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URGENT MEDICAL DEVICE FIELD SAFETY NOTICE

Medfusion® Syringe Pump Model Series 3500 and 4000

Syringe Recognition

Type of Action:	Correction (Field Safety Notice)
Date:	January 12, 2018
Attention:	Distributors of (and Clinicians who use) the Medfusion® Syringe Pump Model Series 3500 and 4000
Affected Devices:	**The following products are potentially affected by this issue:**

Medfusion® 3500 Series Syringe Pump

Medfusion® 4000 Series Syringe Pump

Model 3500 Product Codes
3500-0600-00
3500-0600-01
3500-0600-50
3500-0600-51
3500-0600-82
3500-306
3500-415
3500-500

Model 4000 Product Codes
4000-0101-50
4000-0101-51
4000-0105-50
4000-0105-51
4000-0106-00
4000-0106-01

Dear Valued Customer,

The purpose of this letter is to advise you that Smiths Medical is issuing a Field Safety Notice for certain Medfusion® Syringe Pump Models, Series 3500 and 4000, which were manufactured or serviced between February 2015 and November 2017.

REASON FOR FIELD SAFETY NOTICE:

Smiths Medical has recently become aware that certain Medfusion® Syringe Pump Models, Series 3500 and 4000, may not be recognizing or may be misidentifying loaded medication syringes. The inability of a pump to recognize a syringe (i.e. the size of the syringe is unknown to the pump) results in an inability to complete pump programming. Misidentification of a syringe may also occur, in which the pump misinterprets the syringe size.

The intent of this Field Safety Notice is to *reinforce the need to always confirm the accuracy of all infusion values to the original order, including verifying syringe size.* Accompanying this Field Safety Notice is a Reference Tool for clinicians to use that specifically highlights methods to verify the syringe size.

RISK TO HEALTH:

The inability of the pump to recognize a syringe can potentially lead to a delay in the initiation of an infusion, due to clinicians being unable to complete programming. Interruption of therapy may also potentially occur if loss of recognition occurs during an active infusion (Note – the pump will alarm in this scenario).

Misidentification of syringe size may potentially result in over-delivery or under-delivery if the clinician does not notice the pump's misidentification of the syringe prior to starting an infusion.

INSTRUCTIONS TO CUSTOMERS:

PLEASE TAKE THE FOLLOWING ACTIONS TO HELP US PROPERLY EXECUTE THIS NOTIFICATION:

1. Please advise all clinicians overseeing use of Medfusion® Syringe Pump Model Series 3500 and 4000 in your facility to utilize the enclosed Reference Tool to verify the syringe size.

2. If the syringe is not recognized or is read as an incorrect size during any part of the programming or the infusion, remove the pump from service for repair by a trained biomedical technician.

3. If you are a distributor please immediately notify your impacted customers of this Field Safety Notice.

4. Review and complete the attached Response Form and return it to SmithsMedical7612b@stericycle.com within 10 days of receipt of this letter. The form must be returned even if you no longer have any of the potentially affected Medfusion® Syringe Pump Model Series 3500 and 4000 in your possession.

If you have any questions regarding this notification, please contact via email at SmithsMedical7612b@stericycle.com.

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

Sincerely,

David Halverson
Global Compliance Manager
Smiths Medical

Enclosures: Response Form, Reference Tool