

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/47

Issued: 25 August 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE

	Section								
Medical Device/Equipment: Vital Signs Ltd Breas AB CPAP PV10 (continuous positive airway pressure delivery system)	▶ ①								
Problem: This device may reset to default settings when mains power has been disrupted (switched off/on).	▶ ②								
Action by: All those who manage patients with sleep disorders, and those responsible for the management of the CPAP PV10 devices.	▶ ③								
Action: <ul style="list-style-type: none"> Identify all affected CPAP PV10s in accordance with the attached appendix and follow Breas's advice. Ensure users/carers are aware of this potential problem, and that they check the settings before each use against the prescribed settings. An upgrade to the internal software is being made available by Vital Signs Ltd. This may be carried out by a healthcare professional or the machine may be returned to the company for an upgrade (free of charge). 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Hospices</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Hospices	Chief Executive of each Agency		NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
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Contacts Details of manufacturer contacts, NIAIC contacts for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC Report any similar incidents to NIAIC	▶ ⑦								

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

1. DEVICE/EQUIPMENT:

Breas AB CPAP PV10 used for the treatment of obstructive sleep apnoea.

2. PROBLEM:

The manufacturer has requested assistance with this recall of affected devices due to the widespread distribution of the CPAP PV10s.

- A return to default settings may cause inadequate pressures to be delivered in the treatment of obstructive sleep apnoea with the potential for excessive daytime somnolence and retention of carbon dioxide.
- There is the possibility that the device may reset to default settings when power is disrupted (switched off/on). The default settings are 4 cmH₂O (the minimum pressure level available) and internal clock resets to 00.00h 01/01/2000.
- Settings can be locked and are indicated by an illuminated LED. If the settings default, the LED switches off.
- There is no alarm warning that this problem has occurred.

3. ACTION BY:

All those who manage patients with sleep disorders, and those responsible for the management of the CPAP PV10 devices.

4. ACTION:

- A management plan will be needed to ensure that users know how to monitor their device settings and users know the procedure for either correcting this fault or who to contact for help.
- Following a risk assessment, if you have concerns about the continued use of this device within certain user groups Vital Signs Ltd should be contacted for further details.

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
- Healthcare Scientists
- Physiotherapists
- Respiratory Care Nurse Specialists
- Respiratory Physiologists
- Sleep Physiologists
- Practice Nurses
- Health Visitors
- Directors of Public Health
- Community Care Staff
- Day Care Centres
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units

6. CONTACTS:

Enquiries to Vital Signs Ltd should be addressed to:

Mrs Jan Hill (general issues) or David Murphy (technical issues)

Vital Signs Ltd

13-14 Eldon Way

Lineside Industrial Estate

Littlehampton

West Sussex

BN17 7HE

E-mail: janet@vital-signs.co.uk

Tel: 0845 6444955

Enquires to NIAIC should quote reference number MDEA(NI)2004/47 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:

Report any similar incidents to NIAIC



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 MDEA(NI)2004/01. 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

APPENDIX to MDEA(NI)2004-47

BREAS®

Marketing Bulletin

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PV10 Firmware Release 2.38

This bulletin contains safety-related information regarding the use of BREAS CPAP device PV10.

Scope:

All BREAS CPAP devices of model PV10 with a maximum CPAP pressure setting of 20 mbar (or 20 cmH₂O) from and including serial number "P020126" up to and including "S170433" are affected by this information and the requested action.

Background:

The following problem has been reported to us in a very few cases: If the internal start-up process is interrupted, the PV10 could automatically reset itself to the internal default settings, meaning that the panel will be unlocked, CPAP pressure will be set to 4 mbar (or 4 cmH₂O) and the internal clock will be reset to 00:00, January 1st, 2000. If this happens, no audio or visual alarm is activated on the PV10.

Interruption of the start-up process can occasionally be caused by intermittent contact with the mains supply (e.g., when turning the power on by plugging in and turning on at the wall socket, by connecting the power cord to the PV10 or by connecting the power cord to the wall socket).

If the unit is already connected to the mains, as would be the normal case, and switched on using the panel switch, this problem will not occur.

A change in the firmware has been made to correct this potential problem and all PV10's with serial number "S170434" and higher have this corrected firmware installed from the factory, therefore new or upgraded units with this firmware (version 2.38 or higher) will deliver therapy without this potential problem.

Patient safety:

If the described problem occurs it will be obvious and the patient will not use the PV10 without first having the settings corrected. If the user instructions are followed before starting treatment, as described in the manual section "Checking the PV10 before use", the patient will realize that the setting doesn't correspond with the prescribed pressure.

However, if the patient is unaware of the setting change, the device will still always continue treatment at 4 mbar (or 4 cmH₂O) which could possibly lead to difficulties treating sleep apnea potentially causing daytime somnolence. However, the patient will normally detect the lower CPAP pressure when starting the treatment.

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Action required:

Local sales organizations (recipients of this bulletin) shall forward this information to their customers (normally Home Health Care providers) and customize this communication to their specific market needs, without changing the facts. The following actions are requested by the recipients of this bulletin:

1. Identify to whom the affected PV10's have been shipped.
2. Customize this communication to your local needs (without changing the facts) and emphasise the need to follow the instructions provided before using the PV10.
3. Distribute your customised communication to the organizations as identified in point 1 above.
4. Verify that the communication has been received, read and understood.
5. Identify if the PV10 is affected by the problem as described:
 - a. After switching the PV10 on, the pressure setting is set to 4 mbar (or 4 cmH₂O) and doesn't correspond with the prescribed pressure.
 - b. The panel on the PV10 was previously locked and is now unlocked.
6. Handling of PV10's affected by this problem:
 - a. Make sure that the prescribed CPAP pressure setting is re-entered.
 - b. If this described problem is noticed, we recommend upgrading the PV10 firmware to version 2.38 or later.

If you should have any issues or questions with the above, please contact BREAS Medical AB, Marketing Dept.