

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2006/45

Issued: 26 July 2006

For:

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



**HEALTH ESTATES**

creating healing environments

	Section
<p><b>Medical Device/Equipment:</b> Syringe pump: IVAC P4000 manufactured by Cardinal Health (formerly known as ALARIS).</p>	▶ ①
<p>There is a remote possibility that: The displayed low flow rate (up to 99.9 ml/h) may spontaneously change its format from tens, units and tenths to the higher range format, hundreds, tens and units (up to 999 ml/h) . For example 20.0 ml/h is displayed as 20ml/h. The set rate does not change. (See Appendix). This could result in an unintended rate being set if the display is misinterpreted.</p>	▶ ②
<p><b>Action by:</b> All nursing, medical and technical staff using these devices.</p>	▶ ③
<p><b>Action:</b> Remove all P4000 pumps from use. Cardinal Health have issued a customer letter informing users of the problem and may offer a preferential rate on the purchase of replacement devices for P4000 pumps made after July 1996. (See Appendix).</p>	▶ ④
<p><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</p> <p style="text-align: right;">Hospices</p>	▶ ⑤
<p><b>Contacts</b> Details of manufacturer contacts for clinical aspects and NIAIC contacts.</p>	▶ ⑥
<p><b>Feedback Requirements to NIAIC</b> None required</p>	▶ ⑦

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

## 1. DEVICE/EQUIPMENT:

This problem is unique to P4000 pumps. No other IVAC/ALARIS P series pumps are affected as they use a different software platform.

## 2. PROBLEM:

Infusion rates are set by pressing the up and down buttons below each of the displayed digits. There is therefore the risk that users who are used to just looking at the number of digits, and ignoring the missing decimal point, may think the rate has changed, so in the case of the example above, may alter the rate to display 200. This misinterpretation would result in a delivered rate of 200ml/h (a ten times over-infusion).

## 3. ACTION BY:

All nursing, medical and technical staff using these devices.

## 4. ACTION:

Remove all P4000 pumps from use. Cardinal Health have issued a customer letter informing users of the problem and may offer a preferential rate on the purchase of replacement devices for P4000 pumps made after July 1996. (See Appendix).

## 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
- Estates Managers
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- Paediatric Units
- Practice Nurses
- Directors of Public Health
- Community Care Staff
- Independent Health and Social Care Providers – Private Hospitals & Clinics and Nursing Homes through RQIA
- Operating Theatre Staff
- Accident & Emergency Departments
- Coronary Care
- Intensive Care
- All wards
- IV specialist nurses
- Palliative care teams
- Oncology departments

## 6. CONTACTS:

Enquiries to the manufacturer/supplier should be addressed to:

Customer Services  
Cardinal Health  
The Crescent  
Jays Close  
Basingstoke  
RG22 4BS

Tel: 0800 917 8776

E-mail: [uk-customer-service@cardinal.com](mailto:uk-customer-service@cardinal.com)

Enquires to NIAIC should quote reference number MDEA(NI)2006/45 and be addressed to:

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

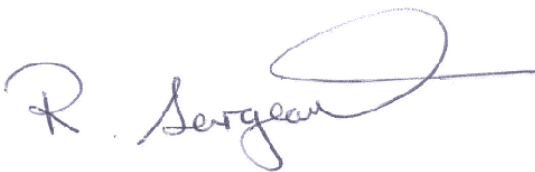
Tel: 028 9052 3868

Fax: 028 9052 3900

Email: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

## 7. FEEDBACK:

None Required



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](http://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) 2006/45

Ref: Potential for change of rate display format in IVAC P4000 Syringe Pumps

Affected Product : IVAC P4000

Date xxxxx

Dear Customer,

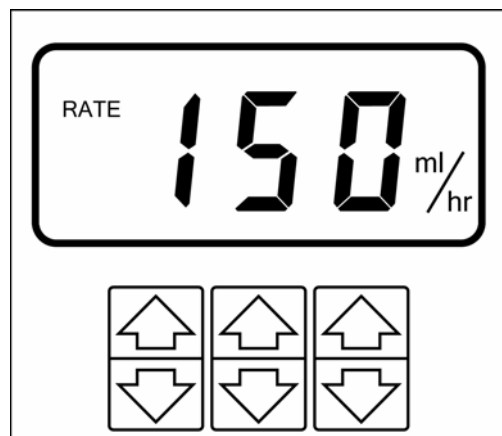
Cardinal Health Alaris® Products International has recently become aware of a rare software anomaly associated with the legacy IVAC P4000 syringe pump. This product was sold between January 1992 and August 1999 under the former company names of Welmed, IVAC® and Alaris Medical Systems.

**Note: This issue is associated with the IVAC P4000 model only. All other IVAC P-Series syringe pump models are unaffected.**

The anomaly is a change in the way that the set infusion rate is displayed on the screen of the pump. In normal use there are two modes of display operation as follows:

## 1. For Low Rates

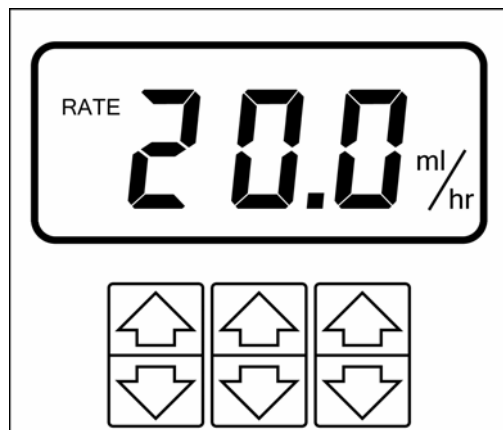
At rates of 99.9ml/h and below the screen shows the rate to one decimal place, (e.g. 20.0ml/h) and allows adjustment of this value in steps of 0.1ml/h.



Normal display operation for rates of  $\leq 99.9$ ml/h

## 2. For High Rates

At rates of 100ml/h and above the screen shows the rate with no decimal places, (e.g. 150ml/h) and allows adjustment to this value in steps of 1ml/h.



Normal display operation for rates of  $\geq 100$ ml/h

## APPENDIX TO MDEA (NI) 2006/45

In both cases the user can adjust the rate using the 'up' and 'down' arrow keys located beneath each digit on the screen.

In the reported anomaly the pump can enter a rare software state in which low rates are displayed in the format normally used for high rates. For example, where 20 millilitres per hour would normally be displayed as '20.0ml/hr' it is instead displayed as '20ml/hr'.



### Display operation during anomaly for rates of $\leq 99.9$ ml/h

The effect of this anomaly is to move the displayed rate one digit to the right, thus changing the keys required to set rates of less than 100ml/h. For example, when setting a rate of 5ml/h the user would normally press the middle, 'up' arrow key five times. However, performing the same key presses during the software anomaly would result in a rate of 50ml/h being set. While the data on the display remains correct, Cardinal Health consider that there is small risk that the anomaly may lead to an incorrect rate being set by the user.

The IVAC P4000 syringe pump is an old design that was last manufactured seven years ago and is no longer considered 'State of the Art'. The legacy nature of this product and the technology on which it is based make it impractical for Cardinal Health to provide a software upgrade to correct the anomaly. Furthermore, the majority of IVAC P4000 pumps manufactured are in excess of ten years old and are therefore beyond their designed operational life. Consequently, Cardinal Health recommends that all IVAC P4000 pumps be removed from use and

decommissioned. For pumps that were manufactured after July 1996 Cardinal Health may offer a preferential rate on the purchase of a replacement device. Please contact your local Cardinal Health representative for details.

In order to help you identify the devices at your facility to which this notice applies, we are providing you with the serial numbers of IVAC P4000 pumps you have purchased.

Yours sincerely

Pierre Rebours  
Director of Quality & Regulatory Affairs  
Cardinal Health Alaris® Products - International