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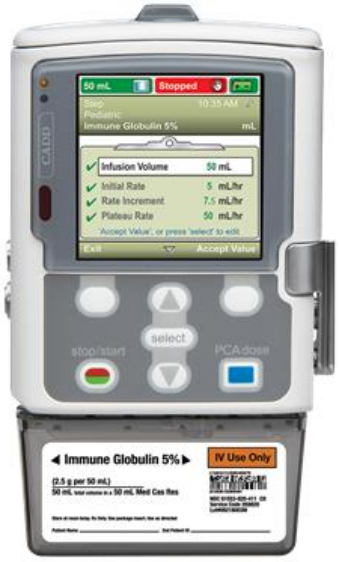
URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

CADD®-Solis VIP Infusion Pump

Affected Devices:	**CADD®-Solis VIP Infusion Pumps**
Type of Action:	**Recall (Clarification of Labeling)**
Date:	**June 2018**
Attention:	**Canadian clinicians and health care providers who oversee the use of the CADD®-Solis VIP Infusion Pump and Distributors of the medical device.**

REASON FOR FIELD SAFETY NOTICE

The purpose of this Field Safety Notice (FSN) is to inform you of concerns raised by Health Canada regarding delivery accuracy of the CADD-Solis VIP pump. This FSN clarifies the environmental factors and product configuration that may have an impact on delivery accuracy for the CADD-Solis VIP pump. **This notification does not involve a retrieval of devices.**



CADD-Solis VIP Infusion Pump

Affected Model Numbers	
21-2120-0100-02	21-2120-0102-51
21-2120-0100-50	21-2120-0102-78
21-2120-0100-51	21-2120-0102-92
21-2120-0100-92	21-2120-0103-02
21-2120-0100-95	21-2120-0103-51
21-2120-0102-02	21-2120-0103-78

Environmental Factors and Delivery Accuracy

The current CADD-Solis VIP system delivery accuracy labeling claims are documented in the CADD-Solis VIP Technical Manuals and Operator Manuals. All labeling claims currently specify delivery accuracy of +/- 6% (nominal). Based on testing performed by Smiths Medical, ASD, under or over-delivery beyond the claimed +/- 6% may occur as a result of back pressure or fluid resistance, which may occur due to:

- properties of the infused fluid, including temperature or viscosity
- height of the pump relative to patient
- use of components such as catheters or filters
- type of administration sets or cassettes
- ambient temperature

Refer to the “Additional Information for Clinicians” section for additional information on factors that may affect delivery accuracy and a clarification regarding pump operation.

RISK TO HEALTH

The CADD Solis VIP infusion pump has the potential to under-deliver or over-deliver medication or fluids beyond the ±6% delivery accuracy claim currently stated in the labelling, due to some environmental factors and product configurations. When testing under non-nominal conditions, the delivery inaccuracy could range from 20% under-delivery to 10% over-delivery. Refer to the section below 'Additional Information for Clinicians' for the detailed test data. See discussion on environmental conditions below.

CADD Solis VIP infusion pumps are used for a variety of infusion therapies. Potential health consequences from under-delivery or over-delivery will depend on the patient condition, the therapy involved, the degree of under-delivery or over-delivery, and possibly the time to discovery of the under-delivery or over-delivery.

Smiths Medical has conducted a post market risk analysis of CADD-Solis VIP system performance. The risk analysis identified the following possible serious adverse health consequences of over/under delivery that are expected to occur at a rate of less than 1 in 10,000 infusions.

Under-delivery:

1) Inadequate symptom control (dependent on therapy being delivered). For example: Increase in pain or increase in cardiac symptoms (heart rate, rhythm, blood pressure);
2) Inadequate or delay of treatment (dependent on therapy being delivered). For example: Sub-therapeutic doses delivered of medication in which a specific volume needs to be infused such as antibiotics, chemotherapy, or nutritional therapy.

Over-delivery:

1) Patients may receive their medicinal product in an inappropriate allowable time frame. For example: In over-delivery of opioids for pain relief, patients may experience somnolence and/or decreased respiratory drive.
2) If the volume infused occurs too rapidly, the reservoir may empty. This may lead, for example, to the pump not maintaining the Keep Vein Open (KVO) rate, which may result in clotting of a patient's catheter.

ADDITIONAL INFORMATION FOR CLINICIANS

Prior to use of the CADD-Solis VIP system, appropriate patient selection should be considered, in combination with environmental factors. These factors may include a home use setting in which patients are not under direct supervision by a health care professional.

Please review the clarified labeling below when considering patient selection, where CADD-Solis VIP pump use is prescribed. Patient instruction should be provided to ensure optimal accuracy is achieved.

Updated Indications For Use (IFU) Delivery Accuracy Information is provided in Blue font below.

Nominal Conditions

± 6% (nominal). At low infusion rates, stated accuracy may not be achieved for short periods. During the total infusion time, the accuracy averages out.

System delivery accuracy is determined under the following nominal conditions:

- Infusion rate of 10 mL/hr
- Ambient temperature of 22° C
- Fluid viscosity of 0.89 cP (e.g., water)
- 0.2 mmHg (0.004 PSI) back pressure (e.g., 2 inch 18 Ga needle)
- Pump is placed at the same height as the infusion site
- Reservoir placed at the same height as the infusion site
- CADD® Administration Set with Flow Stop Free Flow Protection (e.g., 21-7321-24)

Accuracy testing was performed using 22 CADD®-Solis Ambulatory Infusion Pumps and 22 CADD® Administration Sets with Flow Stop Free Flow Protection.

WARNING:

- Ensure that the ± 6% system delivery accuracy specification is taken into account when programming the pump and/or filling the reservoir. Failure to do so may result in medication in the reservoir becoming depleted sooner than expected. If the pump is being used to deliver critical or life sustaining medication, the interruption in the delivery of medication could result in patient injury or death.
- System delivery inaccuracies beyond ± 6% may occur as a result of back pressure or fluid resistance, which depends upon temperature, drug viscosity, catheter size, extension set tubing (for example, microbore), in-line components (such as filters and needleless access connectors), and placing the infusion reservoir and/or pump above or below the level of the patient. System delivery inaccuracy may result in under or overdelivery of medication.

Patient Selection

It is important to consider patient selection with regard to clinical factors and environmental factors. These factors can include the route of administration, the prescribed medication, and the system configuration chosen to ensure acceptable delivery accuracy is appropriate for your patient.

For example, when delivering highly viscous medications (e.g., select antibiotics or TPN formulations) at higher rates (e.g., 150 mL/hr), consider using the High Volume Remote Reservoir Administration Set 21-7381-24, which includes a 1.2 µm filter.

Non-Nominal Test Conditions

The adjusted flow rate accuracy for non-nominal environmental conditions when using a CADD® standard volume Administration Set with Flow Stop Free Flow Protection is summarized below as determined per testing methods defined in industry standard IEC 60601-2-24.

Tested Environmental Conditions and Product Configurations

Test Condition	System Delivery Accuracy
Back pressure increase of 100 mmHg (1.9 PSI)	-10% to 4%
21 Gauge Epidural Catheter	-20% to -1%
Temperature < 15°C	-8% to 3%
Temperature > 40°C	-9% to 10%
Viscosity of 5.12 cP (50% Water / 50% Dextrose Solution)	-19% to 2%
Pump/reservoir height one foot above the infusion site	-6% to 6%
Pump/reservoir height one foot below the infusion site	-9% to 10%
Filter (0.2 µm and 1.2 µm)	-7% to 8%
Non-Flow Stop Administration Sets	-9% to 6%
All 50/100 ml Medication Cassette Reservoirs	-8% to 11%
All 250 ml Medication Cassette Reservoirs	-13% to 8%

INSTRUCTIONS FOR ALL USERS AND DISTRIBUTORS

1) Immediately notify all users, clinicians and health care providers who oversee the use of any CADD®-Solis VIP Pumps in your possession of this Field Safety Notice and provide a copy of the enclosed Product Labeling Insert to each of these users. DISTRIBUTORS: You are required to immediately notify your customers of this Field Safety Notice and provide a copy of the enclosed Product Labeling Insert to all customers.

2) Complete and return the attached Response Form to SmithsMedical8919@stericycle.com within 10 days of receipt of this Field Safety Notice. DISTRIBUTORS: Ensure your end-customers are provided this form along with their requirement to respond to Smiths Medical. **The form must be returned even if you do not have any CADD®-Solis VIP Pumps in your possession.**

3) For health care providers: Prior to use of this product, familiarize yourself with the system delivery accuracy, which is dependent on environmental conditions and system configuration, specified above and found in the "Replacement Information for Operator's Manual" insert. This insert replaces the delivery accuracy information provided in the Solis VIP Operator's Manuals (pages 129 and 130) and Technical Manuals (pages 13 and 14).

4) If you are not a medical professional and using this product for home use, please contact your health care provider for an explanation of this notice.

This Field Safety Notice is being issued in collaboration with Health Canada.

If you have any questions regarding this Field Safety Notice, please contact Stericycle via: (EMAIL) SmithsMedical8919@stericycle.com, (FAX) 1-888-912-7346.

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

Gary Barrett
Vice President Quality Systems, Regulatory & Compliance
Smiths Medical

Attachments:

Response Form
Product Labeling Insert