smiths medical

6000 Nathan Lane N.
Minneapolis, MN 55442

URGENT: FIELD SAFETY NOTICE

CADD-Solis™ Ambulatory Infusion Pumps

27th March 2024

Dear Valued CADD-Solis Customers:

Smiths Medical is issuing this letter to notify you of the following potential CADD-Solis Ambulatory Infusion Pump issues. Most of the issues identified below result from a historical review of records.

This notification details the issues, the affected models and software versions. If you are unsure of the software versions 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 many of the 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 CADD software installed on your pumps when available.

List of Issues and Affected Versions:

Issue	Description	Affected Version(s)	* Corrected Version
1	**Upstream Occlusion**	CADD-Solis A, C, E, F v1.1.1 v1.1.2	v3.0.0 (2012)
2	**Stop and Power Keys Unresponsive**		
3	**Manual Mode Air Detector**		
4	**Single Bubble Air Detection**		
5	**Error Codes Not Displayed at Power Up**	CADD-Solis VIP v1.2.1 v1.2.2 v1.3 v1.4	v1.5 (2018)
6	**Audible Alarm**	CADD-Solis v4.0 v4.0.1 v4.1	v4.2 (2019)
7	**Low Sensitivity Air in Line Detection Threshold**	CADD-Solis v4.1 v4.2 CADD-Solis VIP v1.3 v1.4 v1.5	CADD-Solis v4.3 (2024) CADD-Solis VIP v1.6 (2024)
8	**PharmGuard Server Password**	PharmGuard Server v2.3 v2.4 v2.5	v2.6 (2023)

* Smiths Medical will contact you to schedule the implementation of the software updates when they are available.

Issue 1 – Upstream Occlusion

Overview of the Issue:
In the following scenario, the pump may not alarm for an upstream occlusion:

1. The upstream occlusion (USO) sensor is turned off in the protocol, the pump is infusing with an administration set and bag, and an upstream occlusion occurs
2. While the occlusion is present, an Administrator logs in with the administrator security code and enables the USO sensor

If nothing is done to clear the USO, the pump will be in delivery mode but not display an alarm for the upstream occlusion.

Potential Risk:
If an upstream occlusion is present without any audible or visual indication to the user, it may result in underdelivery 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 affects CADD-Solis pumps with software A, C, E, F, v1.1.1, and v1.1.2 and was addressed in software v3.0.0 (2012) and all subsequent versions.

Issue 2 – Stop and Power Keys Unresponsive

Overview of the Issue:
In the following scenario, the Start/Stop key may become unresponsive:

1. During an infusion, the user presses the Power key but doesn't make a selection (Yes/No) on the confirmation screen
2. After two minutes, the pump reverts to the Home screen
3. In this state, the pump is running, but any input to the Start/Stop and Power keys is ignored

Potential Risk:
Continuing infusion after the user attempts to stop the pump 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 affects CADD-Solis pumps with software A, C, E, F, v1.1.1, and v1.1.2 and was addressed in software v3.0.0 (2012) and all subsequent versions.

Issue 3 – Manual Mode Air Detector

Overview of the Issue:
If the user selects a protocol from the library with the Air Detector turned off and subsequently selects to program the pump in Manual Mode, the Air Detector remains off. In Manual Mode, the Air Detector should be turned on, but in this case, it remains off.

Potential Risk:
If the user does not notice that the air detector is turned off from the previous protocol, air could pass through the pump without detection. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affects CADD-Solis pumps with software A, C, E, F, v1.1.1, and v1.1.2 and was addressed in software v3.0.0 (2012) and all subsequent versions.

Issue 4 – Single Bubble Air Detection

Overview of the Issue:
After the user clears a single bubble air alarm, primes the tubing to remove the air, and restarts the pump, the next single air bubble that should trigger a single bubble air-in-line alarm does not trigger the alarm. This behavior continues until enough air passes through the air detector to trigger an accumulated air-in-line alarm.

Potential Risk:
If the pump does not alarm for single bubble air in line, air could pass through the pump without detection. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affects CADD-Solis pumps with software A, C, E, F, v1.1.1, and v1.1.2 and was addressed in software v3.0.0 (2012) and all subsequent versions.

Issue 5 – Error Codes Not Displayed at Power Up

Overview of the Issue:
After the user turns on the pump, the pump starts the power-up sequence during which it performs various self-tests and tests for alarm conditions. During the power-up sequence, if the pump detects a failure (e.g., code corruption, processor failure), it will trigger a system fault alarm indicating that an unrecoverable error may have occurred. If the system fault is triggered before the display is initialized, the amber indicator light is continuously illuminated accompanied by an audible two-tone alarm, but the display will remain blank.

Potential Risk:
The inability to display error codes for the failure 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 affects CADD-Solis VIP pumps with software v1.2.1, v1.2.2, v1.3, and v1.4 and was addressed in software v1.5 (2018) and all subsequent versions.

Issue 6 – Audible Alarm

Overview of the Issue:
It is possible that a defective audible alarm component is not detected. If so, when an alarm occurs, the amber indicator light will illuminate, and the pump will display the alarm message, but the audible portion of the alarm will not sound.

Potential Risk:
If the audible signal fails and the user cannot see the visual indicator and display, the user may not be aware that an alarm condition has stopped infusion, which may further delay the interrupted therapy. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affects CADD-Solis pumps with software v4.0, v4.0.1, and v4.1 and was addressed in software v4.2 (2019) and all subsequent versions.

Issue 7 –Low Sensitivity Air in Line Detection Threshold

Overview of the Issue:
In 2017, Smiths Medical changed the Low Sensitivity Air in Line alarm threshold in an effort to reduce false alarms. A review of complaints before and after the change found that the change had no impact on the type or rate of complaints. Therefore, Smiths Medical is reverting the Low Sensitivity Air In Line alarm threshold to the previous settings in alignment with industry standards. For CADD-Solis v4.1, v4.2 and CADD-Solis VIP v1.3, v1.4, v1.5, the Low Sensitivity Air In Line alarm threshold is 2 mL (single bubble) or 4 mL over 15 minutes (accumulated). The updated Low Sensitivity threshold values are 0.4 mL (single bubble) or 1.0 mL over 15 minutes (accumulated). The change is not a result of adverse events being reported.

Potential Risk:
Vascular air embolism during infusion therapy can pose a health risk depending upon the amount of air, the route of administration, and the underlying vulnerability of the patient. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

Affected Models:
This issue affects CADD-Solis v4.1, v4.2 and CADD-Solis VIP v1.3, v1.4, v1.5 and will be addressed in CADD-Solis v4.3 (2024) and CADD-Solis VIP v1.6 (2024).

Actions for Users:
Be aware of alarms for air in line and follow the instructions for use. When available, upgrade to the latest software version, including the reversion back to the previous Low Sensitivity threshold.

Issue 8 –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 password that was entered. **To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.**

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

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Required Actions for Users:

Users can continue to use CADD-Solis pumps and follow the actions below:

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 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.

Follow up Actions by Smiths Medical:

Smiths Medical is sending this notification to all affected CADD-Solis customers and is addressing the issues described in this notice through software updates. Smiths Medical will contact you to schedule the implementation of the software updates.

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	servicece@icumed.com	Additional information or technical assistance,
Customer Support	https://www.icumed.com/about-us/contact-us	Additional information or assistance

Your country regulatory agency has been notified of this action.

Smiths Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,

Jim Vegel
Vice President of Quality

Enclosures:

- Response Form (See below)

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URGENT FIELD SAFETY NOTICE: RESPONSE FORM

CADD-Solis™ Ambulatory Infusion Pumps

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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?

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 FSN 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.