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UPDATED URGENT MEDICAL DEVICE RECALL NOTICE

MEDFUSION® 3500 and 4000 SYRINGE PUMPS - POTENTIAL INAPPROPRIATE BOLUS/LOADING DOSE DELIVERY

Affected Device Models: Medfusion® 3500 and 4000 Syringe Pumps

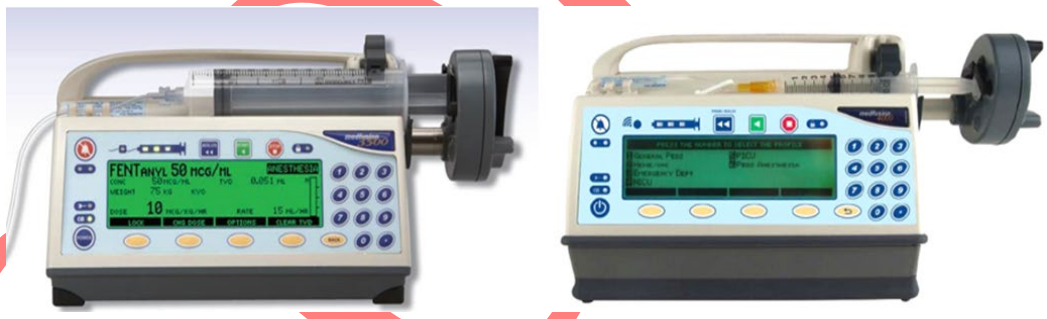
Type of Action: Correction

Date: August 17, 2020

Attention: Director of Nursing, Director of Risk Management, ER/NICU/ICU Clinicians, Recall Coordinator, Biomedical Department, Pharmacy

Affected Devices: Only Medfusion® 3500 and 4000 syringe pumps with the following Firmware Versions are within scope of this notice:

Affected Model	Affected Firmware Version
Medfusion® 3500	6.0.0
Medfusion® 4000	1.5.0, 1.5.1, 1.6.0, 1.6.1, 1.7.0



The firmware version of the pump may be identified by powering on the unit and observing the firmware version displayed on the screen. This notice is applicable only to the pumps operating on the firmware versions listed on the first page of this notice

Dear Customer,

The purpose of this Recall Notice is to advise you that Smiths Medical has initiated a voluntary recall notification for certain Medfusion® 3500 and 4000 Syringe Pumps installed with the firmware versions listed in the affected device table above. Please note that this is a recall and **not a product removal**. As of May 13, 2020, a total of 53485 (world-wide) devices are included in this recall notification. This recall is being performed with the knowledge of Food and Drug Administration.

REASON FOR RECALL

Smiths Medical became aware of an unanticipated behavior in certain Medfusion® 3500 and 4000 Syringe Pumps. If a bolus or loading dose is interrupted and specific sequence of events occurs, inappropriate delivery (over or under-delivery of a bolus or loading dose) may occur.

WARNING

THE PROGRAMMING SEQUENCE DESCRIBED BELOW MAY LEAD TO INAPPROPRIATE DELIVERY

1. Programs a Bolus or Loading Dose
2. Initiates the Bolus or Loading Dose
3. Interrupts the Bolus or Loading Dose
4. Primes Using the Pump
5. Resumes the Bolus or Loading Dose **instead of beginning a new infusion**

RISK TO HEALTH

If a user follows the sequence of pump programming selections detailed above, medication over-infusion or under-infusion may occur, which may not be detected until after occurrence. This inappropriate delivery (over or under-delivery of a bolus or loading dose) may lead to serious injury or possibly death, depending on the type of treatment being administered and the patient's condition.

This sequence of events may occur, for example, if a patient is on a continuous infusion of medication and receiving intermittent boluses and the medication syringe and tubing need to be replaced during one of the bolus infusions.

Smiths Medical has received a total of 4 reports associated with this issue, all involving over-delivery of medication. One of these reports resulted in a serious injury; there were no reports of death.

INSTRUCTIONS TO CUSTOMERS AND DISTRIBUTORS

INSTRUCTIONS TO CLINICIANS

For any reason, when a bolus or loading dose delivery is interrupted and then mechanically primed using the PRIME FUNCTION, cancel the remaining bolus or loading dose and begin a new infusion to avoid potential inappropriate delivery.

Users of the Affected Devices listed in the table on page 1 must not resume an interrupted bolus dose or loading dose if mechanical priming using the PRIME FUNCTION has been performed during bolus dose or loading dose interruption. After priming, when prompted to continue the interrupted bolus dose or loading dose, only continue medication delivery by beginning a new infusion.

All customers who purchased Affected Devices listed in the table on page 1 should identify any of these products within their possession and refer to the detailed instructions contained within this notice as an **OPERATIONAL REQUREMENT**.

Actions by Smiths Medical:

1. Smiths Medical developed an Operators Manual Insert that is being sent with this Updated Recall Notification.

2. Smiths Medical is developing software updates to fix this software defect. We estimate that these software updates will be available in late 2021. When the software updates are available, Smiths Medical will contact you to initiate the scheduling process to receive these updates.

PLEASE INDICATE YOUR UNDERSTANDING AND ACKNOWLEGEMENT OF THIS NOTICE BY COMPLETING THE STEPS LISTED BELOW.

1. Locate all Medfusion® 3500 and 4000 Syringe Pumps in your possession. Verify the firmware version to determine if your pump(s) is impacted by this notice.
2. Ensure all personnel who may utilize the pump are aware of this recall.
3. Distributors, if you have distributed potentially affected product to your customers, please immediately forward this notice to them. Request that they complete the response form and return it to bolusdelivery@smiths-medical.com.
4. Complete and return the attached Response Form to bolusdelivery@smiths-medical.com to acknowledge your receipt and understanding of this Recall Notice within 10 days of receipt.

No return of product is necessary. This notification is being provided for awareness only. Smiths Medical continues to investigate this matter and will follow up with affected customers.

Adverse events or quality problems experienced with the use of this product must be reported to Smiths Medical via globalcomplaints@smiths-medical.com.

Questions regarding this recall notification may be forwarded to fieldactions@smiths-medical.com.

If you wish to contact the FDA regarding any adverse events or quality problems associated with this notice, the contact information is listed below.

- **FDA Online** : **www.fda.gov/medwatch**
- **Call FDA at** : **1-888-INFO-FDA**

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

Sincerely,

Dr. G. Barrett
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Enclosures:

Attachment 1 – Recall Notice Response Form
Attachment 2 – Operators Manual Insert