

Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/31

Issued: 23 October 2003

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
Medical Device/Equipment: Medtronic SynchroMed® Implantable Drug Pump.	▶ ①
Problem: Incompatibility of diamorphine solution with the SynchroMed® implantable drug pump.	▶ ②
Action by: All clinicians that implant or manage patients implanted with SynchroMed® implantable drug pumps, and Trust Pharmacy Managers.	▶ ③
Action: Do not use diamorphine solutions in SynchroMed® implantable drug pumps.	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers For onward distribution see Section 5	Hospices ▶ ⑤
Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥
Feedback Requirements to NIAIC Feedback is necessary for this Alert. Please see specific feedback requirements in section 7.	▶ ⑦

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Medtronic SynchroMed® Implantable Drug Pump.

2. PROBLEM:

The Medicines and Healthcare products Regulatory Agency (MHRA) is aware of five incidents in the United Kingdom where the use of diamorphine solution has resulted in malfunction of the SynchroMed® pump. In four of these incidents, pump malfunction led to cessation of drug delivery (motor stalling) resulting in return of patient symptoms. In the remaining incident (still under investigation) pump malfunction led to over-infusion of diamorphine solution and the patient suffered a cardiorespiratory arrest.

Failure analysis of the four cases of motor stalling by Medtronic has shown that motor stalling was associated with the long-term administration of diamorphine solution, where the materials of the internal components were damaged. Diamorphine (diacetyl morphine) in aqueous solution will degrade over time, producing an insoluble active compound (6-monoacetyl morphine), which is an acetate and is believed to have caused the damage to the pump.

Current Instructions For Use for the SynchroMed® implantable drug pump **do not** include diamorphine in the list of medications that are compatible with the pump.

In October 2002 Medtronic distributed an "Educational Brief: Revised Drug Formulation SynchroMed® Infusion System", which listed drugs and additives known to be incompatible with the SynchroMed® implantable drug pump. Diamorphine was **not included** in this listing since its adverse effect had not been recognised at that time. To clarify this situation Medtronic plans to distribute further information shortly.

It is estimated that there are 1200 SynchroMed® drug pumps currently implanted in the UK.

3. ACTION BY:

All clinicians that implant or manage patients implanted with SynchroMed® implantable drug pumps, and Trust Pharmacy Managers.

4. ACTION:

- For patients currently receiving diamorphine solution via the SynchroMed® pump, clinicians should consider :
 - changing to an alternative medication compatible with the pump as soon as possible (note that changing the patient's medication requires careful assessment and observation by experienced personnel);
 - elective replacement of the pump when patient management dictates.
- Clinicians should be aware that other drugs are contraindicated for delivery via SynchroMed® implantable drug pumps. Where doubt exists, check the instructions for use as supplied with the pump, or seek the manufacturer's advice.

5. ONWARD DISTRIBUTION TO:

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

- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Estates Managers
- Medical Directors
- Nurse Directors
- Trust Pharmacy Managers
- Director of Anaesthetics
- Directors of Radiotherapy/Oncology
- Neurologists and Neurological Surgeons
- Anaesthetists
- Radiotherapists
- Medical Oncologists
- Clinicians involved with pain clinics
- Theatre Managers
- Adult and Paediatric Intensive Care Units
- Accident & Emergency Departments
- Independent Health and Social Care Providers including Independent Clinics and Nursing Homes – through R&I Units

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Jacques Thielen
Medtronic Bakken Research Center BV
Endepolsdomein 5
6220 GW Maastricht
The Netherlands

Tel: 0031 43 3566 756

Fax: 0031 43 3566 504

E-mail: jacques.thielen@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2003/31 and be addressed to:

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

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

NIAIC Liaison Officers are requested to confirm by 6 November 2003 to e-mail address

NIAIC@dhsspsni.gov.uk using reference MDEA(NI)2003-31 that **staff identified under “Action By” have received this Alert to enable them to take appropriate action.**

A NIL response is required should the subject of this Alert not apply to your organisation.



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2003/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety