

# Medical Device/Equipment ALERT

Ref. MDEA(NI)2005/92

Issued: 15 December 2005

For:

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



**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

	Section						
<b>Medical Device/Equipment:</b> ALARIS (IVAC) <sup>®</sup> P Series pumps with Fiamm sealed lead acid batteries.	▶ ①						
<b>Problem:</b> Fiamm batteries in P Series pumps can prematurely lose capacity during the first and second years of operation. If this happens: <ul style="list-style-type: none"> <li>The normal six hours of operation expected from a fully charged battery may not occur. The period of operation may be as little as 30 minutes.</li> <li>The expected 30 minutes of operation between the BATTERY LOW alarm and the BATTERY EMPTY alarm cannot be guaranteed.</li> <li>This can result in an interruption to therapy if the pump is running on battery only and could lead to possible death or serious injury if prompt action is not taken to reconnect mains power when the audible and visible 'BATTERY EMPTY' alarm is generated e.g. during transport when mains power may not be available.</li> </ul>	▶ ②						
<b>Action by:</b> All nursing, medical and technical staff using these devices.	▶ ③						
<b>Action:</b> <ul style="list-style-type: none"> <li>Clinical staff should determine if the pumps are likely to be used for transfer or transport.</li> <li>If so the technical staff should identify suspect pumps and check whether they have Fiamm batteries. If they have Fiamm batteries contact Intraveno (see contacts) to order replacement batteries. See Appendix for manufacturer's letter.</li> </ul>	▶ ④						
<b>Distributed by NIAIC to:</b> <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">Hospices</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>NIAIC Liaison Officers</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	Hospices	Chief Executive of each HSS Trust	NIAIC Liaison Officers	Chief Executive of each Agency		▶ ⑤
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<b>Contacts</b> Details of manufacturer and NIAIC contacts.	▶ 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:

P Series pumps with serial numbers between and including those below, or having replacement batteries that were fitted or supplied as spares by Intraveno between 25 April 2003 and 20 February 2005 (under part number 0000EL00004).

Model number	Product Name	First Serial No.	Last Serial No.
10012****	IVAC P1000	100126080	100126105
20013****	IVAC P2000	200137562	200137613
30013****	IVAC P3000	300131675	300132987
5001****	IVAC P5000 PCAM	500106854	500106855
		500108258	500110247
		500108953	500108962
60013****	IVAC P6000	600129395	600129783
60023****	IVAC P6000 TIVA	600217651	600218664
60033****	IVAC P6000 TIVA TCI	600303997	600304818
70013****	IVAC P7000	700102955	700123364
70023****	IVAC P7000 Actilyse	700201429	700201433

## 2. PROBLEM:

Cardinal Health (ALARIS Medical Systems) have determined that the Fiamm batteries in P series pumps can prematurely lose capacity during the first and second years of operation. Normally a battery will allow the pump to run for six hours at typical infusion rates. When the battery is depleted the pump gives a BATTERY LOW warning. At this point a good battery will power the pump for another 30 minutes before the BATTERY EMPTY alarm is activated. With Fiamm batteries the total operating time may be as little as 30 minutes from a fully charged state and the 30 minutes of battery life following the BATTERY LOW warning cannot be guaranteed. Cardinal Health state that the pump will still alarm for at least ten minutes once the BATTERY EMPTY alarm is activated, but it will have stopped infusing.

## 3. ACTION BY:

All nursing, medical and technical staff using these devices.

## 4. ACTION:

- Clinical staff should determine if the pumps are likely ever to be used for transfer or transport.
- If so the technical staff should identify suspect pumps and check whether they have Fiamm batteries.
- If they have Fiamm batteries contact Intraveno to order replacement batteries.

## 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
- Medical, Nursing and Care Staff
- Ambulance Staff and Paramedics
- Supplies Staff (RSS)
- Special Care Baby Units
- All Wards
- Equipment Libraries, Stores, and EBME Departments
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSSRIA
- Operating Theatre Staff
- Outpatient Departments
- Accident & Emergency Departments
- Intensive Care
- Resuscitation Officers
- Day Procedure Units

## 6. CONTACTS:

Enquiries to the manufacturer should be addressed to:

Damien Deehan  
Intraveno  
Unit 68 Enterprise House  
Balloo Avenue  
BANGOR  
BT19 7QT

Tel: 028 91450290  
Mobile: 07711074609  
Email: [damien.deehan@intraveno.com](mailto:damien.deehan@intraveno.com)

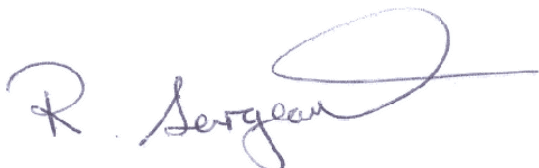
Enquires to NIAIC should quote reference number MDEA(NI)2005/92 and be addressed to:

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)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](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)2005/92

Ref: **Potential for Premature Failure of Fiamm Sealed Lead Acid Batteries in IVAC® P Series Infusion Pumps**

Date xxxxx

Dear Sir

Our records indicate that your hospital is currently using IVAC® P Series Syringe Pumps containing **Fiamm Sealed Lead Acid Batteries**. We are writing to inform you that our post market surveillance process has identified a potential for the premature failure of some of these batteries under certain conditions.

We have conducted an investigation into the premature failures and have identified a potential for the Fiamm 6V 3.4Ah battery to lose some charge retention in the first and second year of operation. This type of premature failure has no detrimental effect on the performance of the pump when powered by AC mains. However, there may be a potential effect while transferring a patient connected to a pump infusing on battery power alone.

In particular, during transfers lasting periods longer than 30 minutes, the IVAC® P Series Syringe Pumps may fail to provide the user with the stated run time of 30 minutes between alarming "battery low" and "battery empty" at which time the pump will alarm and stop infusing.

This issue could affect users who regularly use IVAC® P Series Syringe Pumps on battery power when transporting patients for a period of longer than 30 minutes.

Consequently, Alaris Medical recommends to customers who are using their IVAC® P Series Syringe Pumps in the manner described above, to consider replacing their Fiamm batteries with an alternative battery as recommended by Alaris Medical.

In addition to the Yuasa 6v 2.8Ah battery, Alaris Medical has now qualified the Panasonic 6V 3.4 Ah battery as an alternative to the Fiamm battery. The Panasonic battery provides equivalent battery run time and testing has shown that properly maintained Panasonic batteries do not fail prematurely. Please refer to the latest Technical Service Manual for further information on battery maintenance.

Our records indicate that your hospital may have received Fiamm batteries from Alaris Medical in several different ways :-

*Quantity* Inside IVAC® P Series Syringe Pumps you have purchased between April 2003 and January 2005

*Quantity* Inside IVAC® P Series Syringe Pumps that Alaris Medical has serviced/repaired for you that contain Fiamm batteries

*Quantity* Fiamm batteries purchased by you from Alaris Medical for spares (0000EL00004)

Total Quantity =

If you have IVAC® P Series Syringe Pumps being used in situations where we are recommending battery replacement, please contact your Alaris Medical Customer Service Department to order the required number of replacement Panasonic batteries.

We sincerely apologise for any inconvenience this issue may cause. An Alaris Medical field engineer will be making contact with you, in the near future, by telephone or by visit to answer any follow up questions or further points of clarification. For further information in the meantime, please contact your Alaris Medical customer service department.

Yours sincerely

*Pierre Rebours*  
Director of Quality and Regulatory Affairs  
CTS International