

URGENT MEDICAL DEVICE CORRECTION**CADD-Solis™ Ambulatory Infusion Pumps and Wireless Communication Module**

10 APRIL 2025:

Dear Valued CADD-Solis Customers:

- Director of Biomedical Engineering
- Director of Nursing
- Director of Risk Management
- Director of Information Technology

Smiths Medical is issuing this letter to notify you of a CADD-Solis Ambulatory Infusion Pump issue.

This notification details the issue, 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 Device Information screen. See Appendix A for the Affected Product Information.

Overview of the Issue:

CADD-Solis pumps may lose communication with the CADD wireless communication module if wireless network setting changes on the hospital network are not compatible with the CADD wireless communication module. This may result in a “Wireless Module Intermittent Connection” high priority alarm, which will stop an ongoing infusion.

Potential Risk:

If a “Wireless Module Intermittent Connection” high priority alarm is triggered, it will interrupt an active infusion. An interruption or delay of therapy can lead to serious patient injury or death, depending on the clinical situation and the type of medication being administered. When this alarm triggers, the pump must be power cycled to clear the alarm.

To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.

Affected Versions:**Wireless Communication Module Intermittent Connection Alarm Issue**

Affected CADD-Solis
Software Versions
4.0, 4.1, 4.2, 4.2.1, 4.3

Actions for Users:

Users should validate any wireless network changes or updates to hospital network settings with the pump/communication module to ensure compatibility of the wireless connection before deploying network setting changes or updates to the production environment.

If this alarm recurs or is unable to be cleared by power cycling the pump, then revert to prior compatible network settings or turn off the wireless function of the communication module (which will not affect any of the pump’s clinical operations).

Required Actions:

1. Locate all affected products 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 the electronic Response Form via the link provided within this email notification within ten days of receipt to acknowledge your understanding of this notification, even if you do not have the affected product.
3. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward your customer list to Sedgwick at icumedical8512@sedgwick.com. Sedgwick will notify customers with email addresses via email and will send physical notifications to customers without email addresses in order for them to complete the Response Form.

Follow up Actions by Smiths Medical:

Smiths Medical is sending this notification to all affected CADD-Solis customers and will address this issue via a software update. Smiths Medical will contact you to schedule the implementation of the software update once it is available.

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 1-(866)-216-8806	To report adverse events or product complaints
Technical Support	TSC.Support@icumed.com 1- 800-241-4002, option 3, 4 (M-F, 8:00 am – 6:00 pm CT)	Additional information or technical assistance
Field Action Processing	icumedical8512@sedgwick.com 1-888-628-0727	Questions about this communication

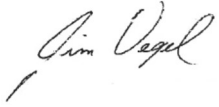
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, use the following contact information.

- www.fda.gov/medwatch
- 1-(888)-INFO-FDA

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,

A handwritten signature in black ink, appearing to read "Jim Vogel". The signature is fluid and cursive, with a long horizontal stroke extending to the left.

Jim Vogel
Vice President of Quality

Enclosures:

- Response Form (separate document)
- FAQs (separate document)

Appendix A: Affected Product List

Item	Description	DI
21-2111-0402-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.2, CE ENGLISH 1/EA	15019517154290
21-2112-0402-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.2, YELLOW, CE ENGLISH 1/EA	15019517154993
21-2112-0100-51	PUMP KIT, CADD-SOLIS, YELLOW, MODEL 2110 1/EA	10610586039232
21-2112-0300-01	PUMP KIT, CADD-SOLIS HPCA PIB, YELLOW KEYPAD, MODEL 2110, NA ENGLISH 1/EA	10610586038808
21-2111-0300-01	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110, NA ENGLISH 1/EA	10610586038778
21-2111-0401-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.1, CE ENGLISH 1/EA	15019517099690
21-2111-0100-51	PUMP KIT, CADD-SOLIS, MODEL 2110, CE ENGLISH 1/EA	30610586039205
21-2112-0401-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.1, YELLOW, CE ENGLISH 1/EA	15019517101003
21-2101-51	PUMP KIT, CADD-SOLIS, MDL 2100, CE ENGLISH 1/EA	10610586031854
21-2111-0400-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.0, CE ENGLISH 1/EA	10610586041037
21-2111-0300-50	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110, OUS ENGLISH 1/EA	10610586038839
21-2101-00	PUMP, TRIAL/LOANER, CADD-SOLIS, MODEL 2100 1/EA	10610586032950
21-2111-0300-00	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110 TRIAL/LOANER, NA ENGLISH 1/EA	10610586038792
21-2111-0402-78	PUMP KIT, CADD-SOLIS, MDL 2110, TRIAL/LOANER, V4.2, CE ENGLISH 1/EA	15019517154887
21-2111-0100-00	PUMP, TRIAL/LOANER, CADD-SOLIS, MODEL 2110 1/EA	10610586039195
21-2112-0300-00	PUMP KIT, CADD-SOLIS HPCA PIB, YELLOW, MODEL 2110, TRIAL/LOANER, NA ENGLISH 1/EA	10610586038822

21-2112-0402-78	PUMP KIT, CADD-SOLIS, MDL 2110, V4.2, TRIAL/LOANER YELLOW, CE ENGLISH 1/EA	15019517155013
21-2101-249	PUMP, DEMO, CADD-SOLIS, MODEL 2100, NOT FOR HUMAN USE 1/EA	10610586034787
21-2111-0401-78	PUMP KIT, CADD-SOLIS, MDL 2110, TRIAL/LOANER, V4.1, CE ENGLISH 1/EA	15019517101010
21-2102-51	PUMP KIT, CADD-SOLIS, YELLOW, MDL 2100 1/EA	10610586033933
21-2112-0401-249	PUMP KIT, CADD-SOLIS, MDL 2110, V4.1, NFHU, YELLOW, CE ENGLISH 1/EA	15019517101041
21-2111-0300-231	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110, NFHU, NA ENGLISH 1/EA	10610586038785
21-2112-0401-78	PUMP KIT, CADD-SOLIS, MDL 2110, V4.1, TRIAL/LOANER YELLOW, CE ENGLISH 1/EA	15019517101034
21-2112-0400-51	PUMP KIT, CADD-SOLIS, MDL 2110, V4.0, YELLOW, CE ENGLISH 1/EA	10610586041051
21-2112-0300-50	PUMP KIT, CADD-SOLIS HPCA PIB, YELLOW, MODEL 2110, OUS ENGLISH 1/EA	10610586038860
21-2111-0300-00	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110 TRIAL/LOANER, NA ENGLISH 1/EA	10610586038792
21-2111-0100-00	PUMP, TRIAL/LOANER, CADD-SOLIS, MODEL 2110 1/EA	10610586039195
21-2111-0100-51	PUMP KIT, CADD-SOLIS, MODEL 2110, CE ENGLISH 1/EA	30610586039205
21-2111-0100-50	PUMP, CADD-SOLIS, MODEL 2110, CE ENGLISH OUS 1/EA	10610586039256
21-2101-51	PUMP KIT, CADD-SOLIS, MDL 2100, CE ENGLISH 1/EA	10610586031854
21-2112-0100-50	PUMP KIT, CADD-SOLIS HPCA, YELLOW KEYPAD, MODEL 2110, CE ENGLISH, OUS 1/EA	10610586039270
21-2101-00	PUMP, TRIAL/LOANER, CADD-SOLIS, MODEL 2100 1/EA	10610586032950
21-2112-0400-01	PUMP KIT, CADD-SOLIS, MDL 2110, v4.0, YELLOW, ENGLISH 1/EA	10610586041822