

URGENT MEDICAL DEVICE CORRECTION**CADD-Solis™ and CADD-Solis VIP™ Ambulatory Infusion Pumps Thermal Damage**

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 for your awareness, to notify you of three (3) issues associated with the potential for thermal damage in CADD-Solis and CADD-Solis VIP infusion pumps. The following list provides a description of the issues and the affected pumps. See the Affected Product Information in Appendix A.

Overview of the Issues:

Issue 1: Damage to the circuit board within the housing of the rechargeable battery pack may cause melting of the plastic housing, specifically on the top and bottom surfaces.

Issue 2: Damage to the Wireless Communication Module circuit board may cause melting of the plastic housing of the Wireless Communication Module battery.

Issue 3: Damaged or dislodged battery separators, or foreign material in the battery compartment, may cause an electrical short condition between the battery contacts.

Potential Risk:

Damage to or inoperable batteries may lead to a delay in therapy or interruption of therapy. 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. The user would be alerted with the normal “Low Battery” or “Depleted Battery” alarms. The presence of excessive heat from damaged or shorted components is also possible, which may result in a thermal injury.

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

Actions for Users:

Inform all affected CADD-Solis and CADD-Solis VIP users of this notice. Provide the instructions below:

1. Ensure all users or potential users of these products are immediately made aware of this notification.
2. Upon receipt of this notification and ongoing during regular maintenance, visually inspect the external condition of the battery pack or Wireless Communication Module and look for evidence of any physical damage. Handle a damaged device with caution. As stated in the battery pack Instructions for Use, if the battery pack housing is cracked or otherwise damaged, replace the battery pack. NEVER use a battery pack that appears damaged. A rechargeable battery pack must be replaced with either another CADD-Solis rechargeable battery pack or with 4 AA batteries.
3. Visually inspect the condition of the battery compartment for evidence of any physical damage. Contact Technical Support for repairs.
4. Always check the battery compartment for fluid or debris before inserting the batteries, and do not allow any fluid or debris to fall into the battery compartment.

5. 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.
6. **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward your customer list to Sedgwick at icumedical3393@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 continuing to investigate this matter to determine if additional actions may be warranted.

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	icumedical3393@sedgwick.com 1-888-683-0379	Questions about this communication

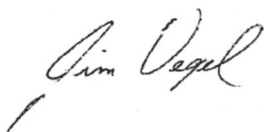
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

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 Information

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
21-2127-0105-01	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