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Smiths Medical ASD, Inc.
1265 Grey Fox Road
St. Paul, MN 55112 USA

URGENT MEDICAL DEVICE RECALL

For MEDFUSION® SYRINGE INFUSION PUMP, MODELS 3010A and 3500

November 16, 2009

Dear Risk/ Safety Managers, Distributors, Clinicians, Critical Care Physicians, Pediatricians, Pediatric Intensivists, Neonatologists; and Nursing, Pharmacy, Clinical/ Biomedical Engineering, and Anesthesia Professionals:

Smiths Medical is conducting a voluntary recall of a limited number of Medfusion® Syringe Infusion Pumps, Models 3010A and 3500, manufactured between August 1, 2008 and June 10, 2009. This voluntary recall is being conducted with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has become aware of an increased trend in reports of "Motor Not Running" ("MNR") and "Motor Rate Error" ("MRE") alarm message events with certain Medfusion® Syringe Infusion Pumps, Models 3010A and 3500 ("Pump"). **This Urgent Recall Notice only applies to Pump Serial Numbers listed in Attachment 2. While not all Pumps on the attached list will experience this issue, we are proactively retrieving all Pumps that may be affected for testing.**

MNR/ MRE are high priority alarm messages which can occur for a variety of reasons as part of the usual self-test functionality of the Pump. The Pump is designed so that when its software detects a system fault during routine self-tests, the Pump stops delivery and provides visual and audible alarms – which include a flashing red indicator, a display screen backlight that oscillates between bright and dim, an alarm message on the screen display and a repeating audible sound - to alert the clinician of the situation. The message, "Motor Not Running" or "Motor Rate Error" also displays on the Pump screen during these alarm message events.

As described above, the Pump stops delivery when a MNR/ MRE alarm message event occurs, preventing the Pump from delivering fluids. There have been no reports of patient injury related to these alarm message events.

Advice on Action to be Taken by the User:
Subject to this Urgent Recall Notice, Smiths Medical is requiring its customers to return all Pumps with the Serial Numbers listed in Attachment 2. The Pumps will be inspected, and repaired if necessary, and returned to your facility. Smiths Medical understands the critical nature of these Pumps and that patient needs will dictate your timing in taking these Pumps out of use for return to Smiths Medical for inspection.

- **If a Pump on the attached list is currently in use, there is no evidence to suggest that immediate removal from service is necessary in the absence of a Motor Not Running/ Motor Rate Error alarm message event. If a Pump experiences a MNR/ MRE alarm message event, it provides visual and audible alarms to alert the clinician of the situation. In this case the Pump must be removed from service immediately.**
- Review your inventory and segregate any Pumps on the attached list which have not yet been placed in service and contact Smiths Medical for return information (following the directions below);
- Review your inventory for all other Pumps on the attached list, prepare a plan for returning these Pumps for inspection, and contact Smiths Medical for return information (following the directions below);
- Complete and return the attached Confirmation Form (see Attachment 1) by fax to 800.237.8033 or by email to medfusionmotor@smiths-medical.com. You will be provided with complete directions on how to return your Pumps for the inspection process; and
- In some cases, your customized Pump settings (PharmGuard® Configuration) may default to factory settings as a result of the repairs performed – make sure to verify your settings and, if necessary, customize your pump before returning to use. Pumps that are defaulted to factory settings will be indicated as such with a notice in the box when the Pump is returned to your facility.

If you or your facility has distributed these affected Pumps to other persons or facilities, please promptly forward the recipients a copy of this Urgent Recall Notice.

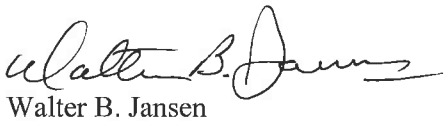
To return Pumps or for questions regarding this Urgent Recall Notice, please contact our Customer Service Department at 1-866-270-7060.

Please report any issues with these Pumps to our Technical Customer Service Department at 1-866-216-8806.

Any adverse reactions experienced with the use of these products and/or quality problems may also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088 (1-800-332-1088), by fax at 1-800-FDA-0178 (1-800-332-0178), by mail at MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852, or online at www.fda.gov/medwatch.

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

Sincerely,



Walter B. Jansen
Manager, Quality Systems
Smiths Medical ASD, Inc.
Enc: Attachment 1 – Urgent Recall Notice Confirmation Form
Attachment 2 – List of Pump Serial Numbers Subject to this Recall Action

ATTACHMENT 1 **Smiths Medical ASD, Inc.**

URGENT RECALL NOTICE CONFIRMATION FORM

For MEDFUSION® SYRINGE INFUSION PUMP, MODELS 3010A and 3500

"Motor Not Running"/ "Motor Rate Error" Alarm Message Events

(see Attachment 2 for the list of Pump Serial Numbers subject to this Recall)

Please complete and return this Form by fax to 1-800-237-8033 or by sending an electronic copy via email to medfusionmotor@smiths-medical.com.

Check all applicable boxes below:

	YES - I have Medfusion® Model 3010A or 3500 Pumps identified by the Serial Numbers in Attachment 1. (Attach a list of your Pump Serial Numbers and call Smiths Medical Customer Service at 1-866-270-7060 for further details on how to return your Pumps for inspection, and if necessary, repair.)	Enter total number of your Pumps listed on Attachment 2 =
	NO - I do not have any Medfusion® Model 3010A or 3500 Pumps as identified by the Serial Numbers in Attachment 2.	
	I no longer have any Medfusion® Model 3010A or 3500 Pumps as identified by the Serial Numbers in Attachment 2. The Pumps have been transferred to the following location:	
	All of my Medfusion® Model 3010A or 3500 Pumps identified by the Serial Numbers in Attachment 2 are no longer in service and have been made inoperable and disposed.	

Printed Name: _____ Department: _____

Signature: _____ Date: _____

Facility Name: _____

Facility Adr: _____

_____

_____

Phone No.: ( ) Ext.: Fax No. ( )