THE METRIX COMPANY

URGENT:

MEDICAL DEVICE RECALL

SECURE (AutoCOMP6, AutoCOMP6 XP, AutoCOMP6 XPS)

June 22, 2016

Dear Sir/Madame:

The purpose of this letter is to advise you that The Metrix Company is voluntarily recalling the SECURE pharmacy compounding devices (AutoCOMP6, AutoCOMP6 XP, AutoCOMP6 XPS). This recall has been initiated because the device is unable to maintain the fill accuracy requirements for the compounded bag as outlined in the user's manual. Therefore, the patient receiving the compounded bag may not receive the correct quantity of individual parenteral nutrition solutions or the correct overall quantity of parenteral nutrition solutions.

No adverse events have been reported to The Metrix Company as a result of this issue.

Our records indicate that you received one or more of the affected products; see the details in the table below. The Metrix Company is asking all customers to follow the steps below:

1. Recalled products must not be used.
2. Locate and quarantine all affected products.
3. If this information is received by a dealer, wholesaler, or distributor/reseller that distributed any of these products to other facilities, then notify your customers as detailed below so that those customers can locate and remove all affected products.
    a. Notify all customers which have been shipped or may have been shipped any of the products listed in the table below. A sample Customer Notification Letter and Response Form are enclosed.
    b. Provide Metrix with a list of the customers notified.
4. Complete the Response form and return it to The Metrix Company according to the instructions on the form.

RECALLED PRODUCT LIST

Metrix Part #	Product Description	Serial Number
58798	Secure AutoCOMP6 High Speed Compounder	All Serial Numbers
58800	Secure AutoCOMP6 XP High Speed Compounder	All Serial Numbers
58800 E	Secure AutoCOMP6 XP High Speed Compounder	All Serial Numbers
58810	Secure AutoCOMP6 XPS High Speed Compounder	All Serial Numbers

Manufacturer of SECURE™ Products

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For any questions please contact:

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This Urgent Voluntary recall is being made with the knowledge of the Food and Drug Administration (FDA). Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. Online at: www.accessdata.fda.gov/scripts/medwatch. For Regular Mail: use postage-paid, pre-addressed FORM FDA 3500 available at www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms.
Sincerely,

Jennifer Clasen
Quality Assurance Manager
The Metrix Company

Attachments: Medical Device Recall Return Response Form
Sample Customer Notification Letter
Sample Customer Response Form