

Medical Device/Equipment ALERT

Ref. MDEA(NI)2007/106

Issued: 6 December 2007



HEALTH ESTATES

creating healing environments

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION	

	Section
<p>Medical Device/Equipment: Paediatric respiratory support device - Infant Flow[®] SiPAP[™] manufactured by Viasys Healthcare.</p>	▶ ①
<p>Problem: There has been an important change to the operator manual that needs to be communicated to end users.</p>	▶ ②
<p>Action by: Neonatal and paediatric intensive care departments and those responsible for the management of these flow driver devices.</p>	▶ ③
<p>Action:</p> <ul style="list-style-type: none"> Obtain a copy of the current operator manual from the Viasys Healthcare website. At the time of publishing this is version Revision G published in July 2006: http://www.viasyshealthcare.com/prod_serv/downloads/197_PN_675-101-101G_Infant%20Flow_SiPAP_OM.pdf Ensure that all relevant staff are aware of the change to the instructions for use and have access to a copy of the current instructions. 	▶ ④
<p>Distributed by NIAIC to:</p> <ul style="list-style-type: none"> Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers 	▶ ⑤
<p>Contacts Details of manufacturer contacts and NIAIC contacts for technical and clinical aspects.</p>	▶ ⑥
<p>Feedback Requirements to NIAIC None required.</p>	▶ ⑦

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

1. DEVICE/EQUIPMENT:

The Infant Flow[®] SiPAP[™] provides a non-invasive form of respiratory support designed for infants in hospital environments and for transporting these patients within the hospital. Infant Flow[®] SiPAP[™] provides bi-level nasal CPAP for the spontaneously breathing neonate.

2. PROBLEM:

The operator manual used to state incorrectly that changes to parameters will only be set if confirmed by pressing the control button.

In fact, changes are automatically accepted in the event that no other button is pressed within 15 seconds.

The operator manual has been corrected. Revision G, page 23 '**changing a control setting**' now states:

'When a control setting such as Ti (inspiratory time) is selected, increase and decrease buttons appear. The control and displayed value for the selected parameter are highlighted. Use the decrease or increase keys to adjust the parameter. Accept the action by pressing the control button again.

In normal treatment screens, parameter changes take immediate effect.

If no button is pressed for 15 seconds during this procedure, highlighted controls are automatically adjusted according to the last key stroke and the screen is restored to its previous configuration.'

3. ACTION BY:

Neonatal and paediatric intensive care departments and those responsible for the management of these flow driver devices.

4. ACTION:

- Obtain a copy of the current operator manual from the Viasys Healthcare website. At the time of publishing this is version Revision G published in July 2006:
http://www.viasyshealthcare.com/prod_serv/downloads/197_PN_675-101-101G_Infant%20Flow_SiPAP_OM.pdf
- Ensure that all relevant staff are aware of the change to the instructions for use and have access to a copy of the current instructions.

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:

- A&E directors
- Anaesthetists
- Children's hospices
- Clinical governance leads
- EBME departments
- Health and safety managers
- Intensive care units
- Maintenance staff
- Maternity units
- Medical directors
- Medical physics departments
- Neonatology departments
- Neonatology directors
- Nursing executive directors
- Obstetricians
- Obstetrics departments
- Paediatric intensive care units
- Paediatric wards
- Paediatricians
- Palliative care teams
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatre managers
- Theatres
- Independent Health and Social Care Providers – Private Hospitals & Clinics through RQIA

6. CONTACTS:

Enquiries to manufacturer should be addressed to:

VIASYS
Detlef Grotheer
7 Leibnizstrasse
97204 Hoechberg
Germany

Tel: + 49 931 4972 111

E-mail: detlef.grotheer@viasyshc.com

Enquiries to NIAIC should quote reference number MDEA(NI)2007/106 and be addressed to:

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

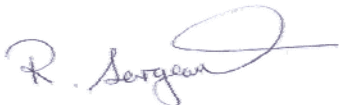
Tel: 028 9052 3868

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)2006/01. 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