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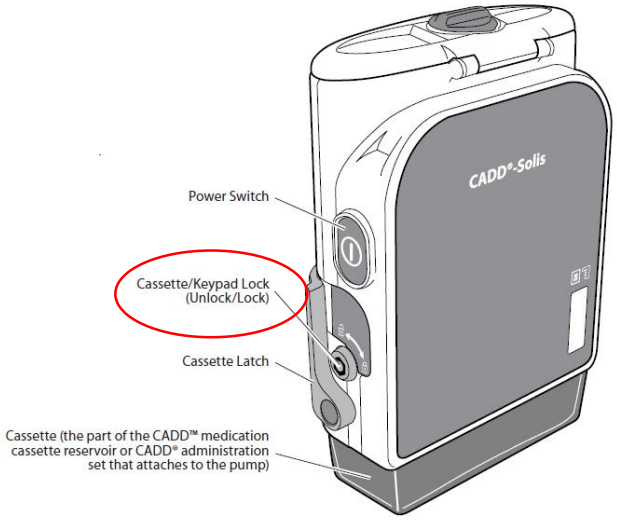
URGENT FIELD SAFETY NOTICE

For CADD®- Solis Ambulatory Infusion Pumps, Model Numbers 2111, 2112, and 2120

Affected Devices:	CADD®-Solis Ambulatory Infusion Pumps
Type of Action:	Field Safety Corrective Action – Correction
Date:	26 May 2015
Attention:	Risk/Safety Managers, Biomedical Professionals, Clinicians who oversee the use of CADD® Solis Pumps, Distributors, and other users of these devices
Details on affected devices:	Serial Number 1061043 through 1067598

Smiths Medical is providing this Urgent Medical Device Recall Notice to advise its customers of a potential issue with CADD®-Solis Ambulatory Infusion Pumps. Smiths Medical is voluntarily taking this action with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of an issue with an intermittent occurrence of binding of the locking assembly on some CADD®-Solis pumps. Binding of the Cassette/ Keypad Lock can occur after latching the CADD®-Solis Medication Cassette Reservoir or Administration Set "disposable" to the pump. When binding occurs, it can prevent the key from fully rotating the Cassette/ Keypad Lock to the locked (engaged) position. To start an infusion with CADD®-Solis Pump Models 2111(Grey Keypad) and 2112 (Yellow Keypad), and Model 2120 (VIP), when in PCA mode, the lock must be fully engaged. CADD®-Solis Pump Model 2120 will start in all other delivery modes without the Cassette/ Keypad Lock being engaged.



If the user is unable to fully engage the Cassette/ Keypad Lock, then Model 2111 and 2112, and Model 2120 in PCA mode, the keypad will be locked and the pump cannot be started. This could cause a delay in the start of an infusion or interruption in therapy if changing a disposable, while an alternative pump is obtained. A delay or interruption of delivery of pain medication may result in escalation of patient pain based on the underlying condition of the patient. Based on

field experience with these products and the reported complaints received to date, an interruption or delay in delivering pain medication would most likely result in minimal patient impact.

Smiths Medical has received no reports of serious injury or death related to this issue.

Not all CADD®-Solis Pumps are affected by this action – This issue is limited to specific Serial Numbers. Serial Number 1061043 through 1067598.

Smiths Medical has resolved the problem associated with the binding of Cassette/ Keypad Locks and implemented a lubrication step during manufacture and during servicing at Smiths Medical Authorized Service Centers.

Advice on Action to be taken by the User:

If you begin to experience resistance when locking a CADD®-Solis pump or if you are unable to fully engage the Cassette/ Keypad Lock while turning the key, then discontinue use of the pump and contact Smiths Medical to arrange for repair. If you are not experiencing resistance when locking your CADD®-Solis Pumps, there is no immediate need to return your pumps for repair. The next time you choose to return your pumps to a Smiths Medical Authorized Service Center for routine service, we will perform the service to prevent the binding from occurring. Smiths Medical is requiring all its customers to acknowledge receipt of this Notice.

1. Complete and return the attached Confirmation Form (see Attachment 1) by Fax to 7027 2092 or by email to info.danmark@smiths-medical.com within 10 days of receipt of this letter.
2. Upon receipt of the completed form, if applicable, a customer service representative will contact you to arrange for repair of your CADD®-Solis Pumps.

Transmission of this Urgent Medical Device Recall Notice

This notice shall be passed on to all personnel who need to be aware within your organization, including points of use, or to any organization where the potentially affected devices have been transferred. If you or your facility has distributed these affected products to other persons or facilities, please promptly forward the recipients a copy of this Notice and copy info.danmark@smiths-medical.com with the contact information of the current pump owner.

Please maintain awareness of this Notice and resulting action for an appropriate period to ensure effectiveness of this correction.

Customers shall report any issues with these products to Smiths Medical 7027 2090 or info.danmark@smiths-medical.com .

If you should have any questions regarding this information, please contact Smiths Medical at 7027 2092.

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

Sincerely,

Lasse Forsén
Manager, Quality Systems
Smiths Medical Denmark

Enclosures: Attachment 1 – Confirmation Form

URGENT FIELD SAFETY NOTICE CONFIRMATION FORM
For CADD®- Solis Ambulatory Infusion Pumps

Please complete and return this Form by Fax to 7027 2092 or by sending an electronic copy via email to info.danmark@smiths-medical.com

☐ **YES** – I acknowledge receipt and understand this Notice, have informed potential users in my organization and will take no further actions at this time.	Total number of affected products: _____
☐ **YES** – I acknowledge receipt and understand this Notice, have informed potential users in my organization. I have CADD®-Solis Pumps and I would like to make arrangements for Smiths Medical to repair my pumps. A Smiths Medical Representative will contact you based on the contact information included on the response form.	Total number of affected products: _____
☐ **NO** – I do not have any of the affected products.	
☐ I no longer have any of the affected products. I transferred them to the following location: *(please provide name, address, and phone number):*	

Please Complete contact information below regardless of what was checked above	
Facility Name:	Facility Address:
Signature:	Facility Shipping Address:
Print Name:	Date:
Department:	
Email:	Phone Number: ( )