

Field Safety Notice

Medical Devices Vigilance System
(MEDDEV 2.12/1 rev 5)

Flocare® Infinity Enteral Feeding Pump (EFP) FSCA dated 13-11-2008 Pump check and application of software version 3.13

Date: November 19th, 2008

Details on affected devices

Product code 35679 Flocare® Infinity – UK/Export

SN 79650001 - 79812214

Description of the problem

Over recent months it has become apparent that a very small number of Infinity pumps may be affected by a software irregularity. This software irregularity can lead to the pump delivering feed at a higher flow rate than the rate programmed before starting the feeding. This irregularity could potentially occur with Flocare® Infinity pumps running software version 2.07 up to and including 3.12, independent of the prefix (e.g. F, G or X).

The probability of occurrence is considered very low, with the risk of overrun happening in 1:1.57 million feeding applications. The probability of an overrun affecting patient health is 1:25 million feeding applications.

Advice on action to be taken

No action by customers is required. We are accelerating our regular service schedule to ensure that all pumps are checked. Customers will be contacted regarding the planned service schedule.

Should customers require further reassurance, they should contact Nutricia for guidance.

Corrective and Preventive measures by the manufacturer

We have identified and resolved the cause of the potential irregularity. Nutricia Medical Devices B.V. has taken the following actions:

- An accelerated maintenance program will be implemented to check the pumps and apply software version 3.13
- All pumps newly produced from November 1st 2008 onwards have been checked and software version 3.13 applied.
- All pumps that pass through the official service centres from November 1st 2008 will be checked and software version 3.13 applied.
- Information on implementation of pump checks outside service centres will be communicated to you via your local Nutricia country organisation.

Transmission of this Field Safety Notice

This field safety notice will be transmitted to all Flocare® Infinity customers by your local Nutricia country organisations. This includes Dietitian Managers, Hospital Clinical Engineering Departments and Directors of Nursing that are using the Flocare® Infinity pump. If you are aware that another customer has not received this notice, please contact your local Nutricia country organisation and inform them of the details. The Nutricia country organisations will ensure that the information is promptly supplied to the indicated party.

Contact reference person

Carol Hunter

20081113

The undersigned confirms that this notice has been notified to the appropriate Regulatory Authority.

Patient safety is of the highest priority for Nutricia. Accordingly, we are accelerating our regular service schedule to ensure that all pumps are checked and software version 3.13 is applied.

Yours sincerely,

A handwritten signature in black ink, consisting of a large, sweeping initial letter followed by several horizontal strokes.