

# MHRA issues urgent safety warning about blood glucose meters

Source: Medicines and Healthcare products Regulatory Agency (MHRA), June 06

UK - The Medicines and Healthcare products Regulatory Agency (MHRA) has identified a safety problem with certain blood glucose meters which could result in risk of insulin overdose and hypoglycaemic coma.

The MHRA has issued advice following a number of reports of adverse incidents where the units of measurement displayed on affected blood glucose meters have changed from mmol/L to mg/dL.

Blood glucose test results displayed in mg/dL are 18 times higher than those expressed in mmol/L. For example, a result of 6 mmol/L would display as 108 mg/dL.

The MHRA is concerned that this change in unit of measurement could lead users to think that the blood glucose result is high and thus alter the treatment regime. This could lead to patients self-administering an insulin overdose and going into a hypoglycaemic coma.

The manufacturer will replace, free of charge, affected meters with new ones for which the unit of measurement cannot be changed. In the meantime, the user should ensure that the meter reads in mmol/L every time they test

Batteries should be changed immediately when the low battery symbol appears. Affected blood glucose meters include FreeStyle and FreeStyle Mini (previously known as TheraSense ) and MediSense Optium Xceed manufactured by Abbott Diabetes Care as well as LifeScan OneTouch, LifeScan InDuo and LifeScan PocketScan manufactured by LifeScan.

Concerned patients should check the MHRA website [www.mhra.gov.uk](http://www.mhra.gov.uk) for further information or contact their healthcare professional.