

URGENT PRODUCT NOTIFICATION

Laval, November 9, 2005

Important Information on the ACCU-CHEK Aviva Blood Glucose Meter

Dear Health Care Professional:

With this letter, Roche Diagnostics would like to inform you about a technical corrective action relating to the ACCU-CHEK Aviva blood glucose meter. The action described concerns only this system.

Roche maintains close contact with its customers around the world through its sales force representatives and the ACCU-CHEK Customer Care Centers. We have received one single complaint worldwide describing a clearly identifiable, too low and non-plausible blood glucose reading following a measurement performed on the ACCU-CHEK Aviva blood glucose meter. To date, in Canada, we have received **no** such reports.

The blood glucose meter is equipped with a high performance processor. Studies have shown that in very rare cases a malfunction between the software and the processor can result in an incorrect reading.

Although no cases have occurred in Canada, it cannot be ruled out that individual systems with this malfunction could be in circulation. **The only systems that might be affected are those with serial numbers below 526 10 999 999.** The serial number is located on the back of the meter (see example).

serial number





URGENT PRODUCT NOTIFICATION

ACCU-CHEK Aviva Meter

November 9, 2005

Page 2

With regards to these systems, we would like to inform you about methods of quality checking that can be used to identify the malfunction described above:

- Remove the battery from the rear of the meter and then wait 5 seconds before replacing it. After the battery has been replaced, start the meter with the "ON" button at top right. This will automatically prompt a quality check of the meter. Meters with this fault will not power on.

If the meter powers "on", your patient can continue to use their ACCU-CHEK Aviva blood glucose meter in the usual manner.

- We also invite you to instruct your patients to perform a control test per mentioned on page 41 of the Accu-Chek Aviva Owner's manual whenever their test result does not agree with how they feel and to remove the battery from the meter again.

If you have any questions on this subject, please contact the ACCU-CHEK Customer Care Center at 1-800-363-7949. Meters showing the type of fault described will be replaced immediately free of charge.

ACTION REQUIRED:

- **If any of your patients using an ACCU-CHEK Aviva need assistance please refer them to ACCU-CHEK Customer Care Center Monday through Friday; 8:00 a.m. to 8:00 p.m. (ET) at 1-800-363-7949.**
- **Ensure that all warranty cards are completed and kept until your Accu-Chek Representative collects them during his/her next visit.**

The actions described above are being conducted with the knowledge of Health Canada.

Despite the extremely low probability of the case described above, all necessary steps for a technical correction have been implemented.

Yours sincerely,

Tom Roberts
Vice President, Patient Care
Roche Diagnostics (Canada)

Allan Lane, Ph.D.
Director, Regulatory Affairs and Quality Management
Roche Diagnostics (Canada)