

URGENT: FIELD SAFETY NOTICE

CADD™ Infusion System Infusion Sets for use with CADD pumps

15th December 2022

Dear Valued CADD Customers:

- Director of Pharmacy
- Director of Nursing
- Director of Risk Management

Smiths Medical is issuing this letter to notify you of two potential issues with CADD Infusion System Infusion Sets. This notification details the issues, the affected items, and the required steps to perform.

Please note specific instructions for treatment of patients requiring life sustaining therapy: For infusion of life sustaining medications, use of alternative CADD infusion sets is recommended. To assure prioritizing availability of alternate infusion sets, please contact Smiths Medical customer service for information on obtaining the alternate CADD infusion sets.

Affected Products:

| | |
|---|--|
| Issue 1: Lack of Delivery or Underdelivery related to Tubing Occlusion | Specified medication cassette reservoirs with flow stop and administration sets used with all CADD pumps, as described in Table 1 below |
| Issue 2: False “No Disposable Attached (NDA)” Alarms | Specified 50 mL and 100 mL medication cassette reservoirs with Flow Stop used with CADD Legacy Infusion Systems, as described in Table 2 below |

Issue 1 – Lack of Delivery or Underdelivery related to Tubing Occlusion

Overview of the Issue:

Manufacturing variations may cause the green CADD Flow Stop arm to compress and partially occlude the tubing before clinical use. If this occurs, there is a potential that the occlusion does not resolve when an affected reservoir or administration set is connected to the pump, and the pump may not detect the occlusion. **This may result in underdelivery or non-delivery of medication, despite the pump displaying that the infusion is running properly.**

CADD Flow Stop Medication Cassette Reservoirs and CADD Flow Stop Administration Sets provide free-flow protection. By design, a green, spring-loaded pivoting arm automatically squeezes the tubing closed when the reservoir or administration set is not installed on a pump. Connecting the reservoir or administration set to the pump causes the pump to push the Flow Stop arm, enabling fluid flow through the tubing. **In certain circumstances, the tubing may remain occluded even though the CADD reservoir or administration set is loaded into the pump.**

Affected Items:

Certain CADD Administration Sets and Medication Cassette Reservoirs with Flow Stop used with all CADD pumps are affected. See Table 1 below for the complete list of affected items.

Potential Risk:

If the tubing is occluded under the Flow Stop arm, the pump cannot detect the occlusion and may not infuse as intended; it may **underdeliver** the fluid/medication or cause an **interruption in therapy**, even though the pump will display that the infusion is running properly. Depending on the medication infusing, an interruption in therapy or underinfusion could cause serious patient harm or death.

To date, Smiths Medical has received reports of fourteen serious injuries and two deaths potentially related to this issue. Smiths Medical could not confirm the deaths were directly caused by the affected product.

Actions for Pharmacists:

- Immediately identify affected products in your possession and ensure these products are separated and labeled as affected by this FSN to avoid use for life sustaining medications.
- For use with life sustaining medications, please contact Smiths Medical customer service for information on obtaining alternative CADD infusion sets.
- If the pharmacist experiences difficulty with filling the cassettes of affected products, consider changing to a new infusion set and contact Smiths Medical Global Complaint Management to report the event.

Actions for Clinicians and Patients:

- Be aware that if you use products affected by this Field Safety Notice with your CADD pump, the medication may appear to be infusing normally, but due to the occluded tubing, may not be infusing at all or may be underinfusing, and the pump will not alarm.
- For patients requiring life sustaining medications, use of alternative CADD infusion sets is recommended. Clinicians can contact the specialty pharmacies and discuss availability of alternative CADD infusion sets. Depending on availability and specific patient situations, clinicians may consider switching patients to an alternative pump.
- When using products affected by this FSN, always prime the set using the pump and watch the fluid flow closely during this process. If the fluid doesn't flow properly or takes an abnormally long time to prime, or if the pump displays a higher than expected priming volume, replace the reservoir or set. The priming volume is listed on the packaging for each administration set.
- If medication remains in the reservoir at the completion of the infusion, contact your clinician and Smiths Medical Global Complaint Management to report the event
- Clinicians, share this letter with your homecare patients and educate them to prime the set using the pump as mentioned above.

Issue 2 – False “No Disposable Attached (NDA)” Alarms

Overview of the Issue:

There is a potential that **CADD-Legacy pumps may not detect that 50 mL and 100 mL CADD Medication Cassette Reservoirs with Flow Stop are attached to the pump when the cassettes are properly attached.** This issue does not impact 250 mL Flow-Stop and non-Flow Stop CADD Medication Cassette Reservoirs.

Manufacturing variations on certain CADD Medication Cassette Reservoirs with Flow Stop may interfere with the pump detecting a properly attached CADD cassette. In such situations, the CADD-Legacy pump will issue a “No Disposable Attached (NDA)” double-beep audible warning if the pump cannot determine that the CADD cassette is properly attached. The pump will initiate an NDA alarm if the NDA double-beep warning is not resolved within 2 minutes. The user must clear the alarm and resolve the cause of the NDA event before using the pump.

As a reminder, Smiths Medical announced the discontinuation of the sale of CADD-Legacy pumps, effective the end of 2019

Affected Items:

50 mL and 100 mL Medication Cassette Reservoirs with Flow Stop when used with CADD-Legacy infusion pumps. See Table 2 below for the complete list of affected items.

Potential Risk:

An NDA alarm will be initiated if the pump does not detect the cassette when the user attempts to start an infusion. This situation results in the pump displaying “No disposable, pump won’t run” and **delays the initiation of therapy.** During infusion, if the pump does not detect the cassette and triggers an NDA alarm, the pump will stop delivery and display “No disposable, clamp tubing,” resulting in an **interruption of therapy.** Depending on the medication infusing, a delay or interruption in therapy could cause serious patient harm or death.

To date, Smiths Medical has received eleven reports of serious injuries, and zero (0) reports of deaths potentially related to this issue.

Actions for Clinicians and Patients:

- Be aware that the pump may not adequately detect the cassette before or during an infusion due to this issue, and an alarm will be triggered. If a pump displays an NDA alarm, the user can attempt to resolve the alarm by repositioning the CADD Medication Cassette Reservoir while connected to the pump, repositioning the reservoir by disconnecting from the pump and reattaching it to the pump, or replacing the reservoir.
- Alternatively, the user can remove the reservoir from the pump and push the plastic ridge highlighted in the circle below towards the arch on the reservoir as indicated by the arrow in Figure 1.
- For patients requiring life sustaining medications, use of alternative CADD infusion sets is recommended. Contact pharmacist to discuss availability of alternative CADD infusion sets. Depending on availability and specific patient situations, clinicians may consider switching patients to an alternative pump.
- If the user cannot resolve the NDA alarm, replace the cassette reservoir, though the issues may recur if that product is also affected by this FSN.
- Clinicians, share this letter with your homecare patients and educate them about the actions above.

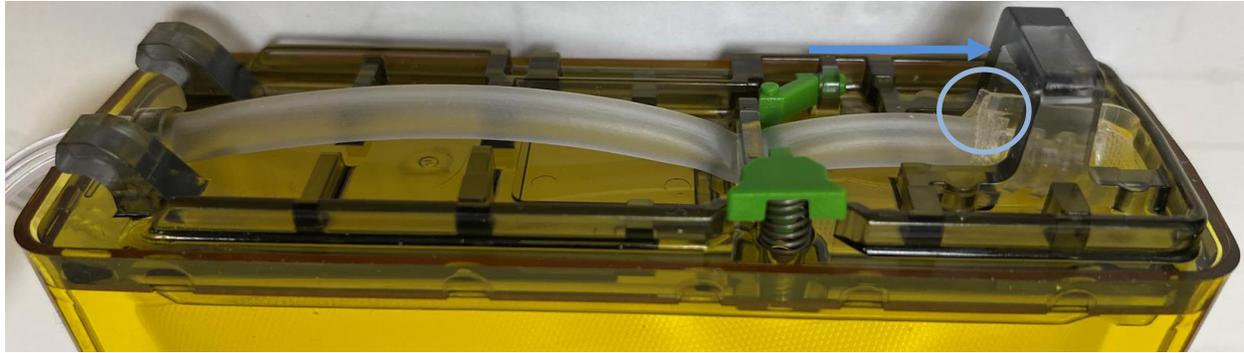


Figure 1. CADD Reservoir

Actions for Pharmacists:

- Immediately identify affected products in your possession and ensure these products are separated and labeled as affected by this FSN to avoid use for life sustaining medications.
- For use with life sustaining medications, please contact Smiths Medical customer service for information on obtaining alternative CADD infusion sets.

For further inquiries, please contact Smiths Medical using the following information:

| Smiths Medical Contact | Contact Information | Areas of Support |
|-----------------------------|--|---|
| Global Complaint Management | globalcomplaints@smiths-medical.com | To report adverse events or product complaints |
| Customer Support | Ireland.customer.service@smiths-medical.com | For any questions regarding this action, for additional information or technical assistance |

Smiths Medical’s Actions

Smiths Medical implemented corrective actions to address the manufacturing variations that led to these issues.

Customer Required Actions

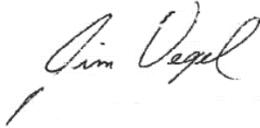
1. Ensure all users or potential users of these devices are immediately made aware of this notification and proposed mitigations.
2. Complete and return the Response Form on the last page, by email to EMEA-Quality@icumed.com **within ten days of receipt** to acknowledge your understanding of this notification.
3. DISTRIBUTORS: If you have distributed potentially affected products to your customers, please immediately forward this notice to them and ask them to return completed forms to you. When you have received all customer responses from your customers, please compile the information into a SINGLE COMPLETED form detailing ALL AFFECTED ITEMS, LOT NUMBERS and QUANTITIES and return this SINGLE COMPLETE FORM to EMEA-Quality@icumed.com.

General Information

Your national competent authority has been notified of this Field Safety Notice.

Smiths Medical is committed to providing quality products and service to our customers. We apologize for any inconvenience this situation may cause.

Sincerely,

A handwritten signature in black ink that reads "Jim Vogel". The signature is written in a cursive style with a prominent loop at the end of the last name.

Jim Vogel
Vice President of Quality

Table 1: Affected Items for Issue 1 – Lack of Delivery or Underdelivery related to Tubing Occlusion

| List Number | Description | Affected Lot Number Range | |
|-------------|--|---------------------------|-----------------|
| | | Beginning Lot Number | Last Lot Number |
| 21-7300-24 | 100-mL Yellow CADD Medication Cassette Reservoir | 3630772 | 4321035 |
| 21-7301-24 | 50-mL CADD Medication Cassette Reservoir | 3630747 | 4321033 |
| 21-7302-24 | 100-mL CADD Medication Cassette Reservoir | 3617363 | 4329617 |
| 21-7308-24 | 250-mL CADD Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included | 4053922 | 4327070 |
| 21-7309-24 | 250-mL CADD Yellow Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included | 4062405 | 4330868 |
| 21-7310-24 | 250-mL CADD Blue Medication Cassette Reservoir with flow stop, clamp, and female Luer Nonvented stopper included | 4062404 | 4311957 |
| 21-7321-24 | CADD Administration Set with female Luer, flow stop, clamp, one-way checkvalve with male Luer | 3773534 | 4304720 |
| 21-7322-24 | CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer | 3776375 | 4321320 |
| 21-7323-24 | CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer | 3776373 | 4315950 |
| 21-7324-24 | CADD Administration Set with bag spike, flow stop, clamp, one-way checkvalve with male Luer | 3773527 | 4321310 |
| 21-7333-24 | CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, Luer activated needleless injection site, and one-way checkvalve with male Luer | 3776362 | 3984144 |
| 21-7336-24 | CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer | 3776360 | 4025381 |
| 21-7339-24 | CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, and one-way checkvalve with male Luer | 3780565 | 4009665 |
| 21-7343-24 | CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, Luer activated needleless injection site and oneway checkvalve with male Luer | 3965344 | 4315928 |
| 21-7346-24 | CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer | 3776356 | 4320131 |
| 21-7349-24 | CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, and one-way checkvalve with male Luer | 3926579 | 4320791 |

| List Number | Description | Affected Lot Number Range | |
|-------------|---|---------------------------|-----------------|
| | | Beginning Lot Number | Last Lot Number |
| 21-7359-24 | CADD Administration Set with male Luer, flow stop, clamp, one-way checkvalve with male Luer | 3776315 | 4304717 |
| 21-7363-24 | CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer | 3773412 | 4315934 |
| 21-7383-24 | CADD Administration Set with bag spike, flow stop, 1.2µ air-eliminating filter, clamp, spiral outlet tubing and one-way checkvalve with male Luer | 3780549 | 3971523 |
| 21-7390-24 | CADD Administration Set with female Luer, flow stop, 7.6cm Y-extension, clamps, one-way checkvalve with female Luer and one-way checkvalve with male Luer | 3780548 | 4308567 |
| 21-7391-24 | CADD Administration Set with bag spike, flow stop, 7.6cm Y-extension, clamps, one-way checkvalve with female Luer and one-way checkvalve with male Luer | 3773276 | 4309466 |
| 21-7394-24 | CADD Administration Set with bag spike, flow stop, 0.2µ air-eliminating filter, clamp, one-way checkvalve with male Luer | 3774739 | 4315948 |
| 21-7395-24 | CADD Administration Set with female Luer, flow stop, 0.2µ air-eliminating filter, clamp, one-way checkvalve with male Luer | 3808536 | 4290737 |
| 21-7600-24 | 100-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit™ connector. Yellow stopper included | 4084914 | 4291416 |
| 21-7609-24 | 250-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit connector. Yellow stopper included | 4072200 | 4302528 |
| 21-7624-24 | CADD Yellow Administration Set with NRFit™ connector with bag spike, flow stop, yellow-striped tubing, clamp and one-way checkvalve with male NRFit connector | 4092506 | 4298383 |
| 21-7649-24 | CADD Yellow Administration Set with NRFit connector with bag spike, flow stop, yellow-striped tubing, 0.2µm air-eliminating filter, clamp, and one-way checkvalve with male NRFit connector | 4076410 | 4279921 |

Table 2: Affected Items for Issue 2– False “No Disposable Attached (NDA)” Alarms

50 mL and 100 mL Medication Cassette Reservoirs with Flow Stop when used with **CADD-Legacy Infusion Systems**.

| List Number | Description | Affected Lot Number Range | |
|-------------|--|---------------------------|-----------------|
| | | Beginning Lot Number | Last Lot Number |
| 21-7300-24 | 100-mL Yellow CADD Medication Cassette Reservoir | 3630777 | 4315903 |
| 21-7301-24 | 50-mL CADD Medication Cassette Reservoir | 3630748 | 4315907 |
| 21-7302-24 | 100-mL CADD Medication Cassette Reservoir | 3630803 | 4315911 |
| 21-7600-24 | 100-mL CADD Yellow Medication Cassette Reservoir with NRFit™ connector with flow stop, yellow-striped tubing, clamp and female NRFit™ connector. Yellow stopper included | 4168766 | 4291416 |

URGENT FIELD SAFETY NOTICE: RESPONSE FORM

CADD™ Infusion System Infusion Sets for use with CADD pumps

15th December 2022

Check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-Quality@icumed.com, Smiths Medical Customer Service and 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 the e-mail addresses above)

I have **NO** affected product (complete and return this form to the e-mail addresses above)

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 by providing them with a response form and asking them to complete it and return it to you? **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 these products should be reported and emailed to Smiths Medical's Global Complaint Management Department (globalcomplaints@smiths-medical.com)