smiths medical

URGENT: FIELD SAFETY NOTICE

Medfusion™ Model 4000 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 4000 Syringe Infusion Pump issues. The issues identified below result from a historical review of records.

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.

List of Issues and Affected Software Versions

Issue	Description	Affected Version(s)		Corrected Software Version
1	**Delivery During Motor Not Running High Priority Alarm**	v1.0.0 v1.1.0	v1.1.1 v1.1.2	v1.5.0 (2014)
2	**Re-administered Loading Dose**	v1.0.0 v1.1.0	v1.1.1 v1.1.2	v1.5.0 (2014)
3	**Incorrect Critical Data Failure Alarm**	v1.0.0 v1.1.0	v1.1.1 v1.1.2	v1.5.0 (2014)
4	**Interruption of Bolus or Loading Dose Delivery**	v1.0.0 v1.1.0	v1.1.1 v1.1.2	v1.5.0 (2014)
5	**Incorrect Total Bolus/Loading Dose Displayed**	v1.1.0 v1.1.1	v1.1.2	v1.5.0 (2014)
6	**Volume Limit Before Bolus/Loading Dose Complete**	v1.1.2		v1.5.0 (2014)
7	**Drug Library Lower Limit Displayed Incorrectly**	v1.6.0	v1.6.1	v1.6.4 (2022)
8	**Depleted Battery Alarm**	All versions previous to v1.6.5		v1.6.5 (2023)
9	**Loss of Wireless Connectivity**	v1.5.0 v1.5.1 v1.6.0	v1.6.1 v1.6.4	v1.6.5 (2023)
10	**PharmGuard Server Password**	PharmGuard Server v2.3	v2.4 v2.5	v2.6 (2023)

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 4000 pumps with software v1.0.0, v1.1.0, v1.1.1, and v1.1.2 and was addressed in software v1.5 (2014) and all subsequent versions.

Issue 2 – Re-administered Loading Dose

Overview of the Issue:
The pump may re-administer a Loading Dose if the user presses STOP when there is less than 1 second remaining in the Loading Dose. If a Loading Dose delivery is STOPPED when the time remaining is between 0 and 1 second and the user presses the START key to continue the Loading Dose delivery, the pump will prompt the user to confirm the Loading Dose delivery with the previously programmed Loading Dose volume. If confirmed, the pump will re-administer the entire Loading Dose.

Potential Risk:
Re-administering the Loading Dose 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 4000 pumps with software v1.0.0, v1.1.0, v1.1.1, and v1.1.2 and was addressed in software v1.5 (2014) and all subsequent versions.

Issue 3 – Incorrect Critical Data Failure Alarm

Overview of the Issue:
During a self-test, the pump may incorrectly detect that a critical data block is corrupted. At the start of an infusion, certain specific combinations of parameters in the drug library can result in the pump displaying a “System Failure: Critical Data Block BGND Test” alarm when there is no issue with the critical data. This alarm should occur only if the background self-test shows the critical data block to be corrupted. In this case, the alarm message is displayed incorrectly.

Potential Risk:
The incorrect Critical Data Failure alarm may lead to a delay in the initiation of 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 4000 pumps with software v1.0.0, v1.1.0, v1.1.1, and v1.1.2 and was addressed in software v1.5 (2014) 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 4000 pumps with software v1.0.0, v1.1.0, v1.1.1, and v1.1.2 and was addressed in software v1.5 (2014) and all subsequent versions.

Issue 5 – Incorrect Total Bolus/Loading Dose Displayed

Overview of the Issue:
When using a Quick Library with Bolus Total Dose enabled in the configuration, the total Bolus/Loading Dose is displayed as “0” (zero) on the “Begin Bolus/Loading Dose Delivery” screen and the corresponding Bolus/Loading delivery screen for weight-based infusions. The Bolus/Loading Dose is delivered as programmed, but the per kilogram dose is incorrectly displayed.

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 4000 pumps with software v1.1.0, v1.1.1, and v1.1.2 and was addressed in software v1.5 (2014) and all subsequent versions.

Issue 6 – Volume Limit Before Bolus/Loading Dose Complete

Overview of the Issue:
When delivering a Bolus/Loading Dose, if the Volume Limit is reached before the Bolus/Loading Dose completes, the pump will continually prompt the user if they want to continue the Bolus/Loading Dose.

Potential Risk:
Stopping the Bolus/Loading Dose delivery 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 4000 pumps with software v1.1.2 and was addressed in software v1.5 (2014) and all subsequent versions.

Issue 7 – Drug Library Lower Limit Displayed Incorrectly

Overview of the Issue:
For single-digit doses (e.g., 0.000x mcg), the lower limit from the PharmGuard Toolbox drug library may not be correctly displayed on the pump (LOW). For example, if the lower limit in PharmGuard Toolbox is 0.0003, the pump may display a LOW limit of 0.0004.

Potential Risk:
Not being able to administer the lowest dose indicated by the Toolbox drug library could result in a delay in 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 4000 pumps with software v1.6.0 and v1.6.1 and was addressed in software v1.6.4 (2022) and all subsequent versions.

Issue 8 – Depleted Battery Alarm

Overview of the Issue:
Once a Depleted Battery alarm is activated, it should persist for three minutes. The battery monitoring algorithm comprises a lithium-ion smart battery and software within the pump. An internal analysis of the battery monitoring algorithm determined that the pump may not be able to meet the three-minute Depleted Battery alarm requirement consistently.

Potential Risk:
If the clinician is unaware of the depleted battery alarm due to a potentially shortened alarm duration, it may result in prolonged interruption or delay 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 4000 pumps with software versions before v1.6.5 and was addressed in software v1.6.5 (2023).

Actions for Clinical Users:
When using the pump on battery power, ensure sufficient battery charge for your intentions and monitor the charge in the battery.

Issue 9 – Loss of Wireless Connectivity

Overview of the Issue:
The WiFi connection between the pump and PharmGuard Server (PGS) may not be available for various reasons, including wireless signal strength at the point of use, the configuration of the wireless network, or lost network parameters on the pump. If the pump cannot communicate with PGS, any Drug Library updates intended for the pump cannot be downloaded. If the Medfusion 4000 pump operates in an environment without PGS, this issue has no impact.

Potential Risk:
Drug Library updates may not be downloaded to the pump when wireless connectivity is lost. **To date, Smiths Medical has received one report of a serious injury potentially related to an updated drug library not being available on the pump.**

Affected Models:
This issue affected Medfusion Model 4000 pumps with software v1.5.0, v1.5.1, v1.6.0, v1.6.1, and v1.6.4 and was addressed in software v1.6.5 (2023).

Actions for Clinical Users:
As indicated in the Medfusion Operator's Manual (pg. 115): It is a best practice to have a defined process for assuring that the new drug library update is installed on all pumps in a timely manner. Please note that manual programming is an option if the clinician cannot find the medication to be administered in the Drug Library.

Actions for Biomedical Users:
Ensure Medfusion Model 4000 pumps with software v1.5.0, v1.5.1, v1.6.0, v1.6.1, and v1.6.4 are updated with software v1.6.5.

Please note that wireless connectivity, configuration, latency, signal strength, and network saturation at the point of use may potentially lead to nuisance alarms.

Issue 10 – PharmGuard Server Password

Overview of the Issue:
If a user attempts to log into PharmGuard Server using LDAP and their password contains any of the HTML special characters [" ' < >], an error occurs. That error is logged in the PharmGuard WebUI log file and the log includes the attempted password recorded in plain text.

Potential Risk:
If this error occurs and someone has access to the Web Server's Windows file system, they could potentially unhide the hidden folder containing the application log files, open the PharmGuard WebUI log file, and find the error string containing the password that was entered. **To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.**

Affected Models:
This issue affected PharmGuard Server v2.3, 2.4, and v2.5 and was addressed in software v2.6 (2023).

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.

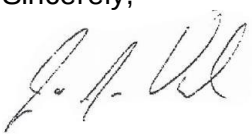
Customer Required Actions

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*

URGENT FIELD SAFETY NOTICE: RESPONSE FORM

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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.