

## Medical Device Correction

**Subject: Potential Risk of fluid ingress associated with Welch Allyn® GS777 Wall Transformer (all models) and Connex® ProBP™ 3400 (handheld, desk mount, wall mount models)**

**FSCA-identifier:** MOD1329

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**Date:** April 22, 2021

**To:** Chief Executive; Facility Risk Manager; Facility Administrator; Facility Engineer; Vigilance Manager; Biomedical Engineering; Medical Device Liaison Officer; Distributor

Welch Allyn, Inc. (a Hill-Rom Company) is issuing this letter to notify you of the potential risk associated with inadvertent fluid ingress secondary to the cleaning of power supplies used with Welch Allyn GS777 Wall Transformer and Connex ProBP 3400 Blood Pressure Devices. The GS777 Wall Transformer was placed on the market in 2012 and is still being sold. The Connex ProBP 3400 Digital Blood Pressure Device was placed on the market in 2010 and is still being sold.

### **Potential Risk:**

There is a risk of an internal electrical short and possible electrical shock occurring if cleaning fluid ingresses into the power supply, and the power supply is plugged into the electrical outlet before the cleaning fluid has completely dried. This notice is being distributed to make users aware of this potential risk and provide instructions for appropriately cleaning the power supply.

The Welch Allyn GS777 is a device that is mounted either on the wall or on a mobile stand. It holds and supplies power to small handheld devices such as ophthalmoscope and otoscope heads. The Connex ProBP 3400 Blood Pressure Device (all models) is a digital blood pressure device that can be used in a handheld, wall-mounted, or mobile configuration.

GS777 Wall Transformer



Connex ProBP 3400 Blood Pressure Device

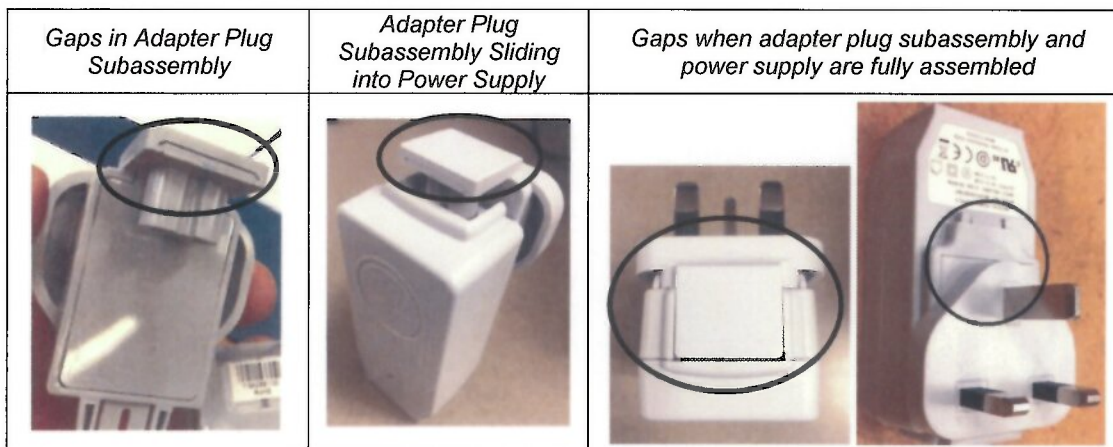


**Background:**

Hillrom has received 10 complaints regarding electrical shorts in the adapter plug assembly when plugging the power supply used with Welch Allyn GS777 Wall Transformers and Connex ProBP 3400 Mobile Blood Pressure Devices into an electrical outlet. To date, we are aware of one reported injury associated with this issue.

Our investigation has confirmed that the reported complaints were the result of unintentional fluid ingress into the power supply caused during cleaning.

Based on our investigation, unintentional fluid ingress is most likely to occur in the gaps of the adapter plug subassembly pictured below.



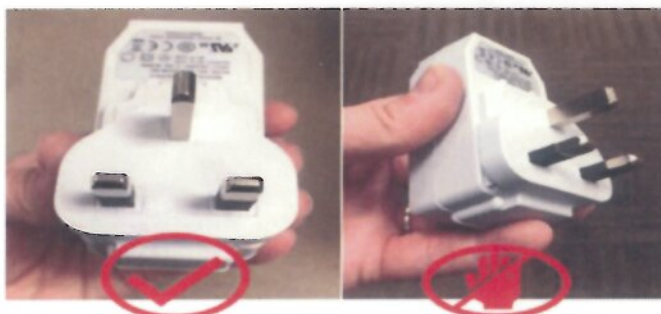
The GS777 and the Connex ProBP 3400 power supplies are not intended to be cleaned with saturated wipes and should not be plugged into an electrical outlet when wet.

**To minimize risk of potential electrical shock be sure to follow these cleaning recommendations:**

**When Cleaning is performed:**

1. Unplug the power supply from the outlet.
2. Make sure the cleaning cloth is not soaked (not dripping or over saturated) with cleaning fluid.
3. Apply minimal pressure on wipe when cleaning; avoid wiping gap areas identified on adapter plug as these areas are most susceptible to liquid ingress.
4. Make sure the power supply and power cord are dry before plugging into electrical outlet.
5. Hold the sides of the power supply when plugging into electrical outlet as pictured below.

Avoid contact with bottom of the power supply where cleaning fluid is mostly likely to have accumulated.



**Action to be taken by the user:**

Please share with potential users in your organization as a reminder to follow the instructions for the proper cleaning techniques. Complete the attached response form and return to [hillrom3880@stericycle.com](mailto:hillrom3880@stericycle.com) within one month.

**Action to be taken by the distributor:**

Please share with end users as a reminder to follow the instructions for the proper cleaning techniques. Complete the attached response form and return to [hillrom3880@stericycle.com](mailto:hillrom3880@stericycle.com) within one month. Contact [hillrom3880@stericycle.com](mailto:hillrom3880@stericycle.com) to receive an electronic copy of this notification and response form and further instructions for notifying your accounts.

**Actions being taken by Hillrom:**

The US Food and Drug Association (FDA) has been notified of this action.

Hillrom is in the process of updating the GS777 and the Connex ProBP 3400 Instructions for Use (IFU) to include the cleaning recommendations listed above. The IFU for the products may be found at these URLs:

GS777 Wall Transformer:

<https://www.hillrom.co.uk/content/dam/hillrom-aem/us/en/sap-documents/LIT/80026/80026575LITPDF.pdf>

Connex ProBP 3400:

<https://www.hillrom.com/content/dam/hillrom-aem/us/en/sap-documents/LIT/80021/80021999LITPDF.pdf>

These links will be updated with the new IFU cleaning instructions once available.

**Reporting adverse reactions or quality problems to the FDA:**

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** [www.fda.gov/medwatch/report/htm](http://www.fda.gov/medwatch/report/htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.



**Contact reference person:**

If you have any questions regarding this safety notice, please contact Hillrom Technical Support at 800-445-3720 or [us.service@hillrom.com](mailto:us.service@hillrom.com).

Hillrom considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification.

Yours sincerely

Hill-Rom Technical Support