

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2003/40

Issued: 9 December 2003

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section
<b>Medical Device/Equipment:</b> Transilluminators used with neonates	▶ ①
<b>Problem:</b> Use of an inappropriate light source for transillumination can result in burns.	▶ ②
<b>Action by:</b> All medical and nursing staff in special care baby units and neonatal intensive care units.	▶ ③
<b>Action:</b> Ensure that the transilluminator is intended to be used with neonates, and the manufacturer's instructions for use are followed.  HPSS Trusts should put in place an implementation plan to ensure that all staff have undertaken the actions described in this alert and the actions are incorporated into training plans for new staff.	▶ ④
<b>Distributed by NIAIC to:</b> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
<b>Contacts</b> NIAIC contacts for technical aspects.	▶ ⑥
<b>Feedback Requirements to NIAIC</b> None required.	▶ ⑦

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

## **1. DEVICE/EQUIPMENT:**

Transilluminators used with neonates

## **2. PROBLEM:**

Use of an inappropriate light source as a transilluminator can result in burns to the patient. The Medicines and Healthcare products Regulatory Agency (MHRA) have informed NIAIC that a neonate recently received a serious burn when a new light source was used as a transilluminator. Additionally, the hospital had an identical unit with a filter fitted, which had been used for some time without injury. The manufacturer subsequently stated that these devices were not intended to be used for this purpose, with or without a filter. There was no mention of use of this light source as a transilluminator in the instructions for use.

## **3. ACTION BY:**

All clinical staff in special care baby units and neonatal intensive care units.

## **4. ACTION:**

1. Before purchasing a light source, verify that its intended purpose meets your requirements.
2. Before use, ensure that the transilluminator is used: -
  - for its intended purpose;
  - in accordance with the manufacturer's instructions for use, paying particular attention to recommendations regarding light intensity.
3. Be aware of the risks if the device is used for a purpose not described within the manufacturer's instructions for use.
4. HPSS Trusts should put in place an implementation plan to ensure that all staff have undertaken the actions described in this alert and the actions are incorporated into training plans for new staff.

## **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
- Medical, and Nursing Staff
- Childrens Hospitals
- Anaesthetists
- Paediatricians
- Theatre Managers
- Paediatric Intensive Care Units
- Special Care Baby Units
- Maternity Wards
- Paediatric Out-Patient Departments
- Paediatric Nurse Consultants

## **6. CONTACTS:**

Enquires to NIAIC should quote reference number MDEA(NI)2003/40 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:

None Required



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

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