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6000 Nathan Lane North
Minneapolis, MN 55442
USA

URGENT: FIELD SAFETY NOTICE

Level 1® H-2 Pressure Chambers

8th August 2022

Dear Valued Customers:
Director of Risk Management
Director of Nursing
Director of Pharmacy

Smiths Medical is issuing this letter to notify you of a potential issue with specific Level 1® H-2 Pressure Chambers that are used with the Level 1® Fast Fluid Flow Fluid Warmers. This issue is in addition to the issue communicated in the Field Safety Notice issued October 06, 2021, regarding the potential for aluminum leaching. This letter details the potential issue, the affected models and the required steps to perform.

Issue:
Smiths Medical implemented a design change to widen the hinge assembly on the Level 1 H-2 Pressure Chambers used with the Level 1 Fast Flow Fluid Warmers (Models H-1025 or H-1200) or added to the H-1000 model. Smiths Medical has become aware that Level 1 H-2 Pressure Chambers with the wider hinge assembly can potentially impact the amount of pressure exerted onto the IV fluid bag while contained within the pressure chamber. This may result in decreased flow rate, stopped flow or residual fluid left within the IV bag.

Pressure chambers with the wide hinge assembly are more susceptible this issue in the following scenarios:
1) kinked tubing on the disposable administration sets.
2) use of the lowest flow rate disposables (DI-50, D-70 or DI-70) when delivering viscous fluids such as chilled blood from 300 mL or smaller IV bags.

Potential Risk:
Decreased flow rate, stopped flow or residual fluid left within the IV bag could potentially result in under-delivery or delay of therapy leading to potential inadvertent hypothermia, hypovolemia, and/or hypotension. To date, Smiths Medical has received three (3) reports of deaths and sixty-four (64) reports of serious injuries potentially related to this issue.

In addition to the risk described above, the following outstanding risk described in the Field Safety Notice issued October 06, 2021, regarding the potential for aluminum leaching remain: Exposure to toxic levels of aluminum could potentially lead to serious injury or possibly death, depending on the treatment being administered and the patient's condition. Symptoms of toxic levels of aluminum exposure may not be readily recognizable and exposure effects may vary including bone or muscle pain and weakness, anemia, seizures, or coma.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed in Switzerland between 19 December 2016 and 10 March 2022. Refer to Table 1 below for a list of affected devices and serial/lot numbers.

Table 1-List of Affected Devices

Affected Product Name	Affected Models	Serial Numbers / Lot Numbers
Level 1® H-2 Pressure Chamber	7204016 & 7204017	Serial Numbers: 44000173 to 44007145
Door Assembly H-2 Plus	7203020	All Lot Numbers

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Required Actions for Users:

To address the described risk, associated with the widened hinge assembly, users must be aware of whether their devices are affected or not, and follow the instructions below:

1. Identify all affected Level 1 H-2 Pressure Chambers in your possession:
   a. Identify the Level 1 H-2 Pressure Chamber serial number (SN). Refer to Figure 1 below for the location of the device SN.

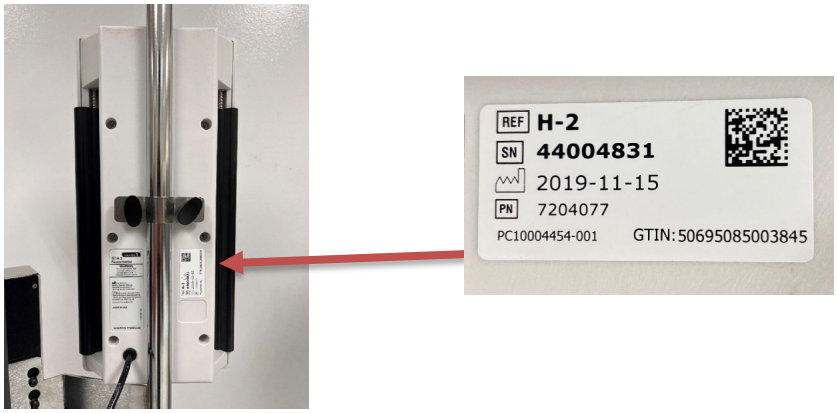

Figure 1: Location of Serial Number on H-2 Pressure Chamber

   b. Check the device's SN against Table 1 above.
      i. If you have a Level 1 H-2 Pressure Chamber with a serial number within the affected serial number range, then you have an affected device.
      ii. If you have a Level 1 H-2 Pressure Chamber with a serial number not included within the affected serial number range, then you will need to verify if the pressure chamber has been modified using a Level 1 H-2 Pressure Chamber Door and Latch Replacement Kit or the H-2 Plus Latch Assembly/Door Assembly. You can confirm this by measuring the width of the pressure chamber door/hinge and latch as shown in Figures 2-3 below.
      iii. If you have a Level 1® Pressure Chamber Door and Latch Replacement Kit, Latch Assembly H-2 Plus or Door Assembly H-2 Plus you will need to verify if these are the wide or narrow hinge assemblies. You can confirm this by measuring the width of the hinge assembly as shown in Figures 2-3 below.

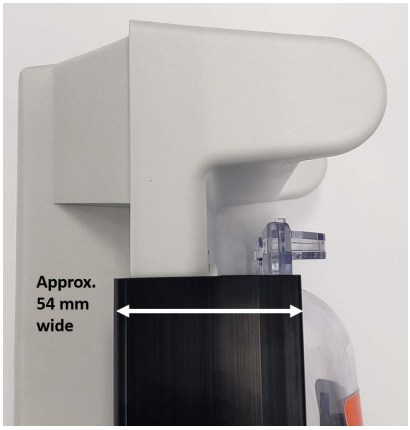

Figure 2: Wide Hinge Width 54mm (Affected Chambers)

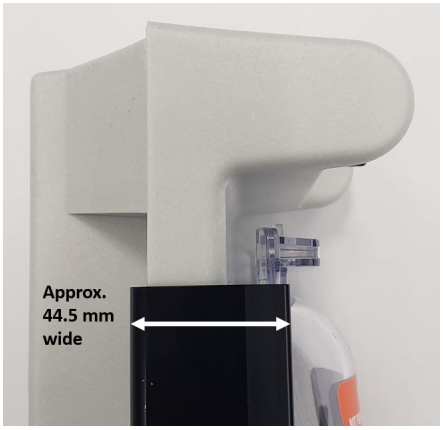

Figure 3: Narrow Hinge Width 44.5mm (Non-Affected Chambers)

2. If the device has the narrower hinge assembly as in Figure 3, then it is not affected, and you can continue to use the device per the instructions in 3b and 3c below.

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3. If the device has the wider hinge assembly as shown in Figure 2, then it is affected, and the hinge should be replaced. Smiths Medical will contact you when the replacement kit is available through the email id PressureChamberFieldCorrection@icumed.com. Until the replacement kit is available, please take the steps described below:
   a. Ensure all users of these devices are immediately made aware of this notification.
   b. Please continue to follow the instructions for users communicated in the Field Safety Notice issued October 6, 2021, which included temporary discontinuation of the Level 1 Fluid Warmer and Level 1 Fluid Warming System and directed users of these products to seek out alternative devices where available. For hospitals without alternative devices immediately available, an assessment on the use of these Level 1 Fluid Warmers should be limited primarily to the most urgent cases. In urgent cases where no replacement devices are available, and only for patients requiring ongoing therapy at ***slower flow rates***, Level 1® HOTLINE® products may be considered. Note, however, that these are not high flow devices and that the products subject to the October 6, 2021 FSCA are typically used in acute settings where high volumes of warmed fluids and blood are administered for clinical situations such as: trauma, post-partum hemorrhage and transplant.
   c. In the instances where the benefits of using the referenced Fluid Warmer products are greater than the potential risks identified in this notice and the notice issued October 6, 2021, and you choose to utilize the affected products per the Operator's Manual and IFUs until the wide hinge is replaced with a narrow hinge, please follow the warnings and cautions below:
      i. Ensure the IV bag intended for use fits properly in the pressure chamber. A hanging hook should be selected that allows the bag port to hang freely in the indented slot at the bottom of the chamber door. If the form of the IV bag does not allow the bag port to hang freely in the indented slot or affects the ability of the chamber door to close or latch, an alternate IV bag should be used.
      ii. As per the Operators Manual, verify that no tubing kinks are present. Use of disposables with kinked tubing can lead to slow or stopped flow over time, especially when using the affected devices. Inspect disposable administration sets for any kinks prior to and during use. Do not use any tubing with kinks and discard them.
      iii. Slow flow over time may be observed in affected devices and the therapy should continually be monitored for slowed flow.
      iv. When delivering viscous fluids such as chilled blood from 300 mL or smaller IV bags, avoid use of the low flow rate disposables such as DI-50, D-70 or DI-70.
      v. As per the Operators Manual, do not use autotransfusion bags.
      vi. The Level 1 Fast Flow Fluid Warmers should not be used to administer TPN solutions

Please inform potential users of the product in your organization of this notification and complete the attached response form. Return the completed form to the e-mail address on the form within 10 days of receipt to acknowledge your understanding of this notification, even if you do not have the affected product.

Distributors: If you have distributed the product further, immediately notify your accounts that received the product identified in the Table 1 above of this notification by providing them with a response form and asking them to complete it and return it to you.

Follow up Actions by Smiths Medical:

In the interest of deploying the correction to this issue in a timely manner, Smiths Medical will be providing a replacement kit and associated instructions to customers so they can modify any affected Level 1 H-2 Pressure Chambers with a narrower hinge assembly. Smiths Medical will contact customers when replacement kits are available. Please note that changing of the hinge by hospital personnel will not affect the warranty.

For further inquiries, please contact Smith Medical using the information provided below.

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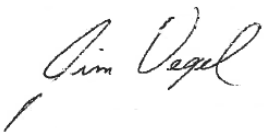
Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@smiths-medical.com	To report adverse events or product complaints
Customer Support	info@smiths-medical.ch	For any questions regarding this action, for additional information or technical assistance

The Competent (Regulatory) Authority of your country has been notified of this action.

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,



Jim Vegel
Vice President of Quality

Enclosures: Response Form

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

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Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-Quality@icumed.com, info@smiths-medical.ch and your local sales representative.

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

☐ **YES**, I have affected product, I have notified users in my facility and I have followed the instructions provided to me (complete and return this form to the e-mail addresses above)

☐ I have **NO** affected product (complete and return this form to the e-mail addresses above)

☐ Devices transferred/no longer owned; please indicate new owner contact information:

- Business Name: _____
- Address/City/State/ZIP: _____
- Contact Name: _____
- Contact Phone/E-mail Address: _____

- Have you distributed the product further to the retail level? ☐ **YES** ☐ **NO**
  - If yes, have you notified your retail customers by providing them with a response form and asking them to complete it and return it to you? ☐ **YES** ☐ **NO** (if no, explain below)

If you have distributed the product further, please provide the list of your retail customers, inclusive of customer name, address, city, state, zip code, telephone number and quantity of product distributed along with your completed response form to the contact information listed above so Smiths Medical can verify effectiveness of the recall notification to the appropriate level.

Adverse events and complaints associated with the use of these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (globalcomplaints@smiths-medical.com)