



Medtronic

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Urgent Field Safety Notice
Enlite™ Glucose Sensor: lot G294U and G224U
Recall

3 November 2014
Medtronic reference: FA633

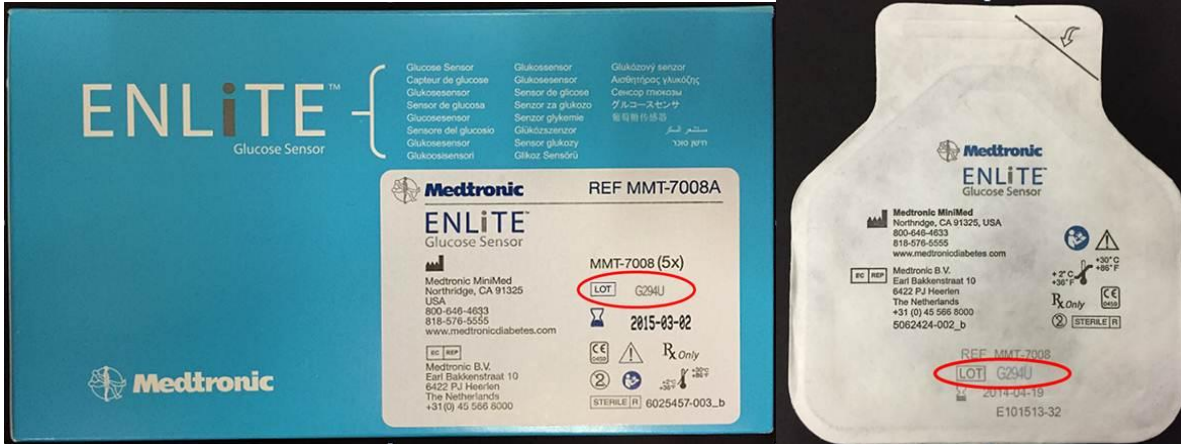
Dear Healthcare Professional:

Medtronic is committed to keeping you and your patients informed of issues and solutions concerning our products and services. We are voluntarily recalling and replacing Enlite sensors which you recently received. This concerns Product Number MMT-7008A / **LOT G294U** and Product Number MMT-7008B / **LOT G224U**, ordered between August 29, 2014 and September 15, 2014.

We are performing this recall because Enlite glucose sensors intended for distribution only in the United States were distributed to you in error.

While performance is not different from the European version, we are replacing the affected sensors with sensors that are properly approved for distribution in the European Union.

LOT number can be found on the Enlite box and on the sensor tray label (see image below)



Required actions:

- To ensure no interruption in your patients' therapy we have sent you replacement sensors for the full quantity your facility received of the affected lots

Upon receipt of the replacement sensors we ask that you return any unused sensors from Lot G294U and G224U. Please contact Medtronic at +44 1923 205167 select option 1, then option 2 for return instructions

- In case you have provided the affected sensors to patients please inform them of this action and provide them with replacement sensors. We have included a patient letter for your convenience

We have notified the Competent Authority for your country (HPRA) of this action.

If you have any questions regarding this action please contact Medtronic at +44 1923 205167 select option 1 and then option 1 again. We appreciate your time and we apologise for any inconvenience this recall may cause you and your patients. We are here to assist you and your patients with any questions or concerns.

Yours Sincerely,

D. G. Dunham

David G. Dunham BSc. PhD
Regulatory Affairs & Quality Manager – UK & Ireland