smiths medical
bringing technology to life

6000 Nathan Lane North
Minneapolis, MN 55442

URGENT: MEDICAL DEVICE CORRECTION

Level 1® H-2 Pressure Chambers

29 July 2022

Dear Valued Customers:

Director of Biomedical Engineering
Director of Nursing
Director of Risk Management
Anesthesia Department Personnel
Emergency Department Personnel
Operating Room Director

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 Flow Fluid Warmers. This letter details the potential issue, the affected models, and the required steps to perform.

Issue:

Smiths Medical implemented a design change (since 2015) to widen the hinge/latch 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/latch 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.

Level 1 H-2 Pressure chambers with the wide hinge/latch assembly are more susceptible to 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 which may lead to serious injury and death. To date, Smiths Medical has received three (3) reports of deaths and sixty-four (64) reports of serious injuries potentially related to this issue.

Affected Product:

Our records indicate that you may have received some of the affected products, which were distributed in the United States between 19 December 2016 and 10 March 2022 and any devices which have been modified with the wider hinge/latch. 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	7204012, 7204016, 7204017, 7204018, 7204019, 7204020, 7204030, 7204034, 7204036, 7204064, 7204065, 7204068, 7204071, 7204074, CON-7204012, H-2JP	Serial Numbers: 44000173 to 44007145 20030142, 20040790, 20051157, 20051158, S10001740, S10001741, S10002495, S10002589, S10006978, S10007279, S10008826, S109A02601, S109A03349, S109A03352, S109A03404, S109A05072, S109A06524, S109A06731

Level 1® Pressure Chamber Door and Latch Replacement Kit	7802722-DE, 7802722-EN	All Lot Numbers
Latch Assembly H-2 Plus	7203019	All Lot Numbers
Door Assembly H-2 Plus	7203020	All Lot Numbers

Required Actions for Users:

To address the described risk, 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.

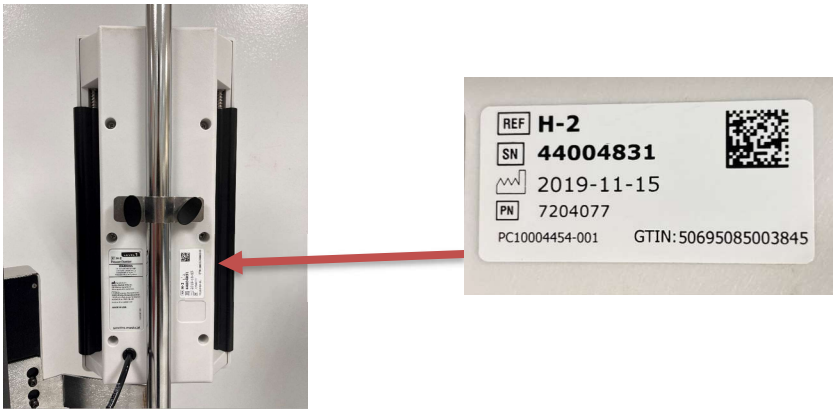

Figure 1: Location of Serial Number on H-2 Pressure Chamber

   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.

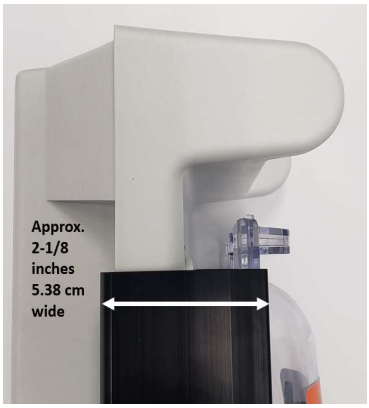

Figure 2: Wide Hinge/Latch Width 2-1/8 inches (5.38 cm) **(Affected Chambers)**

Figure 3: Narrow Hinge/Latch Width 1-3/4 inches (4.45 cm) **(Non-Affected Chambers)**

2. If the device has the narrower hinge/latch assembly as in Figure 3, then it is not affected, and you can continue to use the device per the Operator's Manual and IFUs.
3. If the device has the wider hinge/latch assembly as shown in Figure 2, then it is **affected,** and the hinge/latch 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. You may continue to use the affected device per the Operator's Manual and IFUs until the wide hinge/latch is replaced with a narrow hinge/latch by following 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 Dl-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.
        vii. Ensure that a manual pressure cuff to pressurize IV fluids is immediately available.

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 fax number or 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 and ask them to contact Sedgwick at 1-800-651-8198 (M-F, 8am-5pm ET) to obtain a response form.

Follow up Actions by Smiths Medical:
Smiths Medical will be providing a replacement kit to modify any affected Level 1 H-2 Pressure Chambers with a narrower hinge assembly. Smiths Medical will contact customers when replacement kits are available. In the meantime, Smiths Medical will be providing customers with a printable placard which may be secured to or displayed near the product with required key actions for users.

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

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@smiths-medical.com 1-(866)-216-8806	To report adverse events or product complaints
Device Correction Inquiries	1-(800)-241-4002, option 4, then prompt 1	For any questions regarding this action
Technical Assistance	1-(800)-258-5361, option 2, then prompt 6	Additional information or technical assistance

The U.S. Food and Drug Administration (FDA) has been notified of this action.

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

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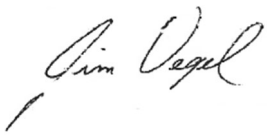
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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