

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Medfusion™ 3500 and 4000 Syringe Infusion Pumps

21st April 2022

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 eight 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.

List of Issues and Affected Products

Issue	Description	Affected Models	Affected Versions	Action
1	False Alarm for Primary Audible Alarm (PAA) System Failure	3500 and 4000	All versions	Until the problem is addressed, take corrective action
2	Unanticipated Depleted Battery Alarms	4000	All versions through 1.6.1	Until the problem is addressed, take corrective action
3	Abnormal Circuit Board Behavior May Cause Internal Clock System Failure	3500 and 4000	3500 S/N M117415 - M117444 M118885 - M119358 4000 S/N 2069340 - 2069369 2073210 - 2074471	Return to Smiths Medical
4	Intermittent Volume Over Time (IVOT) Delivery Mode - Infusion Continues after System Failure	3500 and 4000	3500 v6.0.0 v6.0.1 4000 v1.0.0 v1.1.0 v1.1.1 v1.1.2	Do not use IVOT delivery mode

5	Clearing of Program Volume Delivered (PVD)	3500 and 4000	<u>3500</u> v5.0.0 v6.0.0 v6.0.1 <u>4000</u> v1.0.0 v1.1.0 v1.1.1 v1.1.2	Do not change syringe size or brand during infusion
6	False Alarm for Rate Below Recommended Minimum for Syringe Size	3500 and 4000	<u>3500</u> V6.0.0 V6.0.1 <u>4000</u> All versions through 1.6.1	Until the problem is addressed, take corrective action
7	Incorrect Bolus or Loading Dose Time Display	3500 and 4000	<u>3500</u> v6.0.0 v6.0.1 <u>4000</u> All versions through 1.6.1	Until the problem is addressed, take corrective action
8	Network Configuration May Affect Pump Communications	4000	All versions through 1.6.1	Until the problem is addressed, take corrective action

Issue 1 – False Alarm for Primary Audible Alarm (PAA) System Failure

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 Failure is triggered, activating a backup alarm. If a PAA System Failure occurs, the pump terminates any active infusion and presents the option to enter the Biomed menu. The PAA System Failure 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 Failure**. In these situations, the pump displays “System Failure: Primary Audible Alarm BGND Test” or “System Failure: Primary Audible Alarm POST,” **stops any active infusion and activates a backup audible alarm**. The pump may be restarted and used to continue the infusion or may be removed from service if the alarm persists.

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 or death, 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 Clinical Users:

1. **Ensure backup pumps are readily available when infusing critical medications where interruptions or delays in therapy could cause serious injury or death.**
2. 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."
3. 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.
 - Press the Power button to turn the pump on.
 - **If the alarm persists, remove the pump from service and obtain a backup pump.**
 - If the alarm has resolved, 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.
 - If the alarm is not resolved, obtain a replacement pump and change the infusion to the replacement pump.

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 identify any issues communicating with the battery pack.

Under certain conditions with excessive pump 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 an unexpected 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.

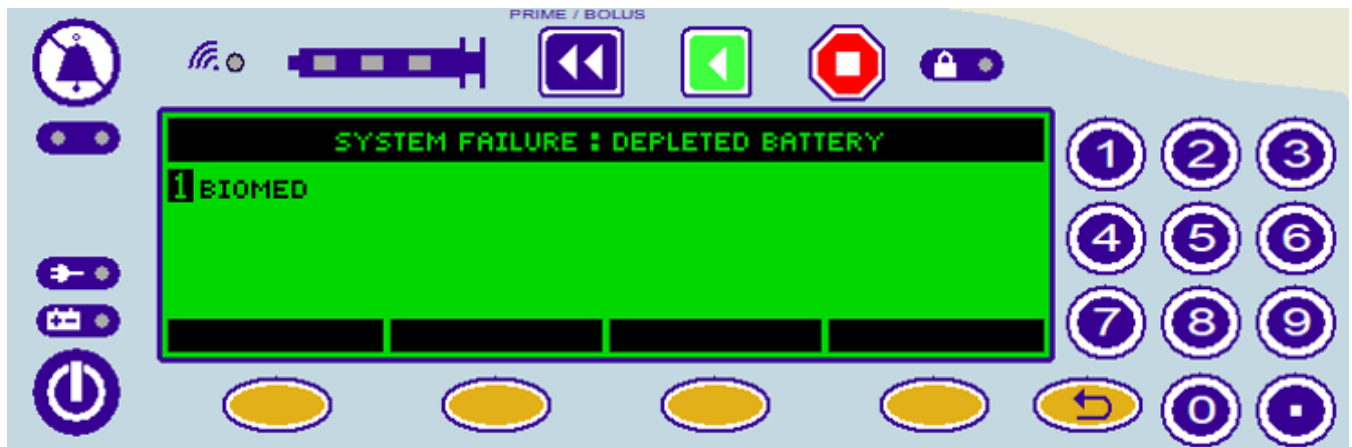


Figure 1: System Failure: Depleted Battery Alarm

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 an unexpected Depleted Battery alarm. If the pump is infusing, interruption or delay 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 Biomedical Engineers:

1. If you are using network settings that are not stated in the Medfusion Network Settings Manual, consider disabling pump wireless communications, which will prevent this issue. Inform clinical users at your facility regarding whether pump wireless communications are disabled. Also, ensure that you validate pump Wi-Fi connectivity after changing network settings.

Actions for Clinical Users:

1. **Ensure backup pumps are readily available when infusing critical medications where interruptions or delays in therapy could cause serious injury or death.**

2. Unless your facility informs you that pump wireless communications are disabled, **be aware that unexpected Depleted Battery alarms may occur** when batteries should have sufficient charge capacity **and that these alarms will stop the infusion.**
 3. Unless your facility informs you that they disabled pump wireless communications, **keep the pumps plugged into AC power whenever possible.**
 4. **If possible, do not use the pumps if they are disconnected from AC power.** If you must use the device on battery power, for example, when transporting a patient who has critical medications infusing, **bring backup pumps** to use in case this issue occurs. **Be aware that this issue may occur on backup pumps as well.** Plug the pumps back into AC power as soon as possible.
 5. If this issue occurs while a pump is on battery power:
 - Press the Power button to turn the pump off.
 - 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.
6. If this issue occurs while the pump is on AC power:
 - a. 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.
 - b. Do not disconnect the pump from AC power since the infusion will stop upon disconnection. If you must use the device on battery power or anticipate that this may be needed during the infusion, for example, when transporting a patient who has critical medications infusing, switch the patient to a **backup pump** prior to transport.

Issue 3 –Abnormal Circuit Board Behavior May Cause Internal Clock System Failure

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 pumps were distributed after April 2021. If the **abnormal behavior of these circuit 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 and death, 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 Clinical Users:

1. Ensure backup devices are readily available when infusing critical medications where interruptions or delays in therapy could cause serious injury or death
2. If this issue occurs,
 - Press the Power button to turn the pump off.
 - 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:
 - i. 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.
 - ii. 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.
 - iii. 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.
- After restarting the infusion, obtain a replacement pump and change the infusion to the replacement pump.
 - Remove the affected pump from service and send it to biomed for service.

Actions for Biomedical Engineers:

1. Contact Smiths Medical at Ireland.customer.service@smiths-medical.com or +35 31 29 41 13 3 for service and repair of these pumps.

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

Overview of the Issue:

Medfusion pumps perform periodic tests to confirm that the pump operates 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.

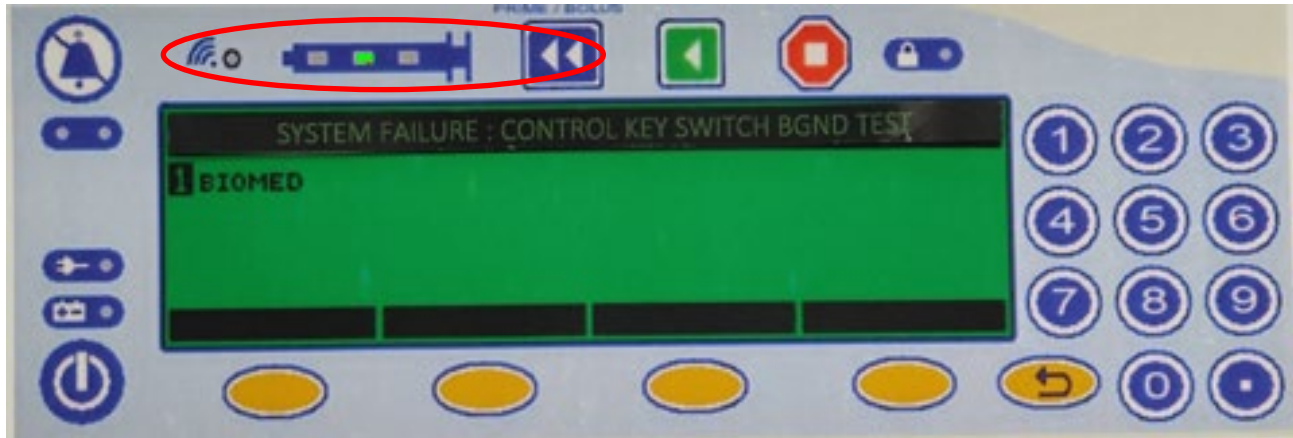


Figure 2: Green light indicates IVOT Infusion Continues after System Failure

Potential Risk:

Failure of the pump to stop running in a System Failure condition could result in over-delivery of medication which could cause serious harm or death. **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 Clinical Users:

1. **Do not use the IVOT delivery mode until this issue is fixed in a future software update.** Program each infusion separately instead of using the IVOT delivery mode program.
2. If an IVOT delivery mode program is inadvertently programmed and this issue occurs:
 - Immediately remove the syringe from the pump to stop the infusion, and press the Power button to turn the pump off.
 - 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:
 - iv. 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.
 - v. 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.
 - vi. 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 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, including serious injury or death. 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 Clinical 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.
3. Be aware that the Program Volume Delivered (PVD) may not be accurate if different syringe sizes or brands are used during the same volume limited infusion.

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

Overview of the Issue:

Under certain conditions, **the pump may use incorrect syringe parameters to determine if the programmed rate is below recommended minimum for the syringe size.** The pump will display a false “Rate Below Recommended Minimum for Syringe Size” alarm if this occurs, though the rate may be appropriate for the loaded syringe. 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 drug library 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, the following two situations when the pump doesn't prompt the user to confirm the syringe brand and size 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

- 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.

When this occurs, 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. Although this issue does not directly impact delivery accuracy, and the pump will display the correct syringe brand and size, **this issue has the potential to affect fluid delivery since it may impact the rapid occlusion detection ability of the pump. “Pressure Increasing” alarms may occur earlier than expected or have false alarms, either with or without an occlusion present.**

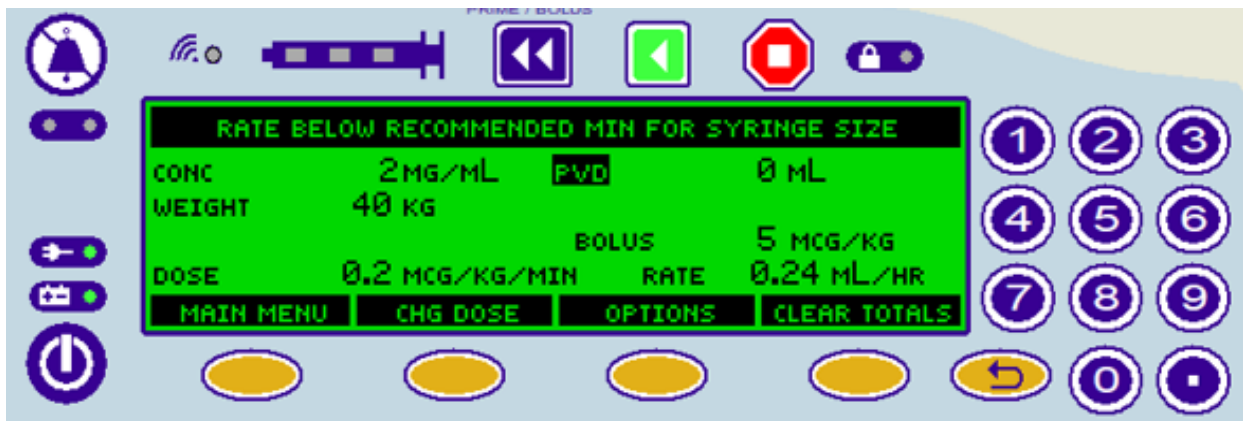


Figure 3: False Rate Below Recommended Minimum for Syringe Size Alarm

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. This issue may cause “Pressure Increasing” alarms to occur earlier than expected or have false alarms, either with or without an occlusion present, which may inappropriately interrupt infusions. This may also cause therapy delays while the clinician addresses the issue and reprograms the infusion. 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 Clinical Users:

- If multiple syringes are needed for an infusion, program each syringe as a new infusion.**
- If you see this false “Rate Below Recommended Minimum for Syringe Size” alarm notification, do not continue the infusion: clear the infusion and re-program the infusion with the desired infusion parameters and syringe.

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.



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, 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:

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 Clinical Users:

- When programming and monitoring Bolus Dose and Loading Dose infusions, verify that the displayed time remaining on the screen is the same as the intended time.
 - If the displayed time remaining is incorrect, your options include:**
 - Depending on the clinical scenario, including consideration of the patient condition and the medication, use your clinical judgement to determine if it is appropriate to continue the infusion with the incorrect remaining time displayed, while closely monitoring the Bolus or Loading Dose to verify that the infusion converts to the continuous infusion at the intended time.
 - Program the intended Loading Dose or Bolus Dose as a separate intermittent infusion. When the infusion completes, program the continuous infusion.
 - Be aware that the issue will recur if the pump (or a replacement pump) is programmed with the same Bolus Dose / Loading Dose, and continuous infusion.

Issue 8 –Network Configuration May Affect Pump Communications

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. If the pump cannot communicate with PGS, it may affect the ability to receive updated drug libraries and Smart Pump Programming (SPP) orders.

Potential Risk:

This issue may result in a delay in wirelessly downloading updated drug libraries from PharmGuard. If a pump has an outdated drug library, there is a potential delay in the initialization of therapy. In addition, if a clinician cannot send SPP orders to the pump, there may be a 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 impacts all Medfusion 4000 pumps up to and including version 1.6.1.

Actions for BioMedical Engineering Users:

1. If you plan to update your network's Domain Name Server, be aware that this issue may occur. Do not change network configurations without validating Wi-Fi connectivity to the pump.
2. If this issue affects your facility, consider using fixed IP addresses instead of network names. If you are using a fixed IP address, ensure that your network has added security measures such as a firewall.
3. Ensure that you communicate with the clinical users of the pumps regarding delays to planned drug library updates and if sending drug programs to the pumps will be impacted.

Actions for Clinical Users:

1. Be aware that there may be delays in updating drug libraries.
2. Be aware that this issue may affect the SPP ability of the pump. A clinician may not be able to send an SPP order to the pump and may need to program the pump manually.

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.com	To report adverse events or product complaints
Technical Assistance	Ireland.customer.service@smiths-medical.com +35 31 29 41 13 3	Additional information or technical assistance

Smiths Medical's Actions

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

For those customers with pumps affected by Issue #3 - Abnormal Circuit Board Behavior May Cause Internal Clock System Failure: Contact Smiths Medical at Ireland.customer.service@smiths-medical.com or +35 31 29 41 13 3 for service and repair.

For all 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

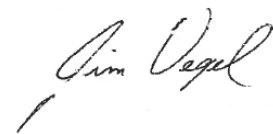
1. **Locate all affected pumps in your possession and ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.**
2. Complete and return the attached Response Form to OUS-SmithsMedfusion@sedgwick.com **within 10 days of receipt** to 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 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 Vogel
Vice President of Quality

Enclosures:

- Attachment 1 – Urgent Medical Device Field Safety Notice Response Form
- Attachment 2 – Frequently Asked Questions

URGENT MEDICAL DEVICE FIELD SAFETY NOTICE
RESPONSE FORM
Medfusion® 3500 and 4000 Syringe Infusion Pump

Business Name
Address 1
Address 2
Address 3
Address 4
City, State, Postal Code, Country

Please acknowledge receipt of the accompanying Urgent Medical Device Field Safety Notice by completing and returning this Response Form to OUS-SmithsMedfusion@sedgwick.com within 10 days. The Response Form must be completed and returned to Smiths Medical’s representatives at Sedgwick even if you have no affected devices in your possession.

DISTRIBUTORS – Please provide a copy of this Response Form and the accompanying Field Safety Notice to all of your customers to whom you distributed affected devices and complete the For Distributors Only table at the bottom of this page.

Please review the statements below and check the appropriate box:

- I do **NOT** have affected devices in my possession. *Proceed to sign acknowledgement below*
- I have affected devices in my possession. *Smiths Medical will contact you to arrange updates.*

I certify that I have read and understand the information in the attached Field Safety Notice.

Name and Title (Please Print)	Signature and Date	Facility Name and Address*
Email Address	Telephone Number	

*If you are submitting a response form for multiple locations, please include the address for each facility you are responding for on the form or in an attachment.

For Distributors Only

I have identified and notified my customers that were shipped or may have been shipped this product

Distributor Name, Address, Email and Phone Number

**Medfusion 3500 & 4000 Field Action
Frequently Asked Questions**

Urgent Medical Device Field Safety Notice

Smiths Medical is issuing an Urgent Medical Device Field Safety Notice informing affected customers about potential risks associated with eight issues with the Medfusion 3500 and 4000 syringe infusion pumps. Smiths Medical is notifying each affected customer and authorized distributors of these issues.

If you have questions about the performance of your Medfusion Syringe pump, please contact Smiths Medical’s Global Complaint Management at globalcomplaints@smiths-medical.com.

1. Q What are the issues?

Smiths Medical is issuing a Notice to inform customers of software issues that can potentially impact infusion delivery. The software issues, associated risks, recommended user actions, and affected models are described in the notice.

2. Q What is the potential risk?

The risk and actions to potentially mitigate the risk are described with each issue in the notice. Interruption of therapy, delay of therapy, and/or over-delivery may occur with certain issues as documented in the notice. Depending on a patient’s condition and the medication being delivered, the risks for patients may include serious injury or death.

3. Q What devices are affected?

The affected devices include all Medfusion 3500 pumps and all versions of the Medfusion 4000 pump. 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.

Medfusion 3500 v3 and v4 pumps are beyond their End-of-Service date and are not included in the scope of the software upgrade.

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 intends to address the issues described in the notice through upcoming software releases. We will update affected pumps within their Service Life at no charge. Smiths Medical will contact customers to schedule the implementation of the software updates when the updates are released.

The pumps that are eligible for the software updates related to this field action are limited to Medfusion pumps within their Service Life. Medfusion 3500 pumps manufactured as v3 or v4 pumps and subsequently updated to v5 or v6 are beyond their service life and are not eligible to receive the software update. For example, if a Medfusion 3500 v4 pump received a board replacement and software update to Medfusion 3500 v5, it is not eligible for the software update even though it operates as Medfusion 3500 v5.

For customers with pumps affected by Issue #3 - Abnormal Circuit Board May Cause Internal Clock System Failure, please contact Smiths Medical at Ireland.customer.service@smiths-medical.com or +35 31 29 41 13 3 to schedule service and repair of these pumps.

5. Q How can customers identify which pumps need corrective actions?

The pump displays the software version on the startup screen after the pump is powered on. Refer to the List of Issues and Affected Products in the notice for a list of affected models and issues.

6. Q Has there been any patient harm related to the issues in the notice?

Yes. Smiths Medical has received reports of several instances of patient harm, including serious injuries and one death related to a subset of these issues. Please refer to the notice for the detailed risk and reported harms associated with each issue.

7. Q Have there been any customer complaints about these issues?

Yes. Customers have reported complaints about these issues.

8. 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.

9. 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.

10. Q Is the information available online?

Yes. The Notice, and FAQs can be found at <https://www.smiths-medical.com/customer-support/alerts-and-notices>

11. Q Is this a voluntary action?

Yes. Smiths Medical is voluntarily taking this action.

12. Q Should customers return affected infusion pumps for remediation?

Customers do not need to return pumps except for the pumps impacted by Issue #3 – Abnormal Circuit Board Behavior May Cause Internal Clock System Failure.

Issue #3 - Abnormal Circuit Board Behavior May Cause Internal Clock System Failure - affects 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. Contact

Smiths Medical at Ireland.customer.service@smiths-medical.com or +35 31 29 41 13 3 for service and repair of these pumps.

13. Q Who should I contact if I have additional questions?

Customers can contact ICU Medical's Technical Support Center at Ireland.customer.service@smiths-medical.com or +35 31 29 41 13 3.

14. Q Will Smiths Medical provide loaner pumps?

No.

15. Q Has Smiths Medical notified the applicable Regulatory Authorities?

Yes.

21. Q How long will it take to perform the corrective action?

Typical inspection and software update (when available), reloading configuration, reloading drug libraries and performing the pump calibration, if needed, is expected to take about 1 hour per pump. Depending on the customer's pump population and other variables, Smiths Medical will define a team size for the customer's location. We will be able to typically process about eight pumps per day per service technician at the customer facility, subject to other variables.

For all issues, 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 customers to schedule the implementation of the software updates when the updates are released.

22. Q Can Smiths Medical perform additional services for the pumps while onsite?

The notice pertains to issues with the potential for risk. Smiths Medical will only focus on completing actions to mitigate the potential risk associated with these issues and any other open field actions.

23. Q Where can I find more information?

Smiths Medical Contact	Contact Information	Areas of Support:
Global Complaint Management	globalcomplaints@smiths-medical.com	To report adverse events or product complaints
Technical Assistance	Ireland.customer.service@smiths-medical.com +35 31 29 41 13 3	Additional information or technical assistance