

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/86

Issued: 29th November 2005

For:

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



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

| | Section |
|---|---------|
| Medical Device/Equipment: MRI Compatible ECG Cables and electrodes: Risk of patient burns. | ▶ ① |
| Problem: Patients undergoing MRI scans with MRI compatible ECG leads and electrodes may suffer burns to the skin if there is less than optimal contact between the skin and the electrodes. | ▶ ② |
| Action by: This notice should be brought to the attention of all appropriate managers, staff and users. | ▶ ③ |
| Action: See recommended precautions. | ▶ 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 | ▶ 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:

MRI Compatible ECG Cables and electrodes.

2. PROBLEM:

Two incidents have been reported in which a patient received skin burns from ECG electrodes during MRI procedures. In both cases the patients were anaesthetised and MRI compatible leads and electrodes were being used. During investigation it was found that the electrodes had exceeded their expiry date and the contact area of some electrodes was drier than would be expected.

The conductive gel used on ECG electrodes can evaporate over time, particularly when they are exposed to air, causing the contact area of the electrode to become dry. Electrodes supplied in multi-packs are particularly vulnerable if the pack is not re-sealed each time it is opened or if it takes a long time to use up a whole pack. Dried electrodes provide a poor quality contact with the patient and cannot be expected to perform as intended.

RF generated electrical currents can be induced in ECG cables for a number of reasons such as the inclusion of loops or resonant lengths (cable configurations that can cause heating effects in an MR environment). If such a current is induced and the quality of contact between the patient's skin and the electrode is less than optimal, this may exacerbate the localised heating at the electrode site making localised skin burns more likely. Induction effects are at their highest when ECG cables are placed near the sides of the scanner's body coil. Cables which are lead out of the scanner at or near the centre of the bore are therefore less susceptible to these effects.

Burns sustained from ECG electrodes during MRI scanning procedures could be mistaken for allergic reactions to the electrodes.

This notice supplements Safety Action Notice SAN(NI)95/25, issued 28 July 1995, "*MRI and Patient Monitoring Equipment Attachments: Possible hazard of burns*".

3. ACTION BY:

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

4. ACTION:

MRI compatible ECG electrodes should be used in accordance with the manufacturer's "Instructions For Use" and prior to the expiry date marked on the packaging.

Electrodes should be bought in quantities that are appropriate to the rate at which they are used. Multi-packs should be carefully re-closed as soon as possible, expelling as much air as possible from the pack.

ECG cables should be separated from the skin wherever possible. Loops and resonant lengths (cable configurations that can cause heating effects in an MR environment) should be avoided at all times. Cables should be led out of the scanner at or near the centre of the bore.

Where a burn or other skin injury is suspected, an assessment should be made before continuing to remove remaining electrodes. In difficult cases, advice should be sought from a more experienced colleague or an appropriate specialist, e.g. tissue viability nurse.

ECG electrodes implicated in patient burns should be placed in quarantine pending local investigation. If the electrodes were supplied in a multi pack the unused electrodes should also be quarantined. Where a manufacture related defect is suspected an adverse incident report should be submitted to NIAIC.

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
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Medical Physics
- MRI Scanning Units
- Radiation Protection Staff
- Radiology / Imaging Department
- Tissue Viability Nurses

6. CONTACTS:

Enquires to NIAIC should quote reference number MDEA(NI)2005/86 and be addressed to:

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

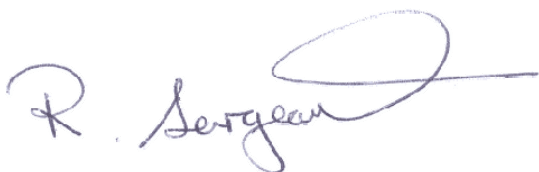
Tel: 028 9052 3868

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