

# IMPORTANT PRODUCT INFORMATION

September 17, 2025

Dear Healthcare Provider:

Baxter Healthcare Corporation is issuing a voluntary product recall for one lot of the oral/axillary probes used with the **Welch Allyn SureTemp Plus** thermometer. Baxter has identified that a small quantity of oral/axillary probes were inadvertently programmed with the rectal probe configuration. When connecting an affected oral/axillary probe to a **SureTemp Plus** thermometer, the thermometer will detect the affected probe as a rectal probe despite the probe's appearance and labeling as oral/axillary.

Under normal circumstances, the oral/axillary and the rectal probes can be distinguished by the color of the ejection button. The oral/axillary probe has a blue ejection button and probe well (See figure 1 below), and the rectal probe has a red ejection button and probe well (See figure 2 below).



*Figure 1. Oral/axillary probe with blue ejection button and probe well*



*Figure 2. Rectal probe with red ejection button and probe well*

Baxter is asking customers to return any affected product and submit a request for replacements. See the actions to be taken by customers section on page 2 for instructions on how to request replacements.

**Affected Product**

Product Code	Product Description	UDI-DI Number	Lot Number
02893-000	4 foot Probe Well kit, oral	00732094025873	612024

The oral/axillary probe well is an accessory, shipped and used with the potentially affected <b>Welch Allyn SureTemp Plus</b> thermometers listed below			
Product Code	Product Description	UDI Number	Serial Numbers
01690-200	<b>Welch Allyn SureTemp Plus</b> 690 thermometer	00732094029352	See Attachment
01690-400	<b>Welch Allyn SureTemp Plus</b> 690 thermometer	00732094029185	
01692-200	<b>Welch Allyn SureTemp Plus</b> 692 thermometer	00732094028980	

**Hazard Involved**

The use of a probe programmed with the wrong configuration will potentially display a lower temperature than the true value. This is not anticipated to result in significant adverse health consequences. Although unlikely, a patient's initial response to treatment may be ineffective, and there may be a delay in managing fever-related symptoms and/or infection requiring the initiation of appropriate therapy for the previously undetected clinical condition. To date, Baxter has not received any reports of injury associated with this issue.

### Actions to be Taken by Customers

1. See Attachment A for details on how to identify the affected product. If you have an affected product, please contact Baxter to request replacements using the contact details outlined below in Action #2.
2. If you have affected product, submit your request for replacement oral/axillary probe well kits or SureTemp Plus thermometers to Welch Allyn technical service by email to [hrc\\_physical\\_assessment@baxter.com](mailto:hrc_physical_assessment@baxter.com) or by calling 800-535-6663. Select the following sequence of options: 2 (technical support), 1(English), 1 (physical exam devices), 3 (thermometry), between the hours of 8:00 AM and 8:00 PM Eastern Time, Monday through Friday.
3. If you received this communication directly from Baxter, acknowledge receipt by following the instructions on the enclosed reply form instruction sheet, even if you have no remaining inventory. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from Accenture LLP on behalf of Baxter to confirm your receipt of this notification.
4. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to them according to their instructions.
5. Please forward a copy of this communication to the Director of Nursing, Facility Risk Manager/ Patient Safety, Biomedical Engineering Department, and any other departments within your institution who use the affected product.

### Further Information and Support

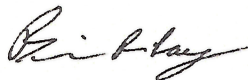
For general questions regarding this communication, please contact **Welch Allyn** technical service at 800-535-6663. Select the following sequence of options: 2 (technical support), 1(English), 1 (physical exam devices), 3 (thermometry), between the hours of 8:00 AM and 8:00 PM Eastern Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Contacting Welch Allyn technical service by sending an email to [hrc\\_physical\\_assessment@baxter.com](mailto:hrc_physical_assessment@baxter.com) or by calling 800-535-6663. Select the following sequence of options: 2 (technical support), 1(English), 1 (physical exam devices), 3 (thermometry), between the hours of 8:00 AM and 8:00 PM Eastern Time, Monday through Friday.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report at [www.accessdata.fda.gov/scripts/medwatch](http://www.accessdata.fda.gov/scripts/medwatch)
  - **Regular mail or Fax:** Download the form from [www.fda.gov/MedWatch/getforms.htm](http://www.fda.gov/MedWatch/getforms.htm) or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178

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

Sincerely,



Brian Ray  
Senior Director, Quality  
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form Instruction Sheet  
Attachment A: Instructions for Identifying Affected Product

## ATTACHMENT A: Instructions for Identifying Affected Product

### FOR PRODUCT IN USE

Connect the oral/axillary probe to the **SureTemp Plus** thermometer and remove the probe from probe well. If the display indicates oral/axillary mode active (See Figure 3 below), continue to use the device. If the display indicates that rectal mode is active (See Figure 4 below), please cease use of the affected product and request a replacement for the oral/axillary probe well kit (product code: 02893-000).

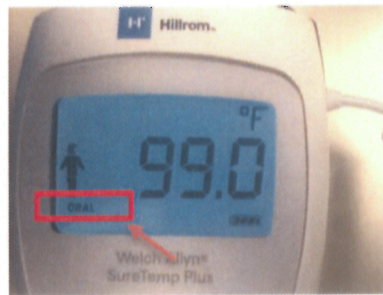


Figure 3. Oral/axillary mode active

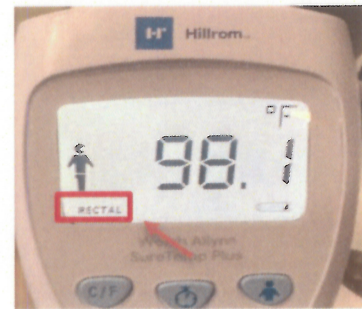


Figure 4. Rectal mode active

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### FOR UNOPENED PRODUCT

Review the package label to identify if you have the affected product:

- For **SureTemp Plus** thermometers, check the serial number located on the carton label (See Figure 5 below) against the list of serial numbers provided in the table attached.
- For oral/axillary probe well kits, check for **lot number 612024** (See Figure 6 below).

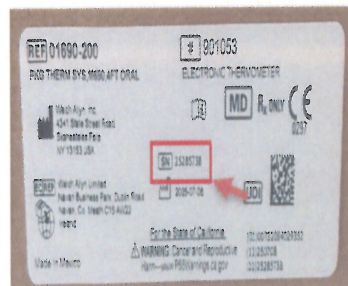


Figure 5. SureTemp Plus thermometer label (carton label) with serial number location highlighted

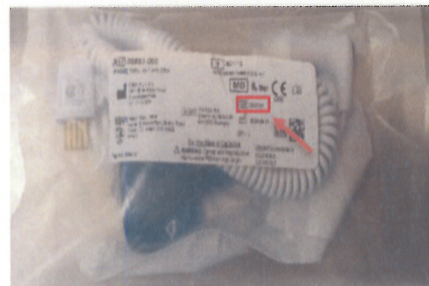


Figure 6. Oral/axillary probe well kit label with lot number location highlighted

## Instructions for Identifying Affected Product

### Affected Serial Numbers – Welch Allyn SureTemp Plus thermometers

The affected serial numbers for <b>Welch Allyn SureTemp Plus</b> 690 thermometers (product code: <b>01690-200</b> ) can be identified within the following:			
Serial number ranges			Serial numbers
24518445 - 24518874	25010002 - 25010249	25046829 - 25047328	25034683
24519158 - 24519234	25020903 - 25020909	25058685 - 25058894	25034770
24519236 - 24519433	25020911 - 25020931	25058898 - 25058907	25034800
24519435 - 24519858	25020933 - 25021402	25058970 - 25059569	25035092

The affected serial numbers for <b>Welch Allyn SureTemp Plus</b> 690 thermometers (product code: <b>01690-400</b> ) can be identified within the following:			
Serial number ranges			
24521201 - 24521350	25046327 - 25046416	25047330 - 25047371	25047373 - 25047539

The affected serial numbers for <b>Welch Allyn SureTemp Plus</b> 692 thermometers (product code: <b>01692-200</b> ) can be identified within the following:			
Serial number ranges			
24520619 - 24520718	25034684 - 25034769	25034988 - 25035085	25035097 - 25035296
24520720 - 24521199	25034771 - 25034799	25035087 - 25035091	25058910 - 25058965
25034363 - 25034682	25034801 - 25034984	25035093 - 25035095	