

Medical Device Recall

TGA Reference Number: RC-2014-RN-00576-1

2 June 2014

Regarding: Vibration Alarm Defect -Accu-Chek[®] Spirit Combo Serial Numbers: 10171897 to 10281629

Dear Accu-Chek[®] Spirit Combo User,

It has come to our attention that an increased frequency of E7 errors may be encountered by some users. This is related to a potentially occurring malfunction of the vibration alarm. In a limited number of cases (less than 0.5%) this may cause the E-7 error message to be displayed. In the rare case a pump system is affected by this issue, the E-7 error message will be displayed when the user tries to switch the pump from stop into run mode. The E-7 error message will be displayed and the user will be notified that the pump is still in stop mode. Safety features such as the continuing audio signal as well as a visual notification will enable the user to detect the issue immediately and thus prevent you from using an incorrectly functioning device. We have investigated the root cause and have already implemented the appropriate corrective measures to the affected components. So starting from product serial number 10281630 the issue has been resolved.

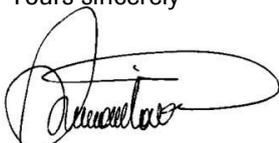
If you experience an E7 error, attempt to clear the error by following the instructions in the operators' manual:

- Remove or disconnect the infusion from your infusion site.
- Replace the battery in the pump. Prime the infusion set. Reconnect the infusion set at your infusion site.
- Put the pump in RUN mode.

After an Error E7: ELECTRONIC ERROR always check your settings like e.g. basal rate profile, time and date. If the Error E7: ELEGTRONIC ERROR occurs repeatedly, please contact the Roche Diabetes Care Contact Centre on 1800-633-457. Use the alternative therapy plan provided by your doctor or healthcare team.

The Therapeutic Goods Administration has been notified of this action.

Yours sincerely



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