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MEDICAL DEVICE ADVISORY NOTICE

Follow-up to 2015 Customer Information Bulletin

Medfusion® 3500 and 4000 Syringe Infusion Pumps

17 May 2022

Dear Valued Medfusion Customers:

- Director of Biomedical Engineering
- Chief Nursing Officer
- Director of Risk Management

In December 2015, Smiths Medical issued a Customer Information Bulletin (attached) to notify customers of an issue with increased Supercap POST (power-on self-test) and Backup Audible Alarm errors. These alarms occur at startup when the pump goes through a self-test.

In November 2021, Smiths Medical retroactively filed a notification for these errors with the FDA, which they deemed to be a Class II Recall. Hence you are receiving this notice again.

Smiths Medical has since determined that devices with the supercapacitors referenced in the Customer Information Bulletin do not require repair. This follow up Advisory Notice is for your information only, and Smiths Medical is continuing to monitor the performance of these devices specific to this component.

Overall Risk:
When this error occurs, the device becomes inoperable which may potentially lead to a delay in therapy. To date, no serious injuries or deaths have been reported because of this issue.

Affected Devices:
Pump model numbers have changed over time as a result of device upgrades; as a result, this list of affected devices has been updated as compared to the 2015 Customer Information Bulletin.

Medfusion Syringe Pump Models: 3010, 3010A, 3010AZE, 3500, 3500-0600-00, 3500-0600-01, 3500-0600-50, 3500-0600-51, 3500-0600-82, 3500-306, 3500-402, 3500-414, 3500-415, 3500-500, 3500E, 3500G, 3500VX-306, 3500VX-500, 4000-0100-50, 4000-0101-249, 4000-0101-50, 4000-0101-51, 4000-0101-78, 4000-0105-51, and 4000-0105-78.

Main Boards (Sold separately through Smiths Medical Service and Repair): G6000243, G6000361, G6000435, G6001260, G6001560, G6001562, and G6002728.

Please visit www.smith-medical.com/customer-support/alerts-and-notices for a list of impacted serial numbers associated with each model number listed above.

For further inquiries, please contact Smiths Medical using the information provided below:

Smiths Medical Contact	Contact Information	Areas of Support:
Global Complaint Management	globalcomplaints@smiths-medical.com 1-866-216-8806	To report adverse events or product complaints
Technical Assistance	1-800-258-5361	Additional information or technical assistance

Customer Required Actions:

1. Complete and return the attached Response Form to smithsmedical5090@sedgwick.com **within 10 days of receipt** to acknowledge your understanding of this notification.
2. Since this is a repeat communication from 2015 no other actions are required.

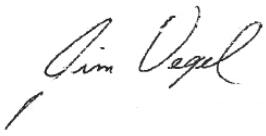
General Information:
This notification is being performed with the knowledge of regulatory authorities, including the US Food and Drug Administration (FDA).

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,



Jim Vegel
Vice President of Quality

Enclosures:
Attachment 1 – Notification Response Form
Attachment 2 – 2015 Customer Bulletin

smiths medical

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

CUSTOMER INFORMATION BULLETIN 03-Dec-2015

Product

Medfusion® 3010, Medfusion® 3500 and Medfusion® 4000 syringe pumps and replacement main boards manufactured between April 2012 and June 2015 may be impacted.

Smiths Medical part numbers:

Syringe Pump Models: 3010, 3010A, 3500-0600-01, 3500-0600-50, 3500-306, 3500-414, 3500-415, 3500-500, 4000-0101-50 and 4000-0101-51, and 4000-0105-51.

Main Boards (Sold separately through Smiths Medical Service and Repair): G6000361, G6000435, G6001260, G6001560, G6001562, and G6002728

Subject

Supercap POST (power on self-test) and *Backup Audible Alarm* error codes.

Summary

This bulletin is intended to provide information to customers, distributors and affiliates who use Medfusion® 3500 or Medfusion® 4000 syringe infusion pumps manufactured between April 2012 and June 2015, and Medfusion 3010 and 3010A (and the above pump models) serviced during the same time period in which a main board was replaced.

Smiths Medical has seen an intermittent issue with increased *Supercap POST (power on self-test)* and *Backup Audible Alarm* error codes outside of the pump warranty period. These alarms occur at start up when the pump goes through the self-test.

Details

A *Backup Audible Alarm* error or *Supercap POST* error is generated when a Medfusion® syringe pump fails the self-test. These self-tests are performed automatically during the pump power up to determine if the backup buzzer and Supercapacitor circuit on the main board are working correctly, including the capacitance and internal resistance of the Supercapacitor. The Supercapacitor provides the electric power / current to perform the backup audible alarm test.

Between April 2012 and June 2015 a component change was made on the Medfusion® syringe pump Supercapacitor component. Subsequent investigation has determined that the replacement Supercapacitor is aging at a faster rate than the original. Although the device performs as expected within the 1 year warranty period, pumps with the replacement supercapacitors that are in use for a longer period of time have a higher risk of experiencing the *Backup Audible Alarm* error or *Supercap POST error.*

The *Backup Audible Alarm* and *Supercap POST* error are programmed to be a *System Failure Alarm*, which requires that a biomed code be entered in order to dismiss the alarm and reset the pump for continued use.

Action

For your convenience, Smiths Medical is providing you a list of serial numbers for pumps in your facility that maybe impacted. Also, if you purchased main boards between April 2012 and June

2015 (for part numbers G6000361, G6000435, G6001260, G6001560 and G6002728), they are included in the attached file.

Smiths Medical is offering to replace the affected supercapacitor. Please contact Smiths Medical to make arrangements to begin the replacement process.

If the S*upercap POST* alarm or the *Backup Audible Alarm* error code occurs prior to the replacement, immediately remove the pump from service for repair by a trained biomedical technician at Smiths Medical or your facility. If a device from the attached serial number list is sent to Smiths Medical for any other unrelated repair, the supercapacitor will be replaced.

For additional assistance, contact Smiths Medical:

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Tel: +1 614 210 7300

www.smiths-medical.com