



January 27, 2011

Medical Specialties Distributors, LLC
800 Technology Center Drive
Stoughton, MA 02072-4707

Dear Customer,

MSD received notification by letter from B. Braun Medical Inc. (copy attached) on January 25, 2011 of the Urgent Medical Device Correction by Moog Medical Devices Group (copy attached) for the ambulatory administration sets used with the Moog Curlin Ambulatory Pumps, which includes the 4000 CMS Ambulatory Pump, the 6000 CMS Ambulatory Pump, and the PainSmart® IOD Ambulatory Pump.

The Urgent Medical Device Correction is being initiated due to the potential false air-in-line alarm may occurring when using the ambulatory administration set. Attached is a list of affected lots. Our records indicate that you may have received one or more of these lots. Further use of the affected product should be discontinued immediately.

Utilizing the attached "Field Correction Acknowledgement Form" record the number of individual units in your current inventory. If you have no inventory, please enter zero on the form. Please return the completed form directly to B. Braun.

Please call the B. Braun Customer Support Department at (800) 227-2862 to arrange for return of affected product. A B. Braun Customer Support Representative will provide you with instructions and handling the affected product. Fax the Recall Acknowledgement to B. Braun Medical Inc. by fax to (610) 849-1197 within two (2) weeks of your receipt.

If you have any questions in relation to the actions needed to be taken please contact MSD's Customer Service Department at 800-967-6400.

Sincerely,

MSD Recall Coordinator

CORPORATE OFFICE of MEDICAL SPECIALTIES DISTRIBUTORS, LLC.
800 Technology Center Drive ■ Stoughton, Massachusetts 02072-4707 ■ (781) 344-6000- Main Fax (781) 344-7244
Customer Service FAX (781) 344-8320 ■ Accounting FAX (781) 344-7415 ■ Biomedical Services FAX (781) 344-8125

THE NATION'S LEADING ALTERNATE SITE HEALTHCARE DISTRIBUTOR



B. Braun Medical Inc.
 901 Marcon Blvd.
 Allentown, PA 18109



**MOOG MEDICAL DEVICE GROUP MEDICAL DEVICE CORRECTION
FIELD CORRECTION ACKNOWLEDGMENT FORM**

Please complete the information below and return as soon as possible to B. Braun. It is important that B. Braun receives the necessary information on the amount of affected products in your possession.

To arrange for the return of product please contact B. Braun Customer Support Department at:
 (800) 227-2862 (within the US)
 (800) 624-2920 (Canada)
 Fax form to: (610) 849-1197

Catalog No.	Lot No.	Qty. in Units in Inventory

Distributor Name: Medical Specialties Distributors, LLC
Distributor Account #: 20059992
Distributor Address: 800 Technology Center Drive Stoughton, MA 02072

Name of Facility Returning Product: _____

Signature: _____

Printed Signature: _____ **Date:** _____

Address: _____



B. Braun Medical Inc.

901 Marcon Blvd.
Allentown, PA 18109
Telephone: (800) 227-2862
Fax: (610) 849-1197

January 25, 2011

MOOG MEDICAL DEVICE GROUP ISSUES
URGENT MEDICAL DEVICE CORRECTION

Dear Distributor:

Moog Medical Devices Group, manufacturer of the ambulatory administration sets used with Moog Curlin Ambulatory Pumps which is distributed by B. Braun Medical Inc., has issued the attached field correction due to potential false air-in-line alarm that may occur when using the ambulatory administration set. Please review the attached notice from Moog Medical Devices Group, which provides the necessary information, list of all affected lots, and actions required.

Our records indicate that you have received one or more of these lots. Further distribution of the affected product should be discontinued immediately. **Please contact your customers that have received these lots and inform them of the medical device correction.**

Please determine the inventory with your customers and have them return the affected product to B. Braun Medical Inc. to ensure proper credit of returned product. Please do not destroy any affected product. Utilizing the attached "Field Correction Acknowledgement Form" record the number of individual units in your current inventory. If you have no inventory, please enter zero on the form. Please return the completed form in the self-addressed envelope provided and fax the completed form to (610) 849-1197 within two weeks of receipt.

To meet regulatory requirements, the attached Field Correction Acknowledgment Form must be completed and returned to B. Braun Medical Inc. Quality Assurance Group via the self-addressed envelope provided or fax even if the total inventory in your possession is zero.

If you have any full or partial cases of these affected products and associated lot numbers in your possession, please call our Customer Support Department at (800) 227-2862 to arrange for return and replacement product. A Customer Support Representative will provide you with instructions for handling the affected product and we will arrange for all products to be returned to B. Braun Medical Inc. Should you have any questions or concerns regarding the attached information, please contact our Customer Support Department at (800) 227-2862 or Moog Medical Devices Group at (800) 970-2337, prompt #7.

Sincerely,

Kimberly Paris
Director of Quality, PA
B. Braun Medical, Inc.

Enclosures

URGENT MEDICAL DEVICE CORRECTION

Moog Medical Devices Group
 4314 Zevex Park Lane
 Salt Lake City, Utah 84123

January 24, 2011

ph 801.264.1001
 fx 801.264.1051
 800.970.2337

RE: Moog Ambulatory Administration Sets for Moog Curlin Ambulatory Pump

www.moog.com/medical

Dear Customer,

Moog is issuing this notification to provide you important information regarding a field correction for the ambulatory administration sets used with the Moog Curlin Ambulatory Pumps, which includes the 4000 CMS Ambulatory Pump, the 6000 CMS Ambulatory Pump, and the PainSmart® IOD Ambulatory Pump. The decision to conduct the field correction is due to a potential false air-in-line alarm that **may occur** when using an ambulatory administration set.



Issue Explanation:

A defect with the resin used in tubing received from a supplier has been discovered. This has resulted in a rough texture on the inner and outer diameter of the tubing segment inserted into the pump. This could lead to the pump sensor registering an air bubble, causing an unresolvable false air-in-line alarm, even if no air bubble is present.

Patient Impact:

There have been no reported adverse patient events as of the date of this notification.

Necessary Customer Actions:

Moog records indicate you have received ambulatory administration sets that may lead to the false air-in-line alarm. Identification of potentially affected product codes and lot numbers are listed in Attachment A. If you have product from these lot numbers, please follow the process as outlined below:

Product Purchased from a Distributor:

Action	Required Information
1. Remove suspect product code from inventory	See Attachment A to determine lots that are suspect
2. Contact your Distributor to arrange replacement product	Provide lot numbers, quantities of product needing to be returned and a shipping address for replacement product
3. Request a shipping return label as per the distributor's process and ship back to their location.	Box up all suspect product and return via shipping label

Product Purchased Directly from Moog

Action	Required Information
1. Remove suspect product code from inventory.	See Attachment A to determine which lots are suspect
2. Contact Moog Customer Service at 1-800-970-2337, prompt #7.	Provide lot numbers, quantities of product needing to be returned and provide a shipping address for replacement product
3. Moog Customer Service will provide a call tag for convenient product return.	Box up all suspect product and return via the call tag

Temporary Clinical Option for Using Pumps:

Until replacement administration sets are shipped, we realize you may need an alternate way in which to provide patient therapy. Following is a suggested **temporary solution**:

- Clinicians can elect to use the Moog Curlin Ambulatory pump(s) by turning the pump air sensor, located in the options menu, to the "OFF" status. (Reference Attachment B for instructions, or refer to the Curlin Ambulatory Pump Users Manual.)
- Use of an administration set with an air-eliminating filter whenever the Air-In-Line Sensor is set to OFF. (See Attachment C for available product codes with an air-eliminating filter.)
- If you do not currently use sets with "in-line air eliminating filters", contact your account manager to assist you with determining alternative options.

Moog is committed to quickly resolving this issue. We have notified the necessary regulatory bodies of the intent to do a voluntary field correction. We apologize for any inconvenience.

Sincerely,

Michael L. Henderson
Group Director, Operations
Moog Medical Devices Group

Attachments for Support:

- A) Product codes and lot numbers
- B) Instructions for air sensor "off" mode
- C) Administration set with filter product codes

Administration Set Model and Manufacturing Lot Identifier

340-4114	340-4130	340-4130-V	340-4128	340-4128-V	340-4126
CF1019715	CF1020403	CF1020102	CF1018201	CF1019019	CF1020408
CF1028109	CF1027402	CF1020103	CF1018802	CF1019023	CF1020901
CF1028109	CRF10149002	CRF10098001	CF1018805	CF1019023	CF1021001
CF1028110	CRF10151002	CRF10144001	CF1019015	CF1021804	CF1023901
CRF10042001	D004711	CRF10145001	CF1019016	CF1022206	CRF10119001
CRF10110001	D005613	D005005	CF1020802	CRF10100001	CRF10120001
CRF10121001	D005614	D005014	CF1022208	CRF10102001	CRF10120003
CRF10123001	D008513	D005014	CF1022801	CRF10104001	CRF10172002
CRF10124001	D010320	D009501	CRF10130001	CRF10139003	CRF1017401
CRF10132003	D010912	D010305	CRF10130001	CRF10160002	D008216
CRF10133002	D010913	D010319	CRF10132001	CRF10161003	D008512
CRF10134001	D012437	D011110	CRF10135001	D004617	D009806
CRF10163003	D013005	D011111	CRF10137001	D005006	D010321
CRF10165001	D013440	D013442	CRF10155003	D006004	D010416
CRF10167002	D013441	D014706	CRF10156001	D011801	D013714
CRF10168001	D014705	D017318	CRF10158002	D012439	D013715
CRF10169003	D016606	D017420	CRF10159001	D013007	D015325
CRF1017501	D016607	D017421	CRF10160001	D014707	D015326
CRF1017602	D020016	D018005	D100317	D016003	D016002
CRF1017702	D020017	D019321	D100318	D016603	D017913
CRF1017901	D020722	D019322	D100318	D016604	D018714
CRF1018002	D021012	D020235	CRF10130001	D016713	D022810
D018718	D021013	D020923	CRF10137001	D017419	D022811
D100319	D021607	D020924	CRF10135001	D018101	D023620
D100320	D026422	D021404	CRF10130001	D019323	D024418
CRF1017501	D026423	D022201	CRF10137001	D020024	D024513
CRF1017702	D027306	D022202	CRF10145001	D020235	D027110
		D022203	CRF10130001	D020235	
		D024921	CRF10135001	D020236	
		D024922	CRF10130001	D020237	
			CRF10130001	D021601	
			CRF10134001	D027014	
			CRF10130001	D015905	

Administration Set Model and Manufacturing Lot Identifier

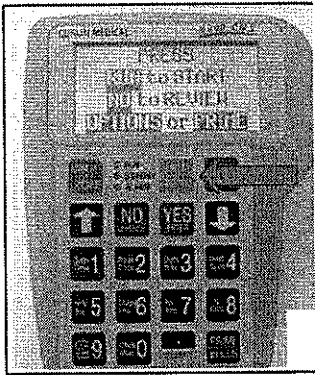
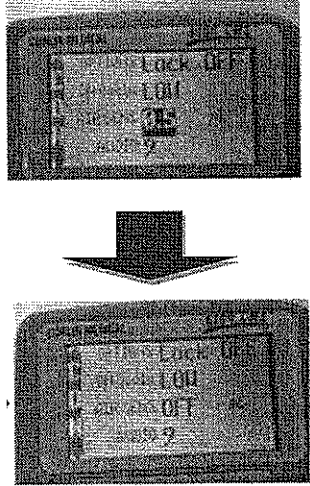
340-4176	340-4144	340-4111	340-4134	340-4115	340-4127
CRF10125003	CF1020106	CF1026001	CF1022901	D005013	CF1022601
CRF10163002	CF1020107	D011109	D004616	D010911	D008217
CRF1018704	D018718	D012438	D004714	D017304	D015328
D100714			D008511	D017317	
			D009805		
			D016001		
			D016605		
			D018715		
			D017148		
340-4137	340-4162	340-4168	340-4169	340-4167	340-4164
D001909	D006005	D100712	D100713	CRF1018302	CF1020405
D932716	D020303			CRF1018307	CRF10116001
					CRF10117001
					CRF10118002
					CRF10162002
					CRF10163001
					D003905
					D010910
					D012440
					D013006
					D013716
					D021702
					D025613



January 24, 2011

ATTACHMENT B

USING THE "OPTIONS" FUNCTION TO TURN OFF THE AIR-IN-LINE SENSOR ALARM

Step	Instructions	Visual
Step 1	Program and verify the therapy.	
Step 2	Upon completion of programming the therapy, select the OPTIONS function. A password will be required if the pump has a set lock level.	
Step 3	Once the Options menu is selected, scroll down (via the arrow or YES key) until AIR SENS is reached. The AIR SENS may show a default of 0.5 mL. Select NO until the OFF mode is on the screen (the pump will offer options of .5 mL, 2mL, and 01.mL). By selecting the NO key, this can be changed to OFF. Select YES to verify your choice.	
Step 4	Select the RUN key to begin the therapy. Answer YES when asked "AIR Sensor OFF, Using an IN Line Filter?"	

ATTACHMENT C

ADMINISTRATION SETS WITH FILTERS - PRODUCT CODES

Product Code	Description of substitute sets containing air-eliminating filters	Clinical Considerations
340-4128	<p>Non-vented bag spike, tubing with free-flow protection, slide clamp, 1.2 micron filter, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)</p> <p>Non-vented bag spike, tubing with free-flow protection, slide clamp, 1.2 micron filter, distal male luer lock connector, add-on check valve. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)</p>	<p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab. Set can be gravity primed prior to breaking away the tab or can be pump primed. 2. Note priming volume. 3. Note instructions for priming air filter (hold filter upright).</p> <p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab backed up by the add-on check valve. The valve must be connected prior to connecting to the patient. 2. Set can be gravity primed prior to breaking away the tab and attaching the back check valve. Set can also be pump primed. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p> <p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab. Set can be gravity primed prior to breaking away the tab or can be pump primed. 2. Note priming volume. 3. Note instructions for priming air filter (hold filter upright).</p>
340-4130	<p>Non-vented bag spike, tubing with free-flow protection, slide clamp, .22 micron filter, distal male luer lock connector, add-on check valve. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)</p> <p>Non-vented bag spike, tubing with free-flow protection, slide clamp, .22 micron filter, distal male luer lock connector, add-on check valve. Latex-free, DEHP-free. Priming Volume: 5.1 mL Length: 94 in (238.8 cm)</p>	<p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab backed up by the add-on check valve. The valve must be connected prior to connecting to the patient. 2. Set can be gravity primed prior to breaking away the tab and attaching the back check valve. Set can also be pump primed. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p> <p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p>
340-4173	<p>Non-vented bag spike, tubing with free-flow protection, slide clamp, ASV 6 inches from distal end, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 7.3 mL Length: 97 in (246.4 cm)</p> <p>Non-vented bag spike, tubing with free-flow protection, .22 micron filter, slide clamp, ASV 6 inches from distal end, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 7.0 mL Length: 97 in (246.4 cm)</p>	<p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p> <p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p>
340-4174	<p>Non-vented bag spike, tubing with free-flow protection, slide clamp, ASV 6 inches from distal end, distal male luer lock connector. Latex-free, DEHP-free. Priming Volume: 7.0 mL Length: 97 in (246.4 cm)</p>	<p>1. Free flow protection provided by the "Flow-Stop" device w/the break away tab and in-line anti-siphon valve. 2. Set can only be primed on the pump. 3. Note priming volume. 4. Note instructions for priming air filter (hold filter upright).</p>