

ABBOTT NUTRITION • ABBOTT LABORATORIES

625 CLEVELAND AVENUE • COLUMBUS, OHIO 43215-1724 • (614) 624-7677

December 18, 2008

RE: Urgent Medical Device Field Action

Dear Abbott Nutrition Customer,

Moog Medical Devices Group has initiated a voluntary removal of its ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps. According to Moog, a software error may affect operation of the pump and may result in either over or under infusion. To address this issue, Moog is upgrading the pump software.

Our records indicate that we have shipped you one or more of the affected ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps:

- #59887 – Purchased pump
- #50897 – Lease or rental pump

Affected pumps include those with serial numbers between 506297001 and 508290050. Please review the enclosed letter from Moog for additional information on how to identify the software error.

If you find that the software error has occurred on any of your ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps, stop using the pump immediately and contact Zevex Customer Advocacy at (800) 970-2337, option 7.

Abbott Nutrition will be facilitating service arrangements for our direct customers. Please see the enclosed "Customer Instruction Sheet" that explains arrangements for pump upgrades. You may also contact Abbott Nutrition Customer Service at (800) 986-8435 Monday through Friday between the hours of 8:30 a.m. and 5:00 p.m. EST with questions.

If you are a distributor, you are required to contact your customers and notify them of this field action.

Your prompt attention to this matter is essential. Additionally, the U.S. Food and Drug Administration may contact you as part of its recall effectiveness checks.

Abbott Nutrition appreciates your cooperation with this Moog initiative and we look forward to continuing to serve you.

Sincerely,

Roger M. Bird
DVP & General Manager
Therapeutic Nutrition
Abbott Nutrition

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Urgent Medical Device Correction

December 18, 2008

**RE: ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps
(SN 506297001 through SN 508290050)**



Dear Valued Customer,

ZEVEX is issuing this Medical Device Correction to provide you important information regarding the ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps (Infinity). It has come to our attention that, in very rare situations, a fault may affect the normal operation of these pumps.

Issue Explanation

When the fault occurs, the pump has experienced a software anomaly error that affects the pump's ability to control the user programmed delivery. This anomaly occurs during the pump power on process. If the anomaly does not occur on power up, the pump will operate normally.

Patient Impact

There have been no reported adverse events as a result of this anomaly, although there is a very remote possibility of patient injury through either over or under infusion if the fault were to occur. This software anomaly occurs only on pump power on. A caregiver can detect a potentially corrupted pump by observation of one or more of the following performance abnormalities after turning the pump on:

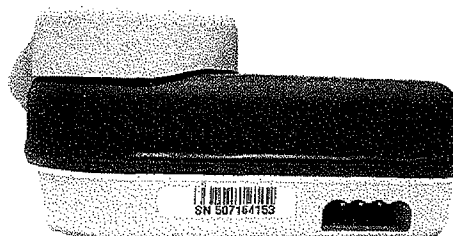
1. **If the caregiver is able to program a feeding rate in excess of 600 ml/hr, or is limited to rates less than 600 ml/hr.** *Corrupted pumps may allow the user to select feeding rates as high as 9999 ml/hr. (note: the pump allows the user to select this rate; however, the pump cannot actually deliver at this rate as the maximum pump rate is at the priming rate of approximately 720 ml/hr. Corrupted pumps may also limit the rate to values below the normal 600 ml/hr limit.*
2. **If the pump runs continuously without pausing (this should be monitored over a period of at least one minute).** *During Normal operation, the pump will pause during each one minute interval to maintain the correct selected delivery rate. A corrupted pump may fail to pause and run continuously until the entire dose is delivered.*
3. **If the pump appears to be operating but the motor is not turning.** *Similar to the failure to pause, a corrupted pump may fail to run and remain only in the pause state. If the pump indicates that it is running (circular arrows are turning on the display), but the rotor does not actually turn and there is no movement of fluid for at least one minute, the pump may have the corrupted data.*

Necessary Actions

You are receiving this notice because our records indicate that you have one or more Infinity enteral feeding pumps that may exhibit the anomaly identified in this correction. ZEVEX has developed a software based fault handling upgrade that requires reprogramming of your Infinity pump.

Potentially affected Infinity pumps include those with serial numbers between 506297001 and 508290050. The serial number is located on a label affixed to the side of the pump next to the power connector port. The serial number is nine digits and is preceded by the letters "SN". For example:

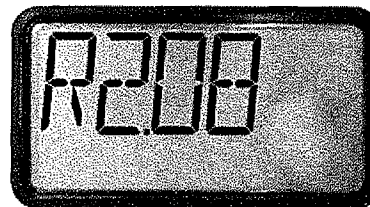
SN 508015027



The serial number is located on a label affixed to the side of the pump next to the power connector port.

Any pumps manufactured or serviced after November 3, 2008 already include the upgraded software and are not affected by this fault. These pumps include those with serial numbers above 508290050 or those with software version 3.14 or greater. The software version is indicated on the screen during the pump power up procedure.

With the upgraded pump software, if a software anomaly occurs, the pump will recognize the anomaly and notify the user by stopping the pump and displaying an Error 63. This error can be cleared by following the instructions in the current user's manual for this error condition. The user turns the pump off and then back on. This allows the system to re-initialize, the corrupted data will be erased and the pump will now operate normally. As part of the data correction, the therapy parameters will be reset to the default values. Before operating the pump, the user will need to reset the therapy parameters to the desired settings.



The software version is indicated on the screen during the pump power up procedure.

Please see the enclosed Abbott "Customer Instruction Sheet" that explains arrangements for pump upgrades. Contact Abbott Customer Service at (800) 986-8435 Monday through Friday between the hours of 8:30 a.m. and 5:00 p.m. EST for questions about this process. For technical or clinical questions, contact ZEVEX Customer Advocacy at (800) 970-2337 then option 7. You may also contact ZEVEX via e-mail at sales@zevex.com.

We also encourage you to report adverse events related to over or under infusion to ZEVEX, Inc. and to MedWatch, the FDA's voluntary reporting program.

You may submit reports to MedWatch by phone at (800) FDA-1088; by Fax at (800) FDA-0178; by mail to MedWatch, Food & Drug Administration 5600 Fisher Lane, Rockville, MD 20857-9787; or on-line at <http://www.fda.gov/medwatch/report.htm>.

We apologize for any inconvenience this will cause you and your staff. We are committed to addressing each of your concerns for your benefit and the well-being of

your patients. Thank you for your continued interest in and consideration of ZEVEX Enteral Feeding products.

If you are a distributor, you are required to contact your customers and notify them of this Urgent Medical Device Correction.

The U.S. Food and Drug Administration has been notified of this communication.

Sincerely,



Michael L. Henderson
Group Director, Quality and Regulatory Affairs
Medical Devices Group
Moog, Inc.

Enclosure

**Urgent Medical Device Field Action
ZEVEX EnteraLite® Infinity® Enteral Feeding Pumps
(SN 506297001 through SN 508290050)**

CUSTOMER INSTRUCTION SHEET

- **Please read this entire package carefully.**
- **Refer to the enclosed “Account Summary” to identify affected pumps, which Abbott Nutrition records indicate were shipped to your facility.**
- **Please check your inventory for the affected serial numbered pumps on the Account Summary. The serial number of the pump is located on a label affixed to the side of the pump next to the power connector port.**
- **Once you’ve reviewed your inventory, complete the Account Summary sheet and fax it to (800) 986-8422.**
- **Abbott Nutrition Customer Service will ship your replacement pumps and will issue a Return Authorization (RA) number for returning pumps to Moog. The following items will be addressed:**
 - **Verification of customer account information**
 - **Replacement pump order**
 - **Total number of pumps to be returned**
 - **Shipping instructions and labels to expedite return of affected pumps to Moog**
- **If you have any questions regarding the Account Summary or process for returning/replacing your pumps, please call Abbott Nutrition Customer Service at (800) 986-8435 Monday through Friday 8:30 a.m. to 5:00 p.m. EST.**

Note: If you are a distributor, you are required to contact your customers and notify them of this Urgent Medical Device Field Action.