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# URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

## CADD®- Solis VIP Ambulatory Infusion Pump

| | |
|---|---|
| **Affected Devices:** | **CADD®- Solis VIP Ambulatory Infusion Pumps** |
| **Type of Action:** | **Removal** |
| **Date:** | **March 18, 2020** |
| **Attention:** | **Clinical Users, Distributors, and Health Care Providers overseeing the use of the CADD®- Solis VIP Infusion Pump** |
| **Affected Devices:** | **See Attached for List of Affected Serial Numbers** |

Dear Customer,

The purpose of this Field Safety Notice (FSN) is to advise you that Smiths Medical has initiated a voluntary Field Safety Corrective Action (FSCA) for specific serial numbers for CADD®- Solis VIP Ambulatory Infusion Pumps.

**REASON FOR FIELD SAFETY CORRECTIVE ACTION:**

Smiths Medical became aware that specific CADD-Solis VIP Ambulatory Pumps may exhibit intermittent performance in the AILD (Air in Line Detector) function. If an AILD does not sufficiently discern fluid from air in line, an air in line event may not be recognized by the pump and may not alarm to notify the clinician.

**RISK TO HEALTH:**

Failure to adequately detect air in line could lead to a potential increase in the risk of an air embolism.

**Smiths Medical has received no reports of deaths or serious injuries related to this issue.**

**All competent authorities have been notified of this action.**

**INSTRUCTIONS TO CUSTOMERS:**

1. Complete the attached Response Form within 10 days and return it to Caddsolis@smiths-medical.com. Please complete and return the form even if you do not have any of the affected product in your possession
2. Once the Response form has been acknowledged, customer services will contact you to arrange collection of your device/s. However, please do not return any accessories as they will not be replaced. Please be sure to include a completed response form in each box of product that is returned.
3. Once the Response form has been acknowledged, customer services will contact you to arrange collection of your device/s. However, please do not return AC Adaptors or power cords as they will not be replaced. Please be sure to include a completed response form in each box of product that is returned.
4. **DISTRIBUTORS or Pharmacy Suppliers: If you have distributed potentially affected devices to your customers, please immediately notify them of this field notification by providing the information detailed in the Field Safety Notice, with the accompanying Response Form 1a. All communication to Smiths Medical**

**must be completed by the Distributor or supplier. Please do not permit your end user to respond directly or return devices for replacement.**

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

If you have any questions regarding this notification, please contact Smiths Medical via email at Caddsolis@smiths-medical.com.

Sincerely,

Dr. G. Barrett
VP Quality Systems, Regulatory and Compliance
Smiths Medical
6000 Nathan Lane North
Minneapolis, MN 55442

Enclosures: Attachment 1 – Field Safety Notice (FSN), Response Form, Response From 1a (Distributors and Suppliers)

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**ATTACHMENT 1**

# URGENT MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

## CADD®-Solis VIP Ambulatory Infusion Pump

Please assist us in executing this Field Safety Corrective Action (FSCA) by completing and returning this Response Form as soon as possible. This will serve as confirmation that you have received and understand the accompanying Field Safety Notice (FSN) and will allow us to ensure that we have reached all customers who may be affected by this issue.

Please complete this Response Form indicating your action to address this field safety notice and return it to **Caddsolis@smiths-medical.com** within 10 days of receipt.

**Account# XXXXXXX** Purchase History:

| Item SKU | Serial Number |
|---|---|
| | |

Once the Response form has been acknowledged, customer services will contact you to arrange collection of your device/s. However, please do not return any accessories as they will not be replaced.

I certify that I have received and understand the information in the attached Field Safety Notice (FSN).

| Name and Title (Please Print) | Telephone Number | Signature |
|---|---|---|
| | | |
| **Email Address (Please Print clearly)** | **Date** | |
| | | |

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**ATTACHMENT 1a**

# URGENT MEDICAL DEVICE FIELD SAFETY NOTICE RESPONSE FORM

## CADD®-Solis VIP Ambulatory Infusion Pump

Please assist us in executing this Field Safety Corrective Action (FSCA) by completing and returning this Response Form as soon as possible. This will serve as confirmation that you have received and understand the accompanying Field Safety Notice (FSN) and will allow us to ensure that we have reached all customers who may be affected by this issue.

Please complete this Response Form indicating your action to address this field safety notice and return the completed form to ***(Distributor Name)*** within 10 days of receipt.

Affected Devices and Serial Numbers:
***(Please complete populate the below fields per your sales records)***

| Item SKU | Serial Number |
|---|---|
| | |

Please contact us at ***(Please enter your contact information here)*** If you have any questions or concerns regarding this field action.

Affected devices should be returned to ***(Distributor Name)*** , however, please do not return any accessories as they will not be replaced. Replacement pumps will be supplied by ***(Distributor Name)*** .

I certify that I have received and understand the information in the attached Field Safety Notice (FSN).

| **Name and Title (Please Print)** | **Telephone Number** | **Signature/Date** |
|---|---|---|
| | | |
| **Email Address (Please Print clearly)** | **Date of Completion** | |
| | | |