

Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/88

Issued: 6 December 2005

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section
<p>Medical Device/Equipment: VIASYS infant nasal CPAP breathing circuits model numbers CG8182 and CG8150 used with Infant Flow[®] VIASYS SiPAP[™] driver.</p>	▶ ①
<p>Problem: Risk of heater wire fitting detaching from the breathing circuit on certain batch numbers (listed overleaf), resulting in pressure loss and discontinuation of oxygen therapy.</p>	▶ ②
<p>Action by: All staff involved in the use and purchasing of these circuits e.g. neonatal and paediatric intensive care staff.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> • Be aware of this potential problem if using these affected circuits or contact VIASYS to arrange for replacements. • When using any of these circuits ensure that the instructions for use are followed and in particular follow the points described overleaf. • Report any further failures to the NIAIC, quoting the batch number of the breathing circuit. • Be aware that VIASYS will be issuing a customer letter on this issue. 	▶ ④
<p>Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers</p>	▶ ⑤
<p>Contacts Details of supplier contacts, NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC No required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The Infant Flow® SiPAP™ provides bi-level continuous positive airway pressure (CPAP) non-invasive respiratory support, designed for newborns and infants in hospital environments such as neonatal and paediatric intensive care units. It can also be used when transporting these patients within the hospital environment.

Model number: CG8150

The affected batch numbers are: 082304, 092104, 020105, 021505, 2007-04, 030805, 072805, 081105, 081805, 082005, 090105, 090205.

Model number: CG8182

The affected batch numbers are: 071904, 111304, 122104, 123004, 021705, 072805, 081105, 081805, 090105.

2. PROBLEM:

The MHRA is aware of several incidents involving VIASYS infant nasal CPAP breathing circuits where the ribbed moulded heater wire fitting has become loose or completely detached from the breathing circuit. The reports indicate that this problem may occur at any point during device set-up, pre-use checks or in use. Additionally, it has been noted that the loosening may not become apparent until the unit has become warmed up. Disconnection of the heater wire from the breathing circuit will result in the flow driver alarming, when set up according to the instructions for use.

VIASYS has confirmed that the loose or disconnecting heater wire fittings are the result of a dimensional fault that was not detected during quality assurance checks. The affected circuits were manufactured from 1 December 2004 through to 13 October 2005. VIASYS has introduced improved quality assurance and new production methods from 13 October 2005.

VIASYS has informed the MHRA that they estimate that the failure rate is 1 in 1000. The unit alarms when there is a loss of therapy and they are not aware of any injury resulting from this problem.

3. ACTION BY:

All staff involved in the use and purchasing of these circuits e.g. neonatal and paediatric intensive care staff.

4. ACTION:

- Conduct performance tests for continuity and leakage before connecting the product to a patient. Pre-use performance checks are described in the operator's manual.
- Regularly visually check that the heater wire fitting is secure during use.
- In the event of the CPAP flow driver unit alarming to indicate a pressure loss, check that the heater wire fitting is secure.
- Ensure that a replacement breathing circuit, alternative CPAP system or alternative means of ventilation is readily available in case of circuit failure, as per the instructions for use.

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
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Independent Health and Social Care Providers – Private Clinics through HSSRIA
- Operating Theatre Staff
- Intensive Care
- Paediatricians
- Respiratory Care Nurse Specialists
- Special Care Baby Units
- Maternity Wards
- Paediatric Units

6. CONTACTS:

Enquiries to the supplier should be addressed to:

VIASYS
Detlef Grotheer
7 Leibnizstrasse
97204 Hoechberg
Germany

Tel: + 49 931 4972 111
Fax: + 49 931 4972 62111

E-mail: detlef.grotheer@viasyshc.com

Enquires to NIAIC should quote reference number MDEA(NI)2005/88 and be addressed to:

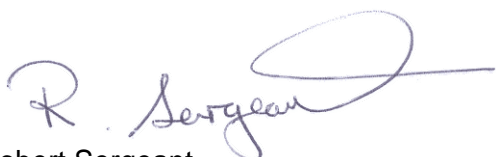
Northern Ireland Adverse Incident Centre (NIAIC)
Health Estates
Estate Policy Directorate
Stoney Road
Dundonald, Belfast, BT16 1US

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