

Patient Safety Alert

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Item:	Blood glucose meters, models OneTouch, Ultra, InDuo, and OneTouch FastTake manufactured by LifeScan, Inc.
Specific Incident:	LifeScan has received reports of adverse events related to the device inadvertently set to the incorrect unit of measure, thereby causing people with diabetes to misinterpret their glucose level by a factor of nearly 15. The LifeScan blood glucose meter models OneTouch, Ultra, InDuo, and OneTouch FastTake can be set up to display two entirely different units of measure: milligram per deciliter (mg/dL) and milli-mole per liter (mmol/L). Since 100 mg/dL = 6.1 mmol/L, setting the proper unit of measure is crucial. In the United States, it is mg/dL . However the units of measure can be unintentionally changed during the task of setting the date and time (See Figure 1). In rare circumstances, dropping the device can also cause a change in unit of measure.
Action:	<ol style="list-style-type: none">1) Diabetes educators, outpatient pharmacists, and other clinicians involved in diabetes management must be notified about the design vulnerabilities of LifeScan devices.2) Clinicians with diabetes patients using LifeScan devices must:<ol style="list-style-type: none">a) No later than the next visit, confirm with all diabetes patients that their glucose meter is properly set up with mg/dL, NOT mmol/Lb) Understand the importance of training the patient on the complex device set-up and calibration.3) Acceptable alternative blood glucose meters are available that do not exhibit this vulnerability and facilities should consider providing those devices instead.
Addl. Information:	Although this product is not on the FSS contract, at least three (3) VISNs have purchased these blood glucose meters. LifeScan, Inc. has temporarily stopped shipments of the devices awaiting product modification to prevent these events.
Source:	LifeScan, Inc. www.lifescan.com FDA http://www.fda.gov/oc/po/firmrecalls/lifescan04_05.html
Contact:	LifeScan, Inc. (800) 515-0915 John Gosbee, Joseph DeRosier, or Bryanne Patail at VA National Center for Patient Safety (NCPS) - (734) 930-5890

Figure 1. LifeScan OneTouch Diagram (from page 5, online guidebook)

http://www.lifescan.com/pdf/ultra_ob.pdf

Note: Every instance that time and date are changed with M and C buttons, the user is offered a chance to change unit of measure.

