**URGENT MEDICAL DEVICE FIELD SAFETY NOTICE**

**Medfusion™ 3500 and 4000 Syringe Infusion Pumps**

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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 potential issues with the Medfusion Syringe Infusion Pump. This notification details the issues, the affected models, and the required steps to perform. If you are unsure of the software version on your pumps, please note that the pump displays the software version on the startup screen after the pump is powered on.

As indicated in the Operator’s Manual, if the Medfusion pump is used to deliver life-sustaining medications, ensure an additional pump is available for situations where an interruption in infusion could be dangerous. If the Actions for Users for each issue aren’t adequate to resume infusion, use a different pump to continue the infusion.

**Issue 1 - Primary Audible Alarm (PAA)**

**Overview of the Issue:**

When notifications to the clinician are required, Medfusion pumps initiate an alarm with both visual and audible indicators. If the pump detects an issue with the audible portion of the alarm, a Primary Audible Alarm (PAA) System Fault is triggered, activating a backup alarm. If a PAA System Fault occurs, the pump terminates any active infusion and enters a Biomed only state. The PAA System Fault can occur during the Power-On Self-Test (POST) or from a background test (BGND) of the alarm circuit when sounding an alarm during infusion.

Under certain conditions, including excessive electrical interference, the pump may falsely detect a PAA System Fault. In these situations, the pump displays “System Failure: Primary Audible Alarm BGND Test” or “System Failure: Primary Audible Alarm POST,” terminates any active infusion and activates a backup audible alarm.

**Potential Risk:**

If this issue occurs, the pump sounds and displays an audible and visual alarm. Delay in therapy or interruption of therapy, which could lead to serious harm, are possible depending on the patient’s condition, the therapy involved, and the amount of time for which therapy is interrupted or delayed. To date, Smiths Medical has received reports of two serious injuries and one death potentially related to this issue.

**Affected Models:**

This issue impacts all Medfusion 4000 and Medfusion 3500 pumps.

**Actions for Users:**

1. Adhere to all warnings in the Operator’s Manual to reduce the potential for electrical interference. For Medfusion 4000, refer to pages 3, 120, and 123. For Medfusion 3500, refer to pages 3 and 115: “Warning: The pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the user should verify normal operation of the pump in the configuration in which it is to be used.”
2. If this issue occurs, the pump will display a “System Failure: Primary Audible Alarm BGND Test” or “System Failure: Primary Audible Alarm POST.” If this occurs, press the Power button to turn the pump off.
3. Press the Power button to turn the pump on. You can resume the infusion from the point when the alarm interrupted the infusion by following these steps:
	* Enter the Profile for the previous infusion. Then select the Recall Last Settings option from the menu. If the Recall Last Settings option isn’t shown, press the More softkey to display additional options.
	* Press Enter to confirm the syringe type and size if the syringe has been replaced. After the syringe has been confirmed, the Continue Same Infusion screen appears.
	* Press Yes on the Continue Same Infusion screen, confirm all delivery settings, and press the Start button to begin infusion.

**Note:** If a pump has a custom configuration created using PharmGuard Toolbox, the Recall Last Settings Option is available only in those profiles it has been included in.

**Issue 2 – Unanticipated Depleted Battery Alarms**

**Overview of the Issue:**

Medfusion 4000 pumps contain a smart lithium-ion battery pack that powers the pump when disconnected from AC power. The smart battery pack periodically communicates with the pump to alert the user when the battery is in a low charge or depleted state and to identify any issues communicating with the battery pack.

Under certain conditions with excessive wireless network activity, the pump may enter a state where the smart battery cannot provide its status to the pump. For example, some network settings, including Transport Layer Security (TLS), may cause excessive network activity. Smiths Medical only supports TLS version 1.0 on the Medfusion 4000 pump. If a version of TLS other than 1.0 is utilized, it may result in excessive network activity, leading to unanticipated depleted battery alarms.

If this situation occurs while the pump is connected to AC power, the pump will display a System Advisory: Battery Communication Timeout alarm. The Battery Communication Timeout (BCT) alarm will occur once and ongoing infusions will continue.

If the pump is unplugged and running on battery, the pump assumes the battery is depleted and sounds a Depleted Battery (DB) alarm, as shown in the following figure (Figure 1), without the Primary Low Battery alarm being triggered. Even if the battery contains sufficient charge capacity, any ongoing infusion will be interrupted.

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Figure 1: System Failure: Depleted Battery Alarm

**Potential Risk:**

If the pump is running on battery power and a Battery Communication Timeout (BCT) alarm occurs, the pump assumes the battery is depleted and issues a Depleted Battery alarm. If the pump is infusing, interruption of therapy may occur as a result. Depending on the patient’s condition, the type of medication being delivered, the length of time the therapy is interrupted, and the level of clinical supervision, prolonged symptoms and a potentially life-threatening situation could occur. To date, Smiths Medical has received reports of four serious injuries related to this issue.

**Affected Models:**

This issue impacts all Medfusion 4000 pumps up to and including version 1.6.1.

**Actions for Users:**

1. Consider disabling wireless communications, which will prevent the occurrence of this issue.
2. Ensure the network is configured to communicate with the pump using TLS 1.0 and validate all changes to network settings.
3. If the pump wireless remains active, keep the pump plugged into AC power.
4. If this issue occurs, press the Power button to turn the pump off.
5. Plug in the AC power cord, and turn the pump on. You can resume the infusion from the point when the alarm interrupted the infusion by following these steps:
	* Enter the Profile for the previous infusion. Then select the Recall Last Settings option from the menu. If the Recall Last Settings option isn’t shown, press the More softkey to display additional options.
	* Press Enter to confirm the syringe type and size if the syringe has been replaced. After the syringe has been confirmed, the Continue Same Infusion screen appears.
	* Press Yes on the Continue Same Infusion screen, confirm all delivery settings, and press the Start button to begin infusion.

**Note:** If a pump has a custom configuration created using PharmGuard Toolbox, the Recall Last Settings Option is available only in those profiles it has been included in.

**Issue 3 – Time Base Alarm**

**Overview of the Issue:**

A specific set of Medfusion pumps may contain a circuit board found to exhibit abnormal behavior in an internal clock. These boards were distributed after April 2021. If the abnormal behavior of these boards occurs during infusion, the pump stops the infusion and alarms for either “System Failure: Time Base BGND Test” or “System Failure: Background Self-Test Timeout.”

**Potential Risk:**

When the pump encounters this error, the pump alarms and stops the current infusion. Delay in therapy or interruption of therapy, which could lead to serious harm, are possible depending on the patient’s condition, the therapy involved, and the amount of time for which therapy is interrupted or delayed. To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.

**Affected Models:**

Medfusion 4000 pumps with serial numbers 2069340 through 2069369 and 2073210 through 2074471 and Medfusion 3500 pumps with serial numbers M117415 through M117444 and M118885 through M119358 are affected by this issue.

**Actions for Users:**

1. If this issue occurs, press the Power button to turn the pump off.
2. Press the Power button to turn the pump on. You can resume the infusion from the point when the alarm interrupted the infusion by following these steps:
	* Enter the Profile for the previous infusion. Then select the Recall Last Settings option from the menu. If the Recall Last Settings option isn’t shown, press the More softkey to display additional options.
	* Press Enter to confirm the syringe type and size if the syringe has been replaced. After the syringe has been confirmed, the Continue Same Infusion screen appears.
	* Press Yes on the Continue Same Infusion screen, confirm all delivery settings, and press the Start button to begin infusion.

**Note:** If a pump has a custom configuration created using PharmGuard Toolbox, the Recall Last Settings Option is available only in those profiles it has been included in.

1. Contact Smiths Medical for service and repair of these pumps.

**Issue 4 – Intermittent Volume Over Time (IVOT) - Infusion Continues after System Failure**

**Overview of the Issue:**

Medfusion pumps perform periodic tests to confirm the pump is operating as intended during infusion. The pump will sound a System Failure alarm if a problem is detected. If a System Failure alarm occurs, the pump alarms and stops any active infusion.

The Intermittent Volume Over Time (IVOT) delivery mode allows the specification of a delivery volume for a specific delivery time, after which the delivery stops for a programmed interval, then the pattern recycles. If a System Failure alarm occurs during the small window of time when the pump is transitioning from IVOT delay to IVOT delivery, the pump may continue to run without the ability to terminate infusion via the Stop or Power keys. In the following figure (Figure 2) , the green light indicates infusion is ongoing even though the pump displays a System Failure alarm.



Figure 2: Green light indicates IVOT Infusion Continues after System Failure

**Potential Risk:**

Failure of the pump to stop running in a System Failure condition could result in over-delivery of medication. To date, Smiths Medical has received reports of one serious injury potentially related to this issue.

**Affected Models:**

Medfusion 4000 pumps with firmware versions 1.0.0, 1.1.0, 1.1.1, or 1.1.2 and Medfusion 3500 pumps with firmware versions 6.0.0 or 6.0.1 are affected by this issue.

**Actions for Users:**

1. If this issue occurs, remove the syringe from the pump to stop infusion, and press the Power button to turn the pump off.
2. Press the Power button to turn the pump on. You can resume the infusion from the point when the alarm interrupted the infusion by following these steps:
	* Enter the Profile for the previous infusion. Then select the Recall Last Settings option from the menu. If the Recall Last Settings option isn’t shown, press the More softkey to display additional options.
	* Press Enter to confirm the syringe type and size if the syringe has been replaced. After the syringe has been confirmed, the Continue Same Infusion screen appears.
	* Press Yes on the Continue Same Infusion screen, confirm all delivery settings and press the Start button to begin infusion.

**Note:** If a pump has a custom configuration created using PharmGuard Toolbox, the Recall Last Settings Option is available only in those profiles it has been included in.

1. Do not use IVOT drug programs from the library.
2. Program each infusion separately instead of using the IVOT program.

**Issue 5 – Clearing of Program Volume Delivered (PVD)**

**Overview of the Issue:**

Clinicians can view the Program Volume Delivered (PVD) for the current infusion in most delivery modes. The PVD displays the infusion volume delivered since the clinician started the infusion. When two different syringe sizes or brands are used during the same volume-limited infusion, the PVD will be reset to zero during the syringe change. The volume of fluid delivered with the first syringe will not be accounted for in the PVD. Pausing and restarting an infusion with a new syringe size or brand may also elicit this behavior.

**Potential Risk:**

The inability to account for the previously delivered volume could result in over-delivery of medication to the patient and the need for medical intervention. To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue. This issue has only been observed internally.

**Affected Models:**

Medfusion 4000 pumps with firmware versions 1.0.0, 1.1.0, 1.1.1, or 1.1.2 and Medfusion 3500 pumps with firmware versions 5.0.0, 6.0.0, or 6.0.1 are affected by this issue.

**Actions for Users:**

1. Do not change to a different syringe size or brand during a volume-limited infusion.
2. If the syringe size or brand needs to be changed during a volume-limited infusion, program each syringe separately.

**Issue 6 – False Alarm for Rate Below Recommended Minimum for Syringe Size**

**Overview of the Issue:**

Under certain conditions, the pump may display a false “Rate Below Recommended Minimum for Syringe Size” alarm. The following figure (Figure 3) contains an example of this alarm screen.

For this issue to occur, there must be multiple syringe sizes of the same brand loaded in the configuration and the programmed flow rate must be lower than the recommended minimum rate for the largest syringe of the same brand in the configuration.

Under those conditions, two situations have the potential to lead to this false alarm.

1. The user changes syringes during infusion and the pump identifies the second syringe size to match the size of the first syringe.

OR

1. The user selects a medication with a Quick Library entry (protocols with prepopulated parameters), and the syringe loaded into the pump matches the syringe specified in the Quick Library.

In either condition, the pump uses the Recommended Minimum Rate for the largest syringe of the same brand in the configuration for the Rate Below Recommended Minimum Rate check instead of the Recommended Minimum Rate for the syringe loaded into the pump. There is no impact on delivery accuracy and the pump will display the correct syringe brand and size.

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Figure 3: False Rate Below Recommended Minimum for Syringe Size Alarm

**Potential Risk:**

The occurrence of a false “Rate Below Recommended Minimum for Syringe Size” alarm does not prevent programming or initiating an infusion but may lead to a delay in the initiation of therapy if the user changes to a smaller syringe. This false alarm scenario does not affect delivery. To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.

**Affected Models:**

Medfusion 4000 pumps with firmware versions up to and including version 1.6.1 and Medfusion 3500 pumps with firmware versions 6.0.0 or 6.0.1 are affected by this issue.

**Actions for Users:**

Confirm the syringe size chosen best fits the desired rate.

If this false alarm occurs, dismiss the alarm and continue with the infusion.

**Issue 7 – Incorrect Bolus or Loading Dose Time Display**

**Overview of the Issue:**

In rare situations, the pump may display an incorrect value for the time remaining during a Bolus Dose or Loading Dose infusion (see Figure 4). If this issue occurs, the pump will infuse correctly to the intended infusion time even though the displayed time remaining is incorrect. The pump appropriately transitions to continuous infusion upon completion of the Bolus Dose or Loading Dose as programmed.

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Figure 4: Example of Incorrect Time Remaining. “REMAINING 48:09 MM:SS” should be displayed as “REMAINING 04:09 MM:SS”

**Potential Risk:**

Displaying incorrect or conflicting information to users could potentially result in the user interrupting the therapy due to confusion. To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.

**Affected Models:**

Medfusion 4000 pumps with firmware versions up to and including version 1.6.1 and Medfusion 3500 pumps with firmware versions 6.0.0 or 6.0.1 are affected by this issue.

**Actions for Users:**

1. Verify that the displayed time remaining on the screen is the same as the intended time.
2. If the displayed time remaining is incorrect, monitor the Bolus or Loading Dose and verify that the infusion converts to the continuous infusion at the intended time.
3. An alternate option is to program the intended Loading Dose or Bolus Dose as a separate intermittent infusion.

**Issue 8 – Domain Name Server (DNS) Port 1001**

**Overview of the Issue:**

If a Medfusion 4000 pump is configured to use a Domain Name Server (DNS) and the wireless network is configured to disallow DNS communications over port 1001, the Medfusion 4000 pump will not communicate with the PharmGuard Server (PGS). The pump utilizes a fixed port number of 1001, which cannot be changed to any other port.

**Potential Risk:**

This issue may result in a delay in downloading updated drug libraries from PharmGuard. If a pump has an outdated drug library, there is a potential delay in the initialization of therapy. To date, Smiths Medical has not received reports of any serious injuries or deaths related to this issue.

**Affected Models:**

This issue impacts all Medfusion 4000 pumps up to and including version 1.6.1.

**Actions for Users:**

1. Do not change network configurations without validating Wi-Fi connectivity to the pump.
2. Consider using fixed IP addresses instead of network names.

Table 1 – List of Issues and Affected Models

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| Issue | Description | Affected Models | Affected Versions |
| 1 | **Primary Audible Alarm (PAA)** | **3500 and 4000** | All versions |
| 2 | **Unanticipated Depleted Battery Alarms** | **4000** | All versions through 1.6.1 |
| 3 | **Time Base Alarm** | **3500 and 4000** | **3500 S/N**M117415 - M117444M118885 - M119358**4000 S/N**2069340 - 20693692073210 - 2074471 |
| 4 | **Intermittent Volume Over Time (IVOT) - Infusion Continues after System Failure** | **3500 and 4000** | **3500**v6.0.0v6.0.1**4000**v1.0.0v1.1.1v1.1.1v1.1.2 |
| 5 | **Clearing of Program Volume Delivered (PVD)** | **3500 and 4000** | **3500**v5.0.0v6.0.0v6.0.1**4000**v1.0.0v1.1.0v1.1.1v1.1.2 |
| 6 | **False Alarm for Rate Below Recommended Minimum for Syringe Size** | **3500 and 4000** | **3500**V6.0.0V6.0.1**4000**All versions through 1.6.1 |
| 7 | **Incorrect Bolus or Loading Dose Time Display** | **3500 and 4000** | **3500**v6.0.0v6.0.1**4000**All versions through 1.6.1 |
| 8 | **Domain Name Server (DNS) Port 1001** | **4000** | All versions through 1.6.1 |

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

|  |  |  |
| --- | --- | --- |
| **Smiths Medical Contact** | **Contact Information** | **Areas of Support** |
| Global Complaint Management | globalcomplaints@smiths-medical.com1-(866)-216-8806 | To report adverse events or product complaints |
| Technical Assistance | 1-(800)-258-5361 | Additional information or technical assistance |
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**Smiths Medical’s Actions**

Smiths Medical is sending this notification to all impacted Medfusion customers. Smiths Medical intends to address the issues described in this notice through upcoming software releases and will update affected pumps that are within their Service Life at no charge. Smiths Medical will contact you to schedule the implementation of the software updates when the updates are released.

**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.
2. Complete and return the attached Response Form to OUS-SmithsMedfusion@sedgwick.com **within 10 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. Request that they complete the response form and return it to OUS-SmithsMedfusion@sedgwick.com

**General Information**

This notification is being performed with the knowledge of the regulatory authorities.

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 FSN Response Form

Attachment 2 – Frequently Asked Questions