smiths medical

URGENT: FIELD SAFETY NOTICE

Medfusion™ Model 3500 Syringe Infusion Pump

29th November 2023

Dear Valued Medfusion Customers:

Smiths Medical is issuing this letter to notify you of the following potential Medfusion Model 3500 Syringe Infusion Pump issues. The issues identified below result from a historical review of records and apply to pump versions before v6.0.0.

This notification details the issues and the affected software versions. If you are unsure of the software version installed on your pumps, please note that the pump displays the software version on the startup screen after the pump is powered on.

Smiths Medical corrected all issues included in this notification in previous software updates and the corrections were carried forward into all subsequent software releases. Please ensure you have the most recent Medfusion software installed on your pumps.

Medfusion Model 3500 v3 and v4 are affected by some of the issues in the table below. However, since these pumps are no longer within their service life, they should no longer be used for clinical care.

List of Issues and Affected Software Versions

Issue	Description	Affected Version(s)	Corrected Software Version
1	**Delivery During Motor Not Running High Priority Alarm**	v3.X v4.X v5.0.0	v6.0.0 (2012)
2	**Infusion Restarted with Incorrect Parameters**	v4.X v5.0.0	v6.0.0 (2012)
3	**Screen Lock**	v4.1.5 v5.0.0	v6.0.0 (2012)
4	**Interruption of Bolus or Loading Dose Delivery**	v5.0.0	v6.0.0 (2012)
5	**Pump Displays Incorrect Bolus/Loading Dose**	v5.0.0	v6.0.0 (2012)
6	**Loading/Bolus Dose Below the Minimum Recommended Rate**	v5.0.0	v6.0.0 (2012)
7	**Motor Rate Error**	v5.0.0	v6.0.0 (2012)
8	**Incorrect Recall Last Settings**	v5.0.0	v6.0.0 (2012)
9	**Corrupt Configuration**	v5.0.0	v6.0.0 (2012)
10	**Auto Lock**	v5.0.0	v6.0.0 (2012)
11	**Toolbox Configuration Loading Dose Time Values**	v5.0.0	v6.0.0 (2012)

Issue 1 – Delivery During Motor Not Running High Priority Alarm

Overview of the Issue:
There is a rare scenario where the pump may continue delivering fluid when the Motor Not Running High Priority alarm condition should stop fluid delivery. If an alarm occurs simultaneously with a change in Delivery Mode (e.g., Loading Dose to Main Delivery, Main Delivery to KVO), the pump may continue delivery in the new Delivery Mode without the user addressing the alarm.

Potential Risk:
Continuing delivery during alarm conditions could result in over-delivery of medication to the patient. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v3.X, v4.X, and v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 2 – Infusion Restarted with Incorrect Parameters

Overview of the Issue:
An infusion could be restarted using the Continue Same Infusion feature with incorrect concentration values if the concentration units are changed after backing out of the infusion programming screens.

Potential Risk:
If the pump is running with incorrect delivery parameters, over or under infusion may occur. **To date, Smiths Medical has received a report of one serious injury potentially related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v4.X and v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 3 – Screen Lock

Overview of the Issue:
It is possible for the pump to become locked on a screen other than the Infusing screen. Once the issue occurs, all keys are locked, making it impossible to unlock the pump.

Potential Risk:
If the infusion is running and the user is unable to interact with the device, there is a possibility that this issue could lead to over-infusion. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v4.1.5 and v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 4 – Interruption of Bolus or Loading Dose Delivery

Overview of the Issue:
If the user presses the power key during a Bolus/Loading Dose delivery, the pump stops delivering the Bolus/Loading Dose and reverts to the normal infusion delivery. The pump will prompt the user to confirm they want to power off the pump.

Potential Risk:
Reverting to normal infusion delivery and stopping the Bolus/Loading Dose delivery could result in a delay or underdelivery of fluid to the patient. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 5 – Pump Displays Incorrect Bolus/Loading Dose

Overview of the Issue:
There is a scenario where the Bolus/Loading Dose screens may display incorrect values. The scenario does not affect the infusion; only the display is incorrect:

The pump will display the wrong values for Bolus/Load and Total Bolus/Loading Dose on the Begin Bolus/Loading Dose screen when these steps occur:

1. The user starts a DOSE/KG/HR infusion with concentration units of MG and delivery units of MCG.
2. The user presses the BOLUS button, chooses “CHG IN ML” and enters and accepts the default time.
3. If the user enters a large volume (e.g., 60 mL) on the CHG IN ML screen, the pump may display a smaller Bolus/Load dose and Total Bolus/Load dose than what the pump will deliver.

Potential Risk:
Displaying incorrect or conflicting information to users could potentially result in the user interrupting the therapy due to confusion, which may also cause a delay in therapy. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 6 – Loading/Bolus Dose Below the Minimum Recommended Rate

Overview of the Issue:
A Loading or Bolus Dose may be infusing below the Low Limit without notification to the user. Due to a calculation error, the pump may display a Low Limit which is too low for a given therapy.

Potential Risk:
Infusing below the Low Limit may result in delivery inaccuracies. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 7 – Motor Rate Error

Overview of the Issue:
A Motor Rate Error Alarm will occur after approximately 27 minutes of delivery if the pump is used with a Terumo or Monojet 3mL syringe and the delivery rate is 0.01 mL/hr. A Motor Rate Error Alarm indicates that the motor is not running at the programmed rate.

Potential Risk:
A Motor Rate Error stops delivery, which could result in a delay in therapy or interruption of therapy. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 8 – Incorrect Recall Last Settings

Overview of the Issue:
When recalling a completed DOSE/KG/TIME or DOSE/M2/TIME infusion, the value for DOSE may be recalled incorrectly. If the user navigates past the Enter Dose screen and then returns to the screen, the pump may use the default Dose value from the Configuration instead of the Dose from the last infusion.

Potential Risk:
Using the default Dose rather than the Dose from the last infusion may result in under or over delivery. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 9 – Corrupt Configuration

Overview of the Issue:
When a new Configuration is loaded to pump and the size is larger than the old Configuration size, the History Log may eventually write over the Configuration. If this issue occurs, the pump may display blank strings, changes in font size, or other unexpected behavior. This issue may also result in the pump displaying a Watchdog Failsafe alarm. Smiths Medical recommends always powering down the pump after loading a Configuration.

Potential Risk:
Corruption of the Configuration could result in a delay in therapy or interruption of therapy. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 10 – Auto Lock

Overview of the Issue:
If the user runs an infusion with an Auto Lock Timer set, presses START, waits for the Auto Lock to expire, and then presses the OPTIONS softkey as the Auto Lock duration expires, the pump will transition to the OPTIONS screen and become frozen.

Potential Risk:
If the infusion is running and the user is unable to interact with the device, there is a possibility that this issue could lead to over-infusion. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

Issue 11 – Toolbox Configuration Loading Dose Time Values

Overview of the Issue:
Medfusion Model 3500 pumps can read a configuration from a pump into PharmGuard Toolbox v1.5. If the configuration on the pump to be read contains a Loading Dose time (Lower Hard Limit, Lower Soft Limit, Initial Value, Upper Soft Limit, or Upper Hard Limit) greater than one hour, PharmGuard Toolbox v1.5 truncates the time such that only the minutes remain. None of the other Loading Dose programming parameters are affected.

Potential Risk:
If the pharmacist does not notice the truncation in their review of the configuration, incorrect time values can be used on pumps which could result in over-delivery of medication to the patient. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affected Medfusion Model 3500 pumps with software v5.0.0 and was addressed in software v6.0.0 (2012) and all subsequent versions.

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	To report adverse events or product complaints
Technical Support / Field Safety Notice	servicece@icumed.com	Additional information or technical assistance, Questions about this Field Safety Notice

Smiths Medical's Actions

Smiths Medical is sending this notification to all affected Medfusion customers and addressed the issues described in this notice through software updates. If you need the latest Medfusion software update, please contact Smiths Medical using the contact information above.

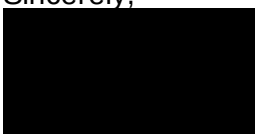
Customer Required Actions

1. **Locate all affected pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations. Please ensure you have the most recent Medfusion software installed on your pumps.**
2. Complete and return the attached Response Form to EMEA-FSN@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification.
3. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

General Information

Your country regulatory agency has been notified of this action.
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

***Note:** Response form on next page*

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

Medfusion™ Model 3500 Syringe Infusion Pump

29th November 2023

Check your inventory and complete the information below, even if you do not have the affected product.

Complete this form and return it by email to *EMEA-FSN@icumed.com*. If you have questions about this form please contact EMEA-FSN@icumed.com or 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 EMEA-FSN@icumed.com).

☐ I have **NO** affected product (complete and return this form to EMEA-FSN@icumed.com)

☐ 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 and asked them to contact Smiths Medical to obtain a response form? ☐ **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 this product should be reported and emailed to Smiths Medical's Global Complaint Management Department at globalcomplaints@icumed.com.