

Mallinckrodt

Mallinckrodt Inc. 675 McDonnell Boulevard P.O. Box 5840 St. Louis, MO 63134

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## **URGENT DRUG RECALL**

November 18, 2005

Subject: DTE GENERATORS

Dear Mallinckrodt Customer:

Mallinckrodt is initiating a voluntary recall of Ultra-TechneKow® DTE Generator Lot numbers 5176, 5177, 5178, 5179, 5180, 5181, 5182; Catalog numbers:

Catalog		
N8831L, 2L	N8891L, 2L	N8911T, 2T
N8841L, 2L	N8891T, 2T	N8911D, 2D
N8851L, 2L	N8901L, 2L	N8921D, 2D
N8861L, 2L	N8901T, 2T	N8931D, 2D
N8871L, 2L	N8901D, 2D	N8941D, 2D
N8881L, 2L	N8911L, 2L	N8951D, 2D

We have identified you as a customer who is likely to have one or more of the listed Generators in your current inventory.

This voluntary recall is being conducted as a result of issues we identified during routine sterility assurance process re-validation. To date, no adverse events have been reported relating to these specified products. However, we are conservatively recalling all DTE Generators within expiry in the interest of patient safety while we continue our investigation.

We request that you immediately discontinue distribution and use of the above-mentioned products. You are required to complete the enclosed business response form so we can initiate the return process. Please fax the completed business response form immediately to (314) 654-8206.

Please return the completed business response form, even if you have none of the specified DTE Generators in stock at this time. We must have your response by November 29, 2005. Product return instructions will be forwarded to you under a separate cover letter.

This recall is being conducted with knowledge of the Food and Drug Administration.

Your patience and cooperation are greatly appreciated. If you have any questions, please call Corporate Product Monitoring at **1-888-744-1414**.

Sincerely,

Corporate Product Monitoring