

VELETRI® (epoprostenol)
Issues Notice for CADD Infusion System Infusion Sets

SUMMARY

ISSUES NOTICE FOR CADD INFUSION SYSTEM INFUSION SETS

- In April 2025, Smiths Medical issued three letters to affected customers providing updated use instructions of CADD-Solis Ambulatory Infusion Pumps and CADD-Solis VIP Ambulatory Infusion Pumps. On June 3rd, 2025, the FDA identified the following issues as a Class I recall.¹ Additional information on the recall communication is available on the FDA website.²⁻⁴
 - **Issue 1: Infusion pump false occlusion alarm**² – 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.
 - **Issue 2: Infusion pump thermal damage issue**³ – Damage to the rechargeable battery pack circuit board, Wireless Communication Circuit Board, or battery separators is associated with the potential for thermal damage in affected infusion pumps. Damage to or inoperable batteries may lead to a delay in therapy or interruption of therapy. 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.
 - **Issue 3: Infusion pump intermittent connection issue**⁴ – 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. When this alarm triggers, the pump must be power cycled to clear the alarm.
- In December 2022, Smiths Medical issued a letter notifying customers of two potential issues with CADD™ Infusion System Infusion Sets. Then, on February 2, 2023, the FDA identified this as a Class I recall; the recall communication is available on the [FDA website](#).⁵ In June 2023, Smiths Medical issued an updated notice to the December 2022 letter, stating that additional lots may potentially be impacted by the 2 issues described below.⁶
 - Issue 1: Lack of delivery or under delivery related to tubing occlusion, despite the pump displaying that the infusion is running properly.
 - Issue 2: False “No Disposable Attached (NDA)” alarms.
- For certain patient situations, use of alternative CADD infusion sets may be recommended.
- Customers in the U.S. with adverse reactions, quality problems, or questions about this recall should contact Smiths Medical at globalcomplaints@icumed.com or 1-866-216-8806. Customers may also contact Smiths Medical customer service (1-800-258-5361).

REFERENCES

1. FDA MedWatch - Class I Recall Notices: Three Infusion Pump Corrections from Smiths Medical. Accessed June 18, 2025. <https://content.govdelivery.com/accounts/USFDA/bulletins/3e24cd6>

2. Infusion Pump Recall: False Alarm Issue with Infusion Pump from Smiths Medical. Accessed June 16, 2025. https://www.fda.gov/medical-devices/medical-device-recalls/infusion-pump-recall-false-alarm-issue-infusion-pump-smiths-medical?utm_medium=email&utm_source=govdelivery

3. Infusion Pump Recall: Infusion Pump Thermal Damage Issue from Smiths Medical. Accessed June 16, 2025. <https://www.fda.gov/medical-devices/medical-device-recalls/infusion-pump-recall-infusion-pump-thermal-damage-issue-smiths-medical>

4. Infusion Pump Recall: Infusion Pump Intermittent Connection Issue from Smiths Medical. Accessed June 16, 2025. <https://www.fda.gov/medical-devices/medical-device-recalls/infusion-pump-recall-infusion-pump-intermittent-connection-issue-smiths-medical>

5. Smiths Medical. Medical Device Correction for CADD Infusion System Infusion Sets for use with CADD Pumps. December 9, 2022.

6. Smiths Medical. Updated Urgent Medical Device Correction for CADD Infusion System Infusion Sets for use with CADD Pumps. June 13, 2023.