

Medical Device Alert

Action

Ref: MDA(NI)2009-004 Issued: 22 January 2009 at 17:00

Device

Enteral feeding pump. Flocare Infinity pump model 35679 and Flocare Infinity Plus pump model 35680 manufactured by Nutricia. Specific serial numbers and software versions.



Problem

Due to a software irregularity, pumps have the potential to deliver feed at a higher rate than that programmed. This may go undetected as the display shows the programmed rate not the actual rate.

The manufacturer has issued an accelerated service programme to apply new software to the affected pumps.

Action by

All staff responsible for prescribing and maintaining enteral feeding devices, particularly dietetic departments and EBME departments.

SABS deadlines

Action underway: 12 February 2009

Action complete: 05 March 2009

Action

- Identify affected pumps (see device section overleaf).
- Ensure that users are aware of the manufacturer's Field Safety Notice (see appendix). Nutricia will contact customers to arrange a service schedule.

Contact

Manufacturer

Michelle Ray
Quality Assurance Manager
Nutricia Limited

Tel: 01225 717 632

Fax: 01225 711 565

E-mail: mray@nutricia.co.uk

Device

Enteral feeding pumps are indicated for the delivery of enteral feed only, for paediatric and adult patients.

Devices affected in the UK are:

- Flocare Infinity pump manufactured by Nutricia. Model 35679. Software versions F2.07 to F3.12 inclusive. Serial numbers 79650001 to 79812214 inclusive.
- Flocare Infinity Plus manufactured by Nutricia. Model 35680. Software versions X2.13 to X3.12 inclusive. Serial numbers 80700001 to 80800186 inclusive.

The software version of the pump is shown on the pump's display when the pump is first switched on.

Distribution

The NIAIC has sent this MDA via SABS to:

- HSC Trust, HSS Board, and Agency's Chief Executive's
- HSC Trust, HSS Board, and Agency's SABS Liaison Officer
- Selected members of the DPSSPSNI
- Hospitals in the independent sector
- Hospices

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

SABS liaison officers for onward distribution to all relevant staff including:

- Clinical governance leads
- Dietetics departments
- Dieticians
- EBME departments
- Equipment stores
- Hospital at home units
- Hospital pharmacies
- Medical directors
- Nursing executive directors
- Nutritional nurse specialists
- Palliative care teams
- Risk managers
- Community children's nurses
- Community hospitals
- Community pharmacies
- District nurses
- Equipment libraries and stores
- Nutritional nurse specialists
- Palliative care teams

The Regulation and Quality Improvement Authority (RQIA) to:

Headquarters for onward distribution to:

- All Nursing Home providers
- Domiciliary care providers
- Independent treatment centres
- Nursing agencies

Boards to:

SABS liaison officers for onward distribution to:

- Risk manager

Central Services Agency (CSA) to:

SABS liaison officers for onward distribution to all relevant staff including:

- Staff with responsibility for purchasing

Contacts

Manufacturer

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NIAIC

Enquiries in Northern Ireland, please send enquiries about this notice to the NIAIC quoting reference number MDA(NI)2009-004 and addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast
BT16 1US

Tel: 02890 523868

Fax: 02890 523900

E-mail: NIAIC@dhsspsni.gov.uk

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

How to report adverse incidents

Incidents relating to medical devices in Northern Ireland must be reported to the Northern Ireland Adverse Incident Centre (NIAIC) as soon as possible.

Further information about reporting incidents can be found in DB(NI)2008-001; and downloadable report forms are available from the NIAIC's website (<http://www.dhsspsni.gov.uk/niaic>).

Alternatively, further information and printed incident report forms are available from: NIAIC at the address above.

(An answerphone service operates outside normal office hours)

Medical Device Alerts are available in full text on the NIAC website

Further information about SABS can be found at <http://sabs.dhsspsni.gov.uk>

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Addressees may take copies for distribution within their own organisations

APPENDIX**Field Safety Notice**

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

**Flocare® Infinity Enteral Feeding Pump (EFP)
FSCA dated 17-11-2008
Pump check and application of software version 3.13**

Date: November 17th, 2008

Details on affected devices

Product code 35679 Flocare® Infinity – UK/Export SN 79650001 - 79812214
With software version F2.07 up to and including F3.12

Product code 35680 Flocare® Infinity Plus – UK/Export SN 80700001 - 80800186
With software version X2.13 up to and including X3.12

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 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 Dietetics Managers and Hospital Electro-Bio-Medical-Engineering (EBME) Departments 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

Michelle Ray
Quality Assurance Manager
Nutricia Limited
Newmarket Avenue
Whitehorse Business Park
Trowbridge
BA14 0XQ

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, appearing to read 'R Birt', is positioned above the printed name and title.

Ruth Birt BSc LLM
Head of Regulatory Affairs