP-B	VSM6700/SPM/CO2/PR/PLUGB
67MCXX-B	VSM6700/SPM/CO2/PLUGB
67MXEP-B	VSM6700/SPM/IR/PR/PLUGB
67MXEX-B	VSM6700/SPM/IR/PLUGB
67MXTP-B	VSM6700/SPN/ST/PR/plugb
67MXTP-B-ECG3A	VSM6700/SPM/ST/PR/PLUGB/ECG3A
67MCTX-B	VSM6700/SPM/ST/PLUGB
67MXXP-B	VSM6700/SPM/PR/PLUGB
67MXXX-B	VSM6700/SPM/PLUGB
67NCTP-B	VSM6700/SPN/CO2/ST/PR/PLUGB
67NCTP-B-ECG3A	VSM6700/SPN/CO2/ST/PR/PLUGB/ECG3A
67NCTX-B	VSM6700/SPN/CO2/ST/PLUGB
67NCXP-B	VSM6700/SPN/CO2/PR/PLUGB
67NCXX-B	VSM6700/SPN/CO2/PLUGB
67NXEP-B	VSM6700/SPN/IR/PR/PLUGB
67NXEX-B	VSM6700/SPN/IR/PLUGB
67NXTP-B	VSM6700/SPN/ST/PR/PLUGB
67NXTP-B-ECG3A	6700/SPN/ST/PR/PLUGB/ECG3A
67NCTX-B	VSM6700/SPN/ST/PLUGB
67NXXP-B	VSM6700/SPN/PR/PLUGB
67NXXX-B	VSM6700/SPN/PLUGB
68MCTP-B	VSM6800/SPM/CO2/ST/PR/RADIO/PLUGB
68MCTP-B-ECG3A	VSM6800/SPM/CO2/ST/PR/RADIO/PLUGB/ECG3A
68MCTX-B	VSM6800/SPM/CO2/ST/RADIO/PLUGB
68MCXX-B	VSM6800/SPM/CO2/RADIO/PLUGB
68MRTP-B	VSM6800/SPM/RRa/ST/PR/RADIO/PLUGB
68MRTX-B	VSM6800/SPM/RRa/ST/RADIO/PLUGB
68MXDX-B	VSM6800/RADIO/SPM/ST/IR/PLUGB
68MXEP-B	VSM6800/SPM/IR/PR/RADIO/PLUGB

Attachment B - List of impacted products

Material #	Material Description
68MXEX-B	VSM6800/SPM/IR/RADIO/PLUGB
68MXTP-B	VSM6800/SPM/ST/PR/RADIO/PLUGB
68MXTP-B-ECG3A	VSM6800/SPM/ST/PR/RADIO/PLUGB/ECG3A
68MXTW-B	VSM6800/SPM/ST/CS/RADIO/PLUGB
68MXTX-B	VSM6800/SPM/ST/RADIO/PLUGB
68MXXP-B	VSM6800/SPM/PR/RADIO/PLUGB
68MXXX-B	VSM6800/SPM/RADIO/PLUGB
68NCEX-B	VSM6800/SPN/CO2/IR/RADIO/PLUGB
68NCEY-B	VSM6800/SPN/CO2/IR/PR/CS/RADIO/PLUGB
68NCTP-B	VSM6800/SPN/CO2/ST/PR/RADIO/PLUGB
68NCTP-B-ECG3A	VSM6800/SPN/CO2/ST/PR/RADIO/PLUGB/ECG3A
68NCTW-B	VSM6800/SPN/CO2/ST/CS/RADIO/PLUGB
68NCTX-B	VSM6800/SPN/CO2/ST/RADIO/PLUGB
68NSTP-B	VSM6800/SPN/ES/ST/PR/RADIO/PLUGB
68NXEP-B	VSM6800/SPN/IR/PR/RADIO/PLUGB
68NXEX-B	VSM6800/SPN/IR/RADIO/PLUGB
68NXTP-B	VSM6800/SPN/ST/PR/RADIO/PLUGB
68NXTP-B-ECG3A	VSM6800/SPN/ST/PR/RADIO/PLUGB/ECG3A
68NXTW-B	VSM6800/SPN/ST/CS/RADIO/PLUGB
68NXTX-B	VSM6800/SPN/ST/RADIO/PLUGB
68NXTX-BT	TRIAL, CVSM 6800 NELLCOR, ST
68NXXP-B	VSM6800/SPN/PR/RADIO/PLUGB
68NXXX-B	VSM6800/SPN/RADIO/PLUGB
7000-APM	CONNEX SPOT ACCY POWER MGMT STAND
BATT99	9 CELL LITHIUM ION BAT SINGLE PACK
CP150-1ENB	CP150_BASIC,AHA,D,EN,NA_PCORD
CP150-1FRB	CP150_BASIC,AHA,D,FR,NA_PCORD
CP150A-1ENB	CP150_INT,AHA,D,EN,NA_PCORD
CP150A-1FRB	CP150_INT,AHA,D,FR,NA_PCORD
CP150AS-1ENB	CP150_INT,AHA,SPIRO,D,EN,NA_PCORD
CP150AW-1ENB	CP150_INT,WIFI,AHA,D,EN,NA_PCORD

CUSTOMER REPLY FORM

URGENT MEDICAL DEVICE CORRECTION

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

March 19, 2025

Product Code	Product Description	Serial Number
Refer to Attachment B	Refer to Attachment B	All

Please complete this reply form even if there is no remaining inventory at your facility.
 Completion of the information below indicates that you (1) understand the contents of the attached letter, (2) performed the actions outlined, and (3) disseminated this information, if applicable.

Completed By: _____ **Title:** _____
Print Name

Phone Number: _____ **Email:** _____

Facility: Please circle the facility (or facilities) in the table below that you are responding for:

Ship-to Name	Shipping Address	Reference (for Baxter internal use only)
Levitt Safety Ltd	2872 Bristol Circle Oakville ON L6H 5T5	FAE-347 MA32497_625_2 (S2051)

Signature: _____ **Date:** _____ / _____ / _____
 DD MM YYYY

Email a scanned copy to baxter@ptm-health.com or fax it to **1-888-490-4660** as a confirmation that you have received this notification. A cover sheet is not required.

Please complete the below, if applicable

For Dealers, Wholesaler, Distributor/Reseller, or Original Equipment Manufacturer (OEM) Only - Check this box to indicate that your company has disseminated this communication to your direct customers.

Number of customers that received the affected product: _____

Number of customers that responded to this communication: _____

I have attached a copy of our Customer Response Tracking List (optional).