
Urgent: Field Safety Notice

Device commercial name	**Nutricia Flocare Infinity II – enteral feeding pump**
Manufacturer SRN	**NL-MF-000012729**
FSN Type	**New**
FSN Reference number	**FSN19240539**
Type of action	**Update information on safety and precautions**
Date	**August 1st 2022**

Attention: Medical Device Managers, Clinical and Nursing Staff, Medical Device Distributors, Medical Device Safety Representatives

Dear Customer,

The purpose of this notification is to inform you that we have initiated a Field Safety Corrective Action (FSCA) for the Flocare Infinity II enteral feeding pumps related to the provisions and inclusion of additional warnings and general precautions in using the Flocare Infinity II pumps for enterally tube fed patients. These updates will be incorporated in the Instructions For Use (IFU) provided with the devices.

Please review the information provided carefully.

Details on affected devices

Article No (REF)	UDI-DI	Description	Serial number	Software version
35676 (40405)	08712400856768	FLOCARE INFINITY II (W-EUROPE)	all	any
35677 (40406)	08712400856775	FLOCARE INFINITY + (W-EUROPE)	all	any
35679 (40407)	08712400856799	FLOCARE INFINITY II (UK EXPORT)	all	any
35680 (40408)	08712400856805	FLOCARE INFINITY + (UK EXPORT)	all	any
35682 (40409)	08712400856829	FLOCARE INFINITY II (N-EUROPE)	all	any
35683 (40435)	08712400856836	FLOCARE INFINITY + (N-EUROPE)	all	any
35685 (40461)	08712400856850	FLOCARE INFINITY II (FRANCE)	all	any

Description of the issue

We have received feedback from a limited number of French customers about an unexpected, unnoticed, disruption in their enteral feeding therapy delivery.

If any delay in therapy and/or stop in enteral food delivery remains unnoticed and undetected for a prolonged period of time, some volume & nutrients sensitive patients might experience under delivery

situation resulting in a poor nutritional status and potential acute consequences including hypoglycaemia requiring medical intervention.

The above situation is a concern mainly for (paediatric) patients, especially if they have underlying metabolic conditions, and require a constant nutrition delivery during unmonitored moments (e.g. overnight homecare therapy).

Corrective and preventive action taken by Nutricia

Although in the current IFU there are warnings and precautions to avoid an occluded feeding tube situation, the IFU will be updated to include more precise precautions in the selection of enteral tube feed delivery therapies, as well as considerations for the type of feeds and substances applied through the enteral feeding lines.

It has been identified that the information in the current IFU can be improved to make this clearer to the users and caregivers.

Until the updated IFU is in place, advice and actions for clinical users are addressed in this notice.

Advice on action to be taken by healthcare professionals and caregivers to avoid possible risks associated with severe under delivery of feed.

Nutricia requests healthcare professionals to communicate the below additional guidelines/ precautions to users and caregivers (such as family members, nurses, homecare givers) of volume & nutrients sensitive patients (e.g. children with metabolic conditions using overnight and/or unmonitored therapy) where a constant nutrition delivery is vital and/or connected with consequential therapies (e.g. an insulin delivery pump):

- Additional surveillance to be put in place to verify good functioning of the enteral feeding system and programmed therapy;
- The health care professional is responsible to determine the therapy setting and clinical needs, as well as the appropriate surveillance scheme and its frequency. If the required surveillance scheme cannot be guaranteed by the care giver, then it is to be discussed with the healthcare professional, who can advise the patient an alternative therapy solution;
- Users are to be reminded that the sound level of the Infinity II pumps audible alarm is to be set in 'HIGH' if the pump is operated in a noisy environment or the health carer is not nearby the pump, such as at night, to ensure the alarm is readily noticed when an alarm is activated;
- It is important that before commencing any enteral feeding therapy, proper consideration is given to the feed appropriateness for tube feeding (thickness, homogeneity, selection of nasogastric tube Ch size, etc.), as to avoid occlusion or any other unexpected pump system behaviour. The condition and appropriateness of the nutrition can be addressed with the healthcare professional, who knows the clinical situation and needs of the patient and can best guide the patient in the selection of appropriate feed;
- If other forms than a standard, ready to feed formula are prescribed as enteral tube feed, it should be done with caution and aligned with the healthcare professional. Feeds supplied as tube feeds must be of a homogenous nature as bigger particles or high viscous foods can result in blockages in the feeding line. It is noted that for instance 'home-made' – mixed tube feeds

might give rise to issues when given as an enteral tube feed as the mixture will not stay in emulsion for a longer period.

- If patients are advised by their healthcare professional to use a mixture of feeds, the feed must be given when there is direct supervision (e.g. parents) to ascertain the feeding therapy is running normally and to ensure proper actions are taken in case there is a pump failure or unexpected behaviours caused by the mix.

Transmission of this Notice

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization and health care professionals to which the affected product(s) have been transferred.

Please ensure that your organization maintains awareness of this notice and the recommended steps until the corrective action, i.e. the update of the IFU, has been completed.

Contact reference person

Nutricia is committed to patient safety and appreciates your detailed review of the information contained in this customer information. If you have any questions regarding this communication, please contact your local Nutricia representative or the local Nutricia office.

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The undersigned confirms that the relevant National Competent Authorities have been advised on this safety notice.

Yours sincerely,

ME Lombaerts
Global Regulatory Manager Medical Devices - PRRC
Nutricia Medical Devices BV