



Llywodraeth Cymru  
Welsh Government

# Medical Device Alert

**16<sup>th</sup> February 2018**

Parc Cathays  
Caerdydd CF10 3NQ

Cathays Park  
Cardiff CF10 3NQ

## **Plum 360 infusion pumps – user actions required to prevent risk of interrupted infusion or delay to treatment**

- Identify affected pumps, which were manufactured from 29 April 2015 to 25 October 2016 inclusive – see the spreadsheet listing device serial numbers which accompanies this Medical Device Alert and the manufacturer's Field Safety Notice (FSN). If you are still unsure, contact the manufacturer.
- Inspect affected pumps as detailed in the FSN. If a loose connectivity engine module or blank display is found, remove the pump immediately from service, and contact manufacturer for repair.
- If the pump powers down without an alarm, use an alternative pump, and contact manufacturer for repair.
- Assist manufacturer to schedule appointments for inspection/repair and ensure pumps are made available to manufacturer for inspection/repair at the scheduled time/date.
- Ensure you have read the Field Safety Notice and have completed and returned the

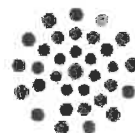
Sent to:

NHS Wales Shared Services Partnership  
Directors of Public Health,  
Chief Executives, NHS Trusts  
Chief Executives, LHBs  
Medical Directors, NHS Trusts  
Nurse Directors, LHBs  
Executive Nurses, NHS Trusts  
NHS Direct  
CSSIW  
Social Services  
HIW

A list of people who need to have early sight of this information is given in the Notice.  
This Notice has been endorsed by the Welsh Government as being relevant to NHS Wales.

### **Points of particular importance in Wales:**

**Healthcare Quality Division  
Welsh Government  
Cathays Park  
Cardiff CF10 3NQ**



## Medical Device Alert

MDA/2018/006

Issued: 15 February 2018 at 13:30

Plum 360 infusion pumps – user actions required to prevent risk of interrupted infusion or delay to treatment

### Summary

Manufactured by ICU Medical (formerly Hospira) – potential for connectivity engine module to disengage from main chassis, which may lead to power down without an alarm.

### Action

- Identify affected pumps, which were manufactured from 29 April 2015 to 25 October 2016 inclusive – see the spreadsheet listing device serial numbers which accompanies this Medical Device Alert and the manufacturer's Field Safety Notice (FSN). If you are still unsure, contact the manufacturer.
- Inspect affected pumps as detailed in the FSN. If a loose connectivity engine module or blank display is found, remove the pump immediately from service, and contact manufacturer for repair.
- If the pump powers down without an alarm, use an alternative pump, and contact manufacturer for repair.
- Assist manufacturer to schedule appointments for inspection/repair and ensure pumps are made available to manufacturer for inspection/repair at the scheduled time/date.
- Ensure you have read the Field Safety Notice and have completed and returned the acknowledgement form as currently the manufacturer has not received sufficient responses.

#### Action by

All medical, nursing and technical staff involved in the use of these devices.

#### Deadlines for actions

Actions underway: 08 March 2018

Actions complete: 15 March 2018

Note: These deadlines are for users to have an action plan in place and not for the repairs to be complete.

**Medical Device Safety Officers** (in England): ask the manufacturer to add you to their distribution list for field safety notices (FSNs). This is to help with reconciliation.

**Remember:** if your organisation receives an FSN from a manufacturer, always act on it. **Do not wait** for a communication from MHRA.



## Device details

The manufacturer provided a customised list of serial numbers with the FSN in June 2017. To identify affected devices either refer to the customised list, or review the attached spreadsheet.

## Manufacturer contacts

ICU Medical Customer Service  
Tel: 020 3357 9400  
Email: UKSupport@icumed.com

## Distribution

If you are responsible for cascading these alerts in your organisation, these are our suggested distribution lists.

### **Trusts (NHS boards in Scotland)**

CAS and NICAS liaison officers for onward distribution to all relevant staff including:

- A&E consultants
- A&E departments
- A&E nurses
- Adult intensive care units
- All departments
- All wards
- Ambulance services directors
- Ambulance staff
- Anaesthesia, directors of
- Anaesthetic medical staff
- Anaesthetic nursing staff
- Anaesthetists
- Anti-coagulation clinics
- Cardiac laboratory technicians
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Cardiothoracic surgeons
- Clinical perfusionists
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- District nurses
- EBME departments
- Endocrinology units
- ENT departments
- ENT medical staff
- Equipment stores
- Equipment libraries and stores

- Gastroenterology departments
- Gastro-intestinal surgeons
- General surgeons
- General surgery
- General surgical units, directors of
- Gynaecologists
- Gynaecology departments
- Gynaecology nurses
- Haematologists
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- Hospital at home units
- In-house maintenance staff
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- IV nurse specialists
- Maintenance staff
- Minor injury units
- Maternity units
- Maxillofacial departments
- Medical directors
- Medical libraries
- Medical oncologists
- Neonatal nurse specialists
- Neonatology departments
- Obstetricians
- Obstetrics and gynaecology departments
- Obstetrics and gynaecology directors
- Obstetrics departments
- Obstetrics nurses
- Oncology nurse specialists
- Operating department practitioners
- Oral surgeons
- Orthopaedic surgeons
- Outpatient theatre managers
- Outpatient theatre nurses
- Paediatric intensive care units
- Paediatric nurse specialists
- Paediatric oncologists
- Paediatric surgeons
- Paediatric surgery, directors of
- Paediatric wards
- Paediatricians
- Paediatrics departments
- Palliative care teams
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Purchasing managers

- Renal medicine departments
- Renal medicine, directors of
- Risk managers
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urological surgeons
- Urology departments

### ***Independent distribution***

#### **Establishments registered with the Care Quality Commission (CQC) (England only)**

- Adult placement
- Care homes providing nursing care (adults)
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

Please note: CQC and OFSTED do not distribute these alerts. Independent healthcare providers and social care providers can sign up to receive MDAs directly from the Department of Health's Central Alerting System (CAS) by sending an email to: [safetyalerts@dh.gsi.gov.uk](mailto:safetyalerts@dh.gsi.gov.uk) and requesting this facility.

## **Enquiries**

### **England**

Send enquiries about this notice to MHRA, quoting reference number **MDA/2018/006** or 2017/006/013/291/012.

### **Technical aspects**

Ruth Lloyd-Williams or Enitan Taiwo, MHRA

Tel: 020 3080 6972 / 7122

Email: [ruth.lloyd-williams@mhra.gov.uk](mailto:ruth.lloyd-williams@mhra.gov.uk) or [enitan.taiwo@mhra.gov.uk](mailto:enitan.taiwo@mhra.gov.uk)

### **Clinical aspects**

Devices Clinical Team, MHRA

Tel: 020 3080 7274

Email: [dct@mhra.gov.uk](mailto:dct@mhra.gov.uk)

### **Reporting adverse incidents in England**

Through Yellow Card <https://yellowcard.mhra.gov.uk/>

### **Northern Ireland**

Alerts in Northern Ireland are distributed via the NICAS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre, CMO Group,  
Department of Health, Social Services and Public Safety

Tel: 028 9052 3868

Email: [niaic@health-ni.gov.uk](mailto:niaic@health-ni.gov.uk)  
<https://www.health-ni.gov.uk/niaic>

#### **Reporting adverse incidents in Northern Ireland**

Please report directly to NIAIC using the forms on our website.

### **Scotland**

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre, Health Facilities Scotland, NHS National Services Scotland

Tel: 0131 275 7575

Email: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

#### **Reporting adverse incidents in Scotland**

NHS Boards and Local Authorities in Scotland – report to Health Facilities Scotland.

Contractors such as private hospitals carrying out NHS work and private care homes that accept social work funded clients – report to Health Facilities Scotland.

Private facilities providing care to private clients report to the Care Inspectorate and MHRA.

### **Wales**

Enquiries in Wales should be addressed to:

Healthcare Quality Division, Welsh Government

Tel: 02920 823 624 / 02920 825 510

Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)

#### **Reporting adverse incidents in Wales**

Report to MHRA through Yellow Card <https://yellowcard.mhra.gov.uk/> and follow specific advice for reporting in Wales in MDA/2004/054 (Wales).

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Addressees may take copies for distribution within their own organisations

**Potential for Connectivity Engine to Disconnect from Main Chassis (FSN dated 21 June 2017):**

**Plum 360 pump serial numbers requiring inspection**

20645402		20645477		20645541		20645613		20645682		20645756
20645403		20645478		20645542		20645614		20645683		20645757
20645404		20645479		20645543		20645615		20645684		20645758
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20645406		20645481		20645545		20645617		20645686		20645761
20645407		20645482		20645546		20645621		20645688		20645763
20645411		20645483		20645547		20645622		20645690		20645764
20645412		20645484		20645548		20645624		20645691		20645767
20645413		20645486		20645549		20645625		20645692		20645769
20645416		20645487		20645551		20645626		20645693		20645771
20645417		20645488		20645552		20645627		20645695		20645772
20645418		20645489		20645553		20645628		20645696		20645773
20645420		20645490		20645554		20645630		20645697		20645774
20645421		20645491		20645555		20645631		20645698		20645775
20645425		20645492		20645556		20645632		20645699		20645776
20645426		20645493		20645557		20645633		20645700		20645777
20645427		20645494		20645558		20645635		20645701		20645778
20645428		20645495		20645560		20645636		20645702		20645781
20645429		20645496		20645562		20645637		20645703		20645782
20645432		20645497		20645564		20645638		20645704		20645783
20645433		20645498		20645565		20645640		20645706		20645784
20645436		20645499		20645567		20645641		20645707		20645785
20645437		20645500		20645568		20645642		20645709		20645787
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20647674		20647780		20647884		20647992		20648099		20648336
20647676		20647781		20647885		20647993		20648100		20648337
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20647679		20647784		20647888		20647996		20648103		20648340
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