smiths medical
bringing technology to life

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Smiths Medical Issues Urgent Medical Device Correction Letter Notifying Customers of a Potential Issue with Level 1® H-2 Pressure Chambers used with Level 1 Fast Fluid Flow Fluid Warmers

FOR IMMEDIATE RELEASE—August 3, 2022—Minneapolis, Minnesota—Smiths Medical issued an Urgent Medical Device Correction Letter to notify affected customers of a potential issue with specific Level 1® H-2 Pressure Chambers used with the Level 1 Fast Flow Fluid Warmers.

In 2015, Smiths Medical implemented a design change 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 it to the H-1000 model. The company has become aware that Level 1 H-2 Pressure Chambers with the wider hinge/latch assembly can potentially impact the pressure exerted onto the IV fluid bag while contained within the pressure chamber, which may result in decreased flow rate, stopped flow, or residual fluid left within the IV bag.

Affected product was distributed in the United States between December 19, 2016, and March 10, 2022. However, all Level 1 H-2 Pressure Chamber devices have the potential to be affected by this issue, because some devices may have received a hinge/latch replacement during that timeframe. 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

Decreased flow rate, stopped flow, or residual fluid left within the IV bag could 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.

Smiths Medical has sent all affected customers and distributors a letter outlining the risk and providing specific steps to determine whether their devices are affected or not and what steps to follow if they have affected product in service. A copy of that letter can be found here.

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 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
- 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

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