

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/27

Issued: 8 June 2004

For:

IMMEDIATE ACTION	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section		
<p>Medical Device/Equipment: Medtronic SynchroMed® and SynchroMed® EL implantable drug pumps and Medtronic Personal Therapy Manager (PTM).</p>	▶ ①		
<p>Problem: Potential for cessation of drug therapy due to a pump memory error.</p>	▶ ②		
<p>Action by: All clinicians managing patients implanted with SynchroMed® and SynchroMed® EL drug pumps.</p>	▶ ③		
<p>Action:</p> <ul style="list-style-type: none"> • Program all SynchroMed® and SynchroMed® EL drug pumps using new N'Vision programmer software (version BBD 02) in accordance with Medtronic's instructions for use. • Identify patients prescribed with a Medtronic Personal Therapy Manager (PTM) and: <ul style="list-style-type: none"> ➢ schedule the reprogramming of their pumps according to urgency; ➢ follow Medtronic's Pump Memory Reset instructions to remove the software anomaly; advise patients on the potential for pump stoppage and on the relevant precautions. 	▶ ④		
<p>Distributed by NIAIC to:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%; border: none;"> 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 </td> <td style="width: 50%; border: none;"> General Medical Practitioners for information in terms of pain management Hospices </td> </tr> </table>	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	General Medical Practitioners for information in terms of pain management Hospices	▶ ⑤
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	General Medical Practitioners for information in terms of pain management Hospices		
<p>Contacts Details of manufacturer contacts and NIAIC contacts.</p>	▶ ⑥		
<p>Feedback Requirements to NIAIC Report occurrences of drug delivery failure / pump memory error to NIAIC and Medtronic.</p>	▶ ⑦		

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

1. DEVICE/EQUIPMENT:

Medtronic SynchroMed® and SynchroMed® EL programmable drug infusion pumps used in conjunction with:

- Medtronic N'Vision™ programmer; and/or
- Medtronic Personal Therapy Manager (PTM).

2. PROBLEM:

Medtronic SynchroMed® and SynchroMed® EL programmable drug infusion pumps may be used with a restricted range of medications indicated for the long-term treatment of pain, spasticity and cancer. Infusion rates are programmed by clinicians (according to patient need) using the Medtronic N'Vision™ programmer together with a dedicated software application card (model 8870). Within the UK, Medtronic estimates that there are approximately 35 distributed units of the N'Vision™ programmer software cards – versions BBB 03 and BBC 01 – that are subject to recall. These are to be replaced with upgraded version BBD 02.

Patients needing a bolus in addition to the programmed infusion regime may also be prescribed a Medtronic Personal Therapy Manager (PTM) to facilitate this. Medtronic estimates that between 250 and 400 PTMs may currently be in use in the UK.

Medtronic has advised the Medicines and Healthcare products Regulatory Agency (MHRA) of an estimated 29 reports in Europe where drug delivery has unexpectedly ceased due to a pump memory error (PME), which may occur when programming with the N'Vision™ programmer or when a PTM is being used. There has been no patient death or serious injury as a result of these incidents. The design of the device is such that when a pump memory error occurs drug delivery stops.

Medtronic has identified the following contributory causes:

1. interruption of the programmer's telemetry
2. electromagnetic interference (EMI)
3. a software anomaly in versions BBB 03 and BBC 01
4. misalignment of the PTM with the pump

During programming, a pump memory error can easily be recognised by a message that will be displayed on the screen of the N'Vision programmer. For a patient using a PTM, flashing indicators will highlight a memory error. In addition, if the audible 'patient alert' feature has already been programmed to 'ON', a double beep alarm will be emitted by the pump to indicate the error.

Cessation of drug therapy due to pump memory error may lead to the resumption of patient symptoms (e.g. pain, spasticity) or insufficient treatment in the case of cytotoxic drug administration if not resolved in a timely manner. However, MHRA considers that it is unlikely that a patient receiving cytotoxic drug therapy would be prescribed a PTM.

If a pump memory error remains uncorrected for an extended period of time, Medtronic SynchroMed® and SynchroMed® EL pumps may suffer long term damage.

Note: SynchroMed II infusion pumps and Medtronic neurostimulators which also use the N'Vision programmer are not believed to be affected by this software issue and are therefore not covered by this Medical Device Alert.

MHRA and NIAIC will continue to monitor this problem through the adverse incident reporting system and will issue further advice as appropriate.

3. ACTION BY:

All clinicians managing patients implanted with SynchroMed® and SynchroMed® EL drug pumps

4. ACTION:

When programming SynchroMed® and SynchroMed® EL pumps, discontinue using N'Vision programmer software card versions BBB 03 and BBC 01 and replace these with the upgraded version BBD 02, following Medtronic's instructions for use.

For patients with a Medtronic Personal Therapy Manager (PTM):

- schedule the reprogramming of their pumps urgently if cessation of drug therapy would have significant clinical consequences, or otherwise according to existing follow-up arrangements;
- follow the Pump Memory Reset instructions provided in Medtronic's Dear Doctor Letter to perform a 'Therapy stop' and then to reprogram the infusion mode.

Advice for patients who use a PTM:

Inform these patients of the potential problem and advise them to:

- contact their clinic urgently if their symptoms recur;
- be conversant with the instructions for use and, particularly:
 - avoid exposure to electromagnetic interference (e.g. mobile phones);
 - ensure correct alignment between the pump and PTM.

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 | • Pain Consultants |
| • Health and Safety Officers/Advisors | • Oncology Clinics |
| • Clinical Governance Leads | • Pain Clinics |
| • Medical Directors | • Directors of Public Health |
| • Nurse Directors | • Health Visitors |
| • Accident and Emergency Departments | • Practice Nurses |
| • Oncology Consultants | • District Nurses |
| • All Wards and Departments | • Independent Health and Social Care Providers – |
| • Community Units | Private Clinics through HSS Board R&I Units |

6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

David G Dunham BSc PhD, Regulatory Affairs Manager – UK & Ireland, Cardiac Rhythm Management Medtronic (UK) Ltd, Suite One Sherbourne House, Croxley Business Centre, Watford WD18 8WW, Tel: 01923 212 213, E-mail: david.dunham@medtronic.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/27 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:

Report occurrences of drug delivery failure / pump memory error to NIAIC and Medtronic.



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 MDEA(NI)2004/01. 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