
Urgent Field Safety Notice

Commercial name of the affected product

Flocare® Infinity™ II enteral feeding pumps

FSCA-identifier

ICC2012-042

Type of action

Application of software update to 3.15

Nutricia Medical Devices BV
 Schiphol Boulevard 261
 1118BH Schiphol Airport
 The Netherlands

Date: 15 April 2013

TO WHOM IT MAY CONCERN

Details on affected devices

Article No.	Description	Serial number
35676	Flocare® INFINITY™ PUMP WE	76760001 onwards (eg pumps from 2007 onwards)
35677	Flocare® INFINITY™ PLUS PUMP WE	77750001 onwards (eg pumps from 2007 onwards)
35679	Flocare® INFINITY™ PUMP UK EXPORT	79760001 onwards (eg pumps from 2007 onwards)
35680	Flocare® INFINITY™ PLUS PUMP UK EXPORT	80750001 onwards (eg pumps from 2007 onwards)
35682	Flocare® INFINITY™ PUMP NE	82760001 onwards (eg pumps from 2007 onwards)
35683	Flocare® INFINITY™ PLUS PUMP NE	83800004 onwards (eg pumps from 2008 onwards)
35685	Flocare® INFINITY™ PUMP FRANCE	85760001 onwards (eg pumps from 2007 onwards)

Description

It became evident that the fill set functionality of the Infinity II enteral feeding pumps is not always used as intended. Incorrect usage of this functionality can recalibrate the pump's baseline resulting in the incapability to alarm while the pump is still in "OCC OUT".

Although a warning is already included in the Instructions for Use not to use the fill-set function besides from filling an empty (air-filled) set, and no further complaints are reported in this respect thusfar, Nutricia Medical Devices (NMD) launched a software update which overcomes that incorrect fill-set usage during an OCC OUT alarm will result in a base line calibration.

Advise on action to be taken by the user

Users do not have to take any actions or are supposed to take any actions. The software will be uploaded during regular service intervals. Users and customers will principally not notice this update as only in starting up the pump, the software version displayed will depict the new number.

Should customers require further information, they should contact the local Nutricia Sales Units for guidance.

Important Notice

Patient safety is of the highest priority to Nutricia. In case the Infinity pump display any alarm, never ignore this and solve the alarm as described in the Instructions for Use.

Do not use any pump functions for any other purpose than described in the Instructions for Use, as this may cause the pump to incorrectly calibrate.

Corrective and preventive action taken

NMD implemented the software update for all Infinity II pumps leaving the factory as of mid March 2013. All new pumps delivered after March 2013, will have the updated software loaded from the factory onwards.

Additionally, all Infinity II pumps already available in the market, with Serial Numbers indicated above, will be loaded with the updated software during regular maintenance and service at the official Service Centers (2 yearly intervals).

The software version is updated **from 3.13 to the new version 3.15**. The preverb letter which defines the model (F=Western Europe , G=French, X=Plus), remains the same through any software release.

Disposal of current stock of the devices or devices in use, is not necessary: all pumps can be continued to be used accordingly.

Transmission of this Notice

This notice needs to be passed on to all those who need to be aware within the organization.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the notice and corrective action.

Contact reference person

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Patient safety is of the highest priority for Nutricia. Accordingly, we have accelerated the necessary modifications for the software update wherever possible to ensure updated pumps are available in the market as soon as possible.

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



RA Manager Nutricia Medical Devices