

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/32

Issued: 23 October 2003

For:

<b>IMMEDIATE ACTION</b>	✓
ACTION	
UPDATE	
INFORMATION REQUEST	



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section								
<b>Medical Device/Equipment:</b> Blood Pressure and Vital Signs patient monitors - DINAMAP PRO 100-400 Series and PRO 1000	▶ ①								
<b>Problem:</b> Risk of electric shock. The mains input socket can be pulled out of the case exposing "live" parts.	▶ ②								
<b>Action by:</b> Estates Managers, Device Managers, Risk Managers, Health and Safety Officers and all Clinical, Medical, Nursing and technical staff who use or handle blood pressure monitors.	▶ ③								
<b>Action:</b> Dinamap monitors should be disconnected from the electrical mains outlet (wall socket) before being moved.	▶ ④								
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table> <b>For onward distribution see Section 5</b>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
Chief Executive of each HSS Trust	Hospices								
Chief Executive of each Agency									
NIAIC Liaison Officers									
<b>Contacts</b> Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥								
<b>Feedback Requirements to NIAIC</b> 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:**

Blood Pressure and Vital Signs patient monitors - DINAMAP PRO 100-400 Series and PRO 1000. Manufactured by GE Medical Systems Information Technologies.

## **2. PROBLEM:**

The Medicines and Healthcare products Regulatory Agency (MHRA) is continuing to receive reports where the mains input socket has detached from the back of the case exposing "live" parts. NIAIC has not received any reports concerning this issue in Northern Ireland. The continuing reports to MHRA are despite the issue of a MHRA Hazard Notice in August 2002 (NIAIC equivalent notice was HN(NI)2002/05) and completion of the manufacturer's modification programme where the power socket was glued to the rear panel.

In one case, the DINAMAP monitor had been left on charge and connected to a mains outlet at the bedside. During transfer of the bed the monitor was moved whilst still connected to the mains outlet. When a member of staff next needed to use the monitor she noticed the disconnected mains lead on the patient's bedside cabinet. Unaware that the mains input socket had detached, she picked up the end of the mains lead and received an electric shock.

In another incident when the DINAMAP was being moved, the socket detached from the rear case and touched the earthed data connector causing an arcing flash.

The Company is aware of this problem and has initiated corrective action. All units in the field that are fitted with the Schurter appliance inlets, whether previously glued or not, will be modified with a metal reinforcing plate. The UK Service Group expects to begin this action by 15th November, with completion in the early portion of 2004. A Customer Letter will be sent out shortly.

DINAMAP monitors manufactured before 6th December 2001, with a serial number lower than 010M3400001, will require rework. Those manufactured after this date with serial number 010M3400001 and above have a different power entry module and are not affected.

**PART OF THE PROBLEM IS DUE TO EQUIPMENT BEING MOVED BEFORE IT HAS BEEN DISCONNECTED FROM THE ELECTRICAL MAINS OUTLET (WALL SOCKET).**

## **3. ACTION BY:**

Estates Managers, Device Managers, Risk Managers, Health and Safety Officers and all Clinical, Medical, Nursing and technical staff who use or handle blood pressure monitors.

## **4. ACTION:**

- Users should be aware that the input socket may pull out from the back of the monitor's case while still attached to the mains cable. This exposes the user to "live" parts on the end of the mains cable presenting a risk of electric shock. (See Appendix for picture and our website [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic) for colour photograph attached to electronic copy of this notice).
- Users should ensure that the mains plug is disconnected from the electrical mains outlet (wall socket) before moving the DINAMAP monitor.
- Do not disconnect the cable from the rear of the monitor before disconnecting from the mains outlet.
- In the event of the mains cable pulling out of the monitor during use, do not touch the mains cable. Ensure the mains plug is disconnected from the mains outlet before examining the cause of the problem. If the input socket has detached completely or partially from the rear of the case, do not attempt to re-connect the mains cable. The unit should be removed from use and quarantined, pending modification.

## 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
- Directors of Anaesthetics
- Adult and Paediatric Intensive care Units
- Adult and Paediatric High Dependency Units
- Medical Directors
- Clinical Directors
- Nurse Directors
- All wards
- Recovery Units
- Medical, Nursing and Care Staff
- Operating Theatre Staff
- Outpatient Departments
- Accident & Emergency Departments
- Day Procedure Units
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Directors of Public Health (Boards)
- Independent Health and Social Care Providers – Independent Clinics through R&I Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Mr Brian Krasner – Regional Service Manager  
GE Medical Systems Information Technologies  
352 Buckingham Avenue  
Slough  
Berkshire  
SL1 4ER  
Tel: 0800 0188678  
Fax: 0800 0922337

Enquires to NIAIC should quote reference number MDEA(NI)2003/32 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](mailto: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](mailto:NIAIC@dhsspsni.gov.uk) using reference MDEA(NI)2003-32 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

## APPENDIX

### BEWARE LIVE TERMINALS - DO NOT TOUCH



See NIAIC website: [www.dhsspsni.gov.uk/niaic](http://www.dhsspsni.gov.uk/niaic) for a colour photograph attached to an electronic copy of this notice. Photograph is similar to the one referred to in HN(NI)2002/05

#### 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](http://www.dhsspsni.gov.uk/niaic)

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