URGENT MEDICAL DEVICE CORRECTION

Medfusion™ Model 3500 and Model 4000 Syringe Infusion Pumps

16 August 2023:

Dear Valued Medfusion Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management

Smiths Medical is issuing this letter to notify you of a potential issue with the Medfusion Model 3500 and Model 4000 syringe infusion pumps. This notification details the issue, the affected models, and the required steps to perform.

Issue:
A force sensor in the occlusion detector may drift out of calibration leading to increased occlusion detection times, false occlusion alarms, or a System Failure Alarm. If the force sensor calibration shift is large enough, the pump will display a System Failure Alarm (including Force Sensor BGND Test, Force Sensor Bridge Test, or Force Sensor Test). However, if the calibration shift is not large enough to trigger a System Failure Alarm, the threshold to detect an occlusion may increase, increasing the time to occlusion detection, or the threshold may decrease, leading to false occlusion alarms. Although shifts in the force sensor calibration may occur over time with any device, an increased potential for such shifts has been reported in devices produced before April 2022 due to mechanical interference between parts of the plunger head assembly. Out of an abundance of caution, we are notifying all customers of this potential issue.

Potential Risk:
An increase in the threshold to detect an occlusion may result in a delay and interruption of therapy.

A decrease in the threshold to detect an occlusion may result in an interruption of therapy due to false occlusion alarms.

When the pump reports a System Failure Alarm, the pump sounds and displays an audible and visual alarm, and the infusion stops.

Delay in therapy, or interruption of therapy could lead to serious harm or death depending on the patient's condition, the therapy involved, and the time for which therapy is interrupted or delayed.

To date, Smiths Medical has received no reports of serious injuries or death related to this issue.

Affected Models:
This issue impacts all Medfusion Model 3500 and Medfusion Model 4000 syringe pumps. Medfusion Model 3500 v3 and v4 are affected by this issue, however since these pumps are no longer within their service life they should no longer be used for clinical care.

Actions to be taken by the Customer:

Actions for Clinical Users:

1. If the pump displays any of the System Failure Alarms noted above (including Force Sensor BGND Test, Force Sensor Bridge Test, or Force Sensor Test), remove the pump from service and obtain a backup pump.

Actions for Biomedical Users:

1. Ensure that all tests in the Annual Maintenance List are performed annually to ensure the continued safe operation of the Medfusion syringe pump. If all tests in the Annual Maintenance List have not been performed in the past 12 months, perform all of the tests in the Annual Maintenance List. For Medfusion syringe pumps less than a year old, you should perform all tests in the Annual Maintenance List including the Force Sensor Check now instead of waiting for the Annual Maintenance interval. Ensure that you are using the latest versions issued in 2023 of the Technical Service Manual (Model 3500 P/N 10012777-005; Model 4000 P/N 10014940-009). Please contact ICU Medical Technical Service to obtain the most recent version of the Technical Service Manual.

2. When performing the Force Sensor Check during the Annual Maintenance test, add the **NEW** verification step highlighted in **BOLD**:
    - Ensure that no syringe is loaded in the pump. Verify that the force reading on the screen is between -0.7 and +0.7 pounds.
    - **NEW:** Load the force gauge with the foot of the gauge positioned toward the head of the plunger driver. Zero the force gauge. **Using the thumbscrew of the force gauge bracket, increase the force applied until the force gauge reads 5 pounds (2.3 kilograms). Verify that the force reading on the screen is between 3.8 and 6.2 pounds.**
    - Using the thumbscrew of the force gauge bracket, increase the force applied until the force gauge reads 15 pounds (6.8 kilograms). Verify that the force reading on the screen is between 12.6 and 17.4 pounds.

3. If calibration cannot be completed, replace the plunger head. The entire plunger head assembly must be removed and replaced with the Plunger Head Service Kit (P/N 22-4003). DO NOT intermix used existing parts with new parts from the kit. Follow the instructions provided with the Plunger Head Service Kit to perform the replacement.

For further inquiries, please contact Smiths Medical using the following information:

Smiths Medical Contact	Contact Information	Areas of Support
Global Complaint Management	globalcomplaints@icumed.com 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	TSC.Support@icumed.com 1-800-241-4002, option 3 (M-F, 8:00 am-6:00 pm CT)	Additional information or technical assistance, including Technical Service Manuals

Field Corrections	FieldCorrections@icumed.com or contact your sales representative	Questions about this Field Correction Notice
Customer Service	customerservice@icumed.com USorder@icumed.com (800) 258-5361	Spare parts and calibration kits

Smiths Medical's Actions:

Smiths Medical is sending this notification to all impacted Medfusion customers.

Customer Required Actions

1. **Locate all Medfusion Model 3500 and Medfusion Model 4000 syringe pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations**.

2. **Ensure all Medfusion Model 3500 and Medfusion Model 4000 syringe pumps in your possession have undergone all tests in the Annual Maintenance List including the new Force Sensor Check within the past 12 months, including new pumps that have not yet undergone annual maintenance.**

3. Complete and return the attached Response Form to smithsmedical6995@sedgwick.com **within ten days of receipt** to acknowledge your understanding of this notification.

4. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to smithsmedical6995@sedgwick.com

General Information

This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

Jim Vegel
Vice President of Quality

Enclosures:
Attachment 1 – Urgent Medical Device Correction Response Form
Attachment 2 – Frequently Asked Questions

Medfusion™ Model 3500 & Model 4000 Field Action Frequently Asked Questions

Urgent Medical Device Correction

Smiths Medical is issuing an Urgent Medical Device Correction informing you about a potential issue with the Medfusion Model 3500 and Model 4000 syringe infusion pumps. Smiths Medical is notifying each affected customer and authorized distributor of this issue.

If you have questions about the performance of your Medfusion syringe pump, please contact Smiths Medical's Global Complaint Management at globalcomplaints@icumed.com.

1. Q What is the issue?

A force sensor in the occlusion detector may drift out of calibration leading to increased occlusion detection times, or a System Failure Alarm.

2. Q What is the potential risk?

An increase in the threshold to detect an occlusion may result in a delay and interruption of therapy.

A decrease in the threshold to detect an occlusion may result in an interruption of therapy due to false occlusion alarms.

When the pump reports a System Failure Alarm, the pump sounds and displays an audible and visual alarm, and the infusion stops.

Delay in therapy, or interruption of therapy could lead to serious harm or death depending on the patient's condition, the therapy involved, and the time for which therapy is interrupted or delayed.

3. Q What devices are affected?

The affected devices include all Medfusion Model 3500 pumps and all Medfusion Model 4000 pumps. All customers who purchased affected pumps will receive the notice and a response form that they are required to complete and return. The response form acknowledges that the customer has received the notice and understands the risks and actions they can take to mitigate them.

While Medfusion Model 3500 v3 and v4 are affected by this issue, they should no longer be used for clinical care as they are no longer within their service life.

Model	Final Shipment	End of Service and Support
Medfusion 3500 v3	Dec. 2014	Dec. 2019
Medfusion 3500 v4	Dec. 2014	Dec. 2019
Medfusion 3500 v5	Dec. 2019	Dec. 2024
Medfusion 3500 v6	August 2021	Dec. 2027

4. Q What action is Smiths Medical taking?

Smiths Medical is updating the Annual Maintenance testing process as described in the Notice.

5. Q **Has there been any patient harm related to the issues in the notice?**
   No. To date, Smiths Medical has received no reports of serious injuries or death related to this issue.

6. Q **What are the most recent versions of the Medfusion Technical Service Manual?**
   Smiths Medical published updated versions of the Technical Service Manual (TSM) in 2023. Please ensure you are using the most recent version:
   - Model 3500: P/N 10012777-005
   - Model 4000: P/N 10014940-009

7. Q **What update is being made to the Annual Maintenance test?**
   When performing the Force Sensor Check during the Annual Maintenance test, add a verification step as described in the Notice:

   NEW: Load the force gauge with the foot of the gauge positioned toward the head of the plunger driver. Zero the force gauge**. Using the thumbscrew of the force gauge bracket, increase the force applied until the force gauge reads 5 pounds (2.3 kilograms). Verify that the force reading on the screen is between 3.8 and 6.2 pounds.**

8. Q **What equipment is needed to perform the Force Sensor Check**
   The Analog Force Gauge is used to perform the Force Sensor Check. The Analog Force Gauge is part of the Medfusion Calibration Kit (P/N 3000CAL). Please contact ICU Medical Technical Support to order a Calibration Kit, if needed.

9. Q **If I have new Medfusion pumps and haven't performed the Annual Maintenance test yet, do I need to perform the Annual Maintenance test now?**
   Yes. Out of an abundance of caution, Smiths Medical recommends performing the Annual Maintenance testing as soon as reasonably practical.

10. Q **If a Medfusion pump has been through the Annual Maintenance test within the past twelve months, does it need to have the new force sensor verification test performed before the next Annual Maintenance test?**
    No. The updated force sensor test does not need to be completed proactively. Include the new verification step in the next regularly scheduled Annual Maintenance test.

11. Q **Have there been any customer complaints about these issues?**
    Yes. Customers have reported complaints about these issues.

12. Q **Can customers continue to use their Medfusion pumps?**
    Yes. Customers can continue to use their pumps by following the Actions for Users in the notice.

13. Q **How is the customer communication sent?**
    Smiths Medical is sending the notice to the Director of Risk Management, Director of Nursing, and Director of Biomedical Engineering of each facility. All Medfusion customers and distributors will receive a Notice, FAQs, and Response Form.

12. Q Is the information available online?
Yes. The notice and FAQs can be found at https://www.icumed.com/support/customer-communications-and-clinical-bulletins

13. Q Is this a voluntary action?
Yes. Smiths Medical is voluntarily taking this action.

14. Q Should customers return affected infusion pumps for remediation?
Customers do not need to return pumps

15. Q Who should I contact if I have additional questions?
Customers can contact ICU Medical's Technical Support Center at 1-(800)-258-5361.

16. Q Will Smiths Medical provide loaner pumps?
No.

17. Q Has Smiths Medical notified the FDA?
Yes.

18. Q Where can I find more information?

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Field Corrections	FieldCorrections@icumed.com or contact your sales representative	Questions about this Field Correction Notice
Customer Service	customerservice@icumed.com USorder@icumed.com (800) 258-5361	Spare parts and calibration kits