

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

Disetronic Medical Systems Inc. (a member of the Roche Group) announces a recall (field corrective action) of the ACCU-CHEK® Spirit insulin pump due to “up” and/or “down” button failures

Contact:

Julie Vincent
317-521-1910

FOR IMMEDIATE RELEASE -- April 30, 2009 -- *This notification applies to all ACCU-CHEK® Spirit insulin pumps with serial numbers from **SN02119552 through SN10006093 (range of SN shipped to the US)**. Pumps with serial numbers including and above SN10006094 are not affected and no action is required by users of these pumps.*

Disetronic Medical Systems Inc. announced today that it is notifying its customers, distributors and healthcare professionals about a potential defect in the “up” and/or “down” buttons of some ACCU-CHEK Spirit insulin pumps. This failure may present as an intermittent or complete loss of function of the “up” and/or “down” buttons. The pump’s “up” and “down” buttons are used for changing the program in the menu or to administer additional insulin through a bolus delivery. If the buttons do not function, users may not be able to change any programmed setting on the pump. If this failure occurs, the pump may not respond with a vibration or acoustic confirmation signal to a button press and the display will remain unchanged. This defect was discovered through the company’s normal quality control monitoring process.

The notifications provide specific actions and details that customers, distributors and healthcare professionals need to take. The pumps in question have serial numbers in the range from SN02119552 through SN10006093 (US market).

If the vibration or acoustic confirmation signal does not occur, the user should disconnect the pump, and switch to a back up pump or an alternative method of insulin delivery. Immediately contact ACCU-CHEK Spirit hotline for a replacement pump or for any other questions regarding this potential defect. Customers should expect the replacement pump within 1-2 business days after contacting ACCU-CHEK Spirit hotline at 1-800-778-5095. This number is available 24 hours a day, 7 days a week.

Disetronic will replace pumps within the affected serial numbers (SN02119552 to SN10006093) that have intermittent or complete loss of function of the “up” and/or “down” button promptly upon contact from the customer with a new pump that is not affected by the potential button failure. If you have any questions regarding this recall or questions pertaining to replacement, please contact ACCU-CHEK Spirit hotline at 1-800-778-5095 for further information. This number is available 24 hours a day, 7 days a week.

“We are making this proactive notification to our customers and other interested parties because we have seen a potential for the “up” and/or “down” buttons on some of our pumps to fail over a period of use,” said Dr. Mathias Neumann, Head of Global Quality Management Diabetes Care, Roche Diagnostics. “We are telling our customers to continue to use their ACCU-CHEK Spirit

insulin pumps, but monitor the functioning of the “up” and “down” buttons. In addition customers are to continue to monitor their blood glucose as directed by their healthcare professional. Additional actions required by customers are detailed in their notification. We are working with the Food and Drug Administration (FDA), who is aware of this recall and this notification.

We have isolated the root cause of the defect and a fix to the problem has been implemented with SN10006094 and above,” said Dr. Neumann. “The problem is an interrupted electronic contact in the flexible board of the “up” and “down” button module caused over time by stress of this board during repeated pressing of the button.”

Users of an ACCU-CHEK Spirit insulin pump, who are experiencing failure of the “up” and/or “down” buttons, should immediately contact ACCU-CHEK Spirit hotline at 1-800-778-5095. This number is available 24 hours a day, 7 days a week.

#