

URGENT MEDICAL DEVICE NOTIFICATION**CADD-Solis™ and CADD-Solis VIP™ Ambulatory Infusion Pumps USO Alarm**

10 APRIL 2025:

Dear Valued CADD-Solis Customers:

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

Smiths Medical is issuing this letter to notify you of an issue affecting all CADD-Solis and CADD-Solis VIP Ambulatory Infusion Pumps. This notification details the issue and the affected models. All CADD Solis Pumps and CADD Solis VIP Pumps are affected by this issue (see Appendix A for the Affected Product Information).

Overview of the Issue:

Under certain conditions, a CADD-Solis pump may trigger an erroneous (false) Upstream Occlusion (USO) Alarm. The erroneous USO alarm may occur when there is a delay of more than one hour between the first prime or infusion of a new CADD Administration Set and the next prime or infusion of the same CADD Administration Set. The USO Alarm is a high priority alarm that will interrupt an ongoing infusion or delay initiation of an infusion. The pump cannot resume or start an infusion until the alarm is cleared.

A USO Alarm may potentially occur if all four of these conditions are met:

- Using a CADD administration set (i.e. not a medication cassette reservoir), and
- Enabling the Upstream Occlusion Alarm, and
- Not programming Keep Vein Open (KVO) or Continuous rate, and
- Priming or infusing shortly after attaching the administration set and the next infusion does not occur for approximately one hour or longer.

This issue will not occur when using a medication cassette reservoir, if the USO Alarm is disabled, if the KVO setting is programmed, or if a Continuous rate setting is programmed.

Potential Risk:

If a USO high priority alarm occurs, 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. To date, Smiths Medical has not received any reports of serious injuries or deaths related to this issue.

Actions for Users:

Be aware that a USO alarm may occur when all the conditions stated above are met. The USO alarm can be cleared during these conditions by removing the administration set from the pump. After re-attaching the administration set, delivery can be restarted without an alarm. Additionally, verify there is no upstream occlusion present.

Required Actions:

1. Ensure all users or potential users of these devices are immediately made aware of this notification.
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 icumedical4369@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 and CADD-Solis VIP customers. An update to the Infusion Pump Operator's Manual will be made to include these conditions.

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	icumedical4369@sedgwick.com 1-888-627-4936	Questions about this communication

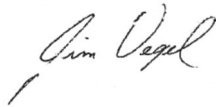
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

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,



Jim Vogel
Vice President of Quality

Enclosures:

- Response Form (separate document)

Appendix A: Affected Product List

List Item	Description	UDI
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
21-2127-0105-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH, MANUAL MODE, 1/EA	15019517150292
21-2120-0105-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH, PHARMGUARD ENABLED, 1/EA	15019517150001
21-2120-0103-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH 1/EA	15019517084368
21-2112-0100-51	PUMP KIT, CADD-SOLIS, YELLOW, MODEL 2110 1/EA	10610586039232
21-2120-0102-51	PUMP, CADD-SOLIS VIP, MDL 2120, ENGLISH 1/EA	10610586042829
21-2112-0300-01	PUMP KIT, CADD-SOLIS HPCA PIB, YELLOW KEYPAD, MODEL 2110, NA ENGLISH 1/EA	10610586038808
21-2120-0104-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH, PHARMGUARD ENABLED 1/EA	15019517126587
21-2120-0103-51	PUMP KIT, CADD-SOLIS VIP, MDL 2120, CE GLOBAL ENGLISH 1/EA	15019517096378
21-2127-0104-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH, MANUAL MODE 1/EA	15019517126600
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
21-2120-0105-00	PUMP KIT, CADD-SOLIS VIP, MDL 2120, TRIAL/LOANER, NA ENGLISH, PHARMGUARD, 1/EA	15019517149999
21-2111-0300-50	PUMP KIT, CADD-SOLIS HPCA PIB, MODEL 2110, OUS ENGLISH 1/EA	10610586038839
21-2120-0103-78	PUMP, CADD-SOLIS VIP, MDL 2120, TRIAL/LOANER CE GLOBAL ENGLISH 1/EA	15019517096392
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
21-2120-0102-78	PUMP, CADD-SOLIS VIP, MDL 2120, ENGLISH, TRIAL/LOANER 1/EA	10610586042836
21-2120-0104-231	PUMP, CADD-SOLIS VIP, MDL 2120, NFHU, NA ENGLISH, PHARMGUARD ENABLED 1/EA	15019517126617
21-2120-0102-249	PUMP, CADD-SOLIS VIP, MDL 2120, ENGLISH, NFHU 1/EA	10610586042843
21-2120-0103-249	PUMP, CADD-SOLIS VIP, MDL 2120, NFHU CE GLOBAL ENGLISH 1/EA	15019517096385
21-2125-0104-01	PUMP KIT, CADD-SOLIS VIP, MDL 2120, NA ENGLISH, FACTORY LIBRARY 1/EA	15019517126594
21-2112-0300-50	PUMP KIT, CADD-SOLIS HPCA PIB, YELLOW, MODEL 2110, OUS ENGLISH 1/EA	10610586038860
21-2120-0102-249	PUMP, CADD-SOLIS VIP, MDL 2120, ENGLISH, NFHU 1/EA	10610586042843
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