

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

URGENT MEDICAL DEVICE CORRECTION NOTICE

**For MEDFUSION® SYRINGE INFUSION PUMP, MODELS 3010 AND 3010a WITH
OBSOLETE SOFTWARE VERSIONS 2.0.2, 2.0.3, AND 2.0.4**

June 22, 2010

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

Smiths Medical is conducting a correction of Medfusion® Syringe Infusion Pumps, Models 3010 and 3010a, **with obsolete software versions 2.0.2, 2.0.3, and 2.0.4**. This voluntary correction is being conducted with the knowledge of the relevant Regulatory Agencies.

Smiths Medical has found that pumps with obsolete software may continue to run past the set volume limit, if all of the following occur:

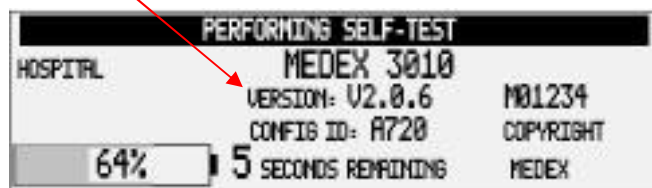
- 1) The Volume Over Time (delivery method) mode is used;
- 2) The Volume Over Time mode is re-accessed through the Recall Last Settings function; and
- 3) The syringe is over-filled (e.g., the syringe is filled for more than one infusion amount).

If the syringe is over-filled, this issue can result in an over-delivery which could, depending on the delivery route of administration, fluid delivered, and/ or patient, result in injury or death. Smiths Medical has received no reports of serious patient injury or death related to this issue.

Advice on Action to be Taken by the User:

Subject to this Urgent Medical Device Correction Notice, Smiths Medical is requiring its customers with Medfusion® Model 3010 and 3010a pump software versions 2.0.2, 2.0.3, or 2.0.4 to upgrade their software to the current version 2.0.6.

- 1) Determine the software version of your Medfusion® Model 3010/ 3010a pump by checking the screen display when powering up the pump - the software version will display on the screen.



June 11, 2010

2) Complete and return the attached Confirmation Form (see Attachment 1) by fax to 800.237.8033 or by email to medfusionsoftware@smiths-medical.com. If Box 1 of the Confirmation Form is checked, Smiths Medical will process an upgrade order automatically. Please make sure that your name and address details are legible, so that we can quickly and accurately process your request.

3) The upgrade kit will contain instructions on how to upgrade the software. Please return the completed Software Update Test Form (page 5 of the instructions), so your pump service records can be updated accordingly.

4) If your facility is unable or unwilling to perform the software upgrade to your affected pumps, please contact our Service Department at 800-258-5361 to make arrangements for returning your pumps to Smiths Medical for the upgrade.

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 Corrections Notice.

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.

If you should have any questions regarding this information, please contact us at 800-258-5361.

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

Sincerely,

Tim Giguere
Manager, Quality Systems
Smiths Medical ASD, Inc.

Enc: Attachment 1 ó Urgent Medical Device Correction Notice Confirmation Form

June 11, 2010

ATTACHMENT 1

Smiths Medical ASD, Inc.

URGENT MEDICAL DEVICE CORRECTION NOTICE CONFIRMATION FORM

For MEDFUSION® SYRINGE INFUSION PUMP, MODELS 3010 and 3010a
<u>Obsolete Software Versions 2.0.2, 2.0.3 and 2.0.4</u>

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

Check <u>all</u> applicable boxes below:		
Box 1	YES - I have Medfusion® Model 3010 or 3010a Pumps with obsolete software (version 2.0.2, 2.0.3, or 2.0.4). Note: If this box is checked an upgrade kit will be sent to the address below automatically.	Enter total number of your Pumps = _____
Box 2	NO - I do not have any Medfusion® Model 3010 or 3010a Pumps with obsolete software (version 2.0.4 or below).	
Box 3	I no longer have any Medfusion® Model 3010 or 3010a Pumps. . The Pumps have been transferred to the following location:	
Box 4	All of my Medfusion® Model 3010 or 3010a Pumps are no longer in service and have been made inoperable and disposed.	

Printed Name: _____ Department: _____

Signature: _____ Date: _____

Facility Name: _____

Facility Address: _____

Phone No.: () Ext.: E-Mail. _____