

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/87

Issued: 29th November 2005

For:

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| IMMEDIATE ACTION | |
| ACTION | |
| UPDATE | |
| INFORMATION | ✓ |



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

| | Section |
|--|---------|
| Medical Device/Equipment: Self-Adhesive Monitoring/Diagnostic Electrodes: Risk of injury upon removal | ▶ ① |
| Problem: Self-adhesive monitoring/diagnostic electrodes may cause skin injuries upon removal. | ▶ ② |
| Action by: This notice should be brought to the attention of all appropriate managers, staff and users. | ▶ ③ |
| Action: Precautions are recommended. | ▶ 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 General Medical Practitioners Hospices | ▶ ⑤ |
| Contacts Details of NIAIC contacts for technical aspects. | ▶ ⑥ |
| Feedback Requirements to NIAIC | ▶ ⑦ |

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

1. DEVICE/EQUIPMENT:

Self-Adhesive Monitoring/Diagnostic Electrodes.

2. PROBLEM:

An incident has been reported in which the skin of an elderly patient was injured during removal of a self-adhesive diagnostic ECG electrode. The patient had friable skin and it is believed the electrode may have been attached for longer than the recommended maximum application time of 1 hour.

As the electrode was removed the adhesive maintained its attachment to the patient's skin causing the skin to tear. Investigation failed to determine whether the injury was caused by excessive contact time or the method of removal. However, it was found that the data used by the company to recommend a maximum application time (stated on the outside of the bulk carton and on the company's website) was obsolete and the "Instructions For Use" provided on the electrode packaging did not advise on maximum application time or removal technique.

There are many different types of self-adhesive electrodes available from a wide range of manufacturers for a variety of monitoring and diagnostic uses, e.g. electrocardiography (ECG), electroencephalography (EEG), electromyography (EMG). Manufacturers do not always recommend a maximum application time or provide "Instructions For Use". Electrode purchases may be based on performance or price without consideration of other factors such as ease of removal, and application times/removal techniques are often determined solely by clinical experience.

3. ACTION BY:

This notice should be brought to the attention of all appropriate managers, staff and users.

4. ACTION:

Self-adhesive monitoring/diagnostic electrodes should be used in accordance with the manufacturer's "Instructions For Use".

Where the "Instructions For Use" are inadequate or none are provided, the manufacturer/supplier should be contacted for advice. Depending on local circumstances, it may be advisable for Supplies Departments to seek this information and make it available locally to their organisation.

It is recommended that the application period of self-adhesive electrodes be limited to the shortest time possible and that it should not exceed the manufacturer's maximum application time.

Prior to removal, the patient's skin should be assessed to determine whether it is at risk of injury. Appropriate care should be used when removing the electrode. In difficult cases, advice should be sought from a more experienced colleague or an appropriate specialist, e.g. tissue viability nurse.

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:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Clinical Governance Leads
- Device Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Maternity Wards
- Paediatric Units
- Practice Nurses
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRAI
- Operating Theatre Staff
- Accident & Emergency Departments
- Allied Health Professionals
- Coronary Care
- Intensive Care
- Resuscitation Officers
- Day Procedure Units

6. CONTACTS:

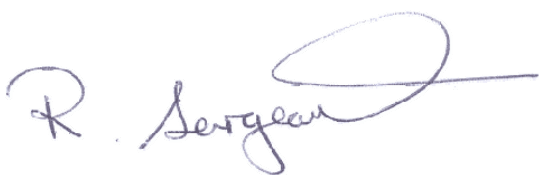
Enquires to NIAIC should quote reference number MDEA(NI)2005/87 and be addressed to:

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:

None required.



Robert Sergeant
NIAIC Operational 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)2005/01. 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