

URGENT FIELD SAFETY NOTICE

Commercial Name of the Affected Device: Abbott FreeGo Enteral Pump

Type of Action: Device Exchange

16th November 2011

Dear Customer,

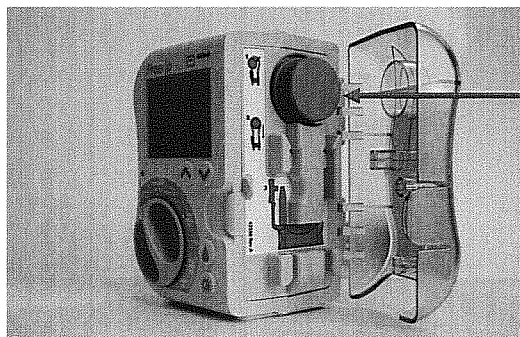
Safety information and corrective actions for the Abbott FreeGo enteral feeding pump (List Number S400)

We would like to inform you about an accelerated service programme for the Abbott FreeGo enteral feeding pump which we are implementing as a result of our market surveillance and complaint analysis.

As Abbott Nutrition's highest priority is the quality of its products we have decided to inform all customers of the following:

1. Abbott Nutrition has received reports relating to the rotor wheel on the FreeGo pump becoming loose. A risk assessment has determined that feed delivery is not affected when the rotor wheel is present as it is held in place by the giving set and the door when the pump is in use. Do not use the FreeGo pump if you identify that the rotor wheel is missing as this would impact delivery.

The root cause of the loose rotor wheel has been identified as inadequate torque of the set screw to the motor shaft and set screw insert displacement. Pumps placed in the market before 29th June 2011 is subject to this service programme. Abbott Nutrition has taken appropriate action to prevent a reoccurrence of this issue.



Rotor wheel

2. Abbott Nutrition has decided to implement an accelerated service programme for those affected pumps. These pumps have been identified through our pump tracking system, and, where necessary, you will be contacted by your local Abbott Nutrition team to arrange for the affected pumps to be exchanged. This will enable Abbott Nutrition to correct the pump rotor wheel.

If you identify any pump as having a loose or missing rotor wheel, please contact Rachel in Hospital to Home on 1 800 22 11 66 to report the complaint and arrange for the delivery of a replacement FreeGo pump.

Please provide this safety information to all relevant personnel within your organisation. If you have any further questions regarding this safety information, please contact us on 1800 22 11 66 during office hours.

Abbott Nutrition sincerely apologises for any inconvenience caused and thank you in advance for your cooperation and support.

Yours sincerely,

A handwritten signature in black ink that reads "Fiona Burke". The signature is written in a cursive style and is positioned above a horizontal line.

Fiona Burke
Country Manager at Abbott Ireland