

Class I Medical Device Recall: Baxa Corporation Abacus Total Parenteral Nutrition (TPN) Calculation Software

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 23, 2009

Product: Abacus Total Parenteral Nutrition (TPN) Calculation Software

Catalogue Numbers:

- 8300-0045: Abacus Calculator Only (Abacus CE)
- 8300-0046: Abacus Single Work Station (Abacus SE)
- 8300-0047: Abacus Multi-Work Station (Abacus ME)

Use: The Abacus TPN Calculating Software is an FDA Class I Laboratory Information Management System (LIMS) Windows-based program used in ordering total parenteral nutrition.

Parenteral nutrition is given intravenously when a person is unable to eat or drink via mouth. It is used on a compounding system to create or calculate TPN formulas. Pharmacists use this software.

The Abacus TPN Calculation Software was manufactured and distributed from August 7, 2006 through April 15, 2009.

Recalling Firm:

BAXA Corporation
14445 Grasslands Dr
Englewood, Colorado 80112

Reason for Recall: A number of errors have been reported by Abacus software users as a result of ordering salt based parenteral nutrition ingredients on an ion based ordering template. Abacus TPN Calculation Software is designed and intended to allow the ordering of electrolytes in only one of two ways: as a salt (such as calcium gluconate 10%) or as an elemental ion (such as calcium). However, if a dosage is entered into the system based on one method, when the template is configured for the other method, a dosing error can occur.

Example Order: 500 milligrams of the 10% gluconate salt = 5ml of a 10% calcium gluconate solution. In contrast, ordering 500 milligrams of the 10% calcium ion = 53.76 ml of calcium gluconate. In this example, ordering based on a salt (calcium

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gluconate) while using an ion (calcium) template will result in 10 times more calcium gluconate than intended.

The problem associated with mix-ups related to salt-based or ion-based ordering of electrolytes is not exclusive to calcium gluconate.

Public Contact: Customers with questions about this recall can contact Baxa Technical Support at 1-800-678-2292. Technical support for the Abacus TPN Calculating Software is available 24 hours a day, 7 days a week.

FDA District: Denver

FDA Comments: This is not a new recall.

This is a classification of the recall initiated in 2009. As of this posting, over 90% of Abacus users have made corrective actions.

On January 23, 2009, Baxa Corporation sent its customers a "Safety Alert" letter. The letter described the product, problem, and action to be taken. The customers were instructed to ensure that users create either a salt-based template **OR** an ion-based template for ordering, and that both methods of ordering are not used in one template. Customers were also instructed to establish ingredient warning limits and to have pharmacists sign off if a warning limit is exceeded. In 2009 and 2010, Baxa issued updates that added limit warnings to the Abacus software.

Class 1 recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#) [1] either online, by regular mail or by FAX.

Additional Links:

- [Firm Safety Alert](#) [2]  [3]

[SOURCE](#) [4]

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<http://www.mdtmag.com/news/2012/05/class-i-medical-device-recall-baxa-corporation-abacus-total-parenteral-nutrition-tpn-calculation-software>

Links:

[1] <http://www.fda.gov/Safety/MedWatch/default.htm>

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[2] <http://www.baxa.com/resources/docs/AbacusSafetyAlertDec2008v6.pdf>

[3] <http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>

[4] <http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm305744.htm>