



Llywodraeth Cymru  
Welsh Government

# Medical Device Alert

7<sup>th</sup> March 2018

Parc Cathays  
Caerdydd CF10 3NQ

Cathays Park  
Cardiff CF10 3NQ

Bag valve mask (BVM) manual resuscitation system – risk of damage to lungs by delivery of excessive pressure

- Identify and immediately quarantine affected devices (see [Field Safety Notice \(FSN\)](#) for model and lot numbers).
- Replace with an alternative device where available.
- If no alternative is available, check the orientation is correct for all valves on quarantined devices before releasing them from quarantine (see Problem). This can be done without opening the packaging. Do not use if the orientation of the valve is incorrect.
- Follow the instructions in the manufacturer's [FSN](#) to return affected devices. Return the response form to Intersurgical, even if you don't have affected devices left in stock.

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

This document is available online at:  
<https://www2.nphs.wales.nhs.uk/contacts.nsf>

Ffôn/Tel: 029 2082 3624/029 2082 5510  
Eboost/Email: [Haz-Aic@wales.gsi.gov.uk](mailto:Haz-Aic@wales.gsi.gov.uk)



# Medical Device Alert

MDA/2018/009

Issued: 02 March 2018 at 15:00

Valid until: March 2019

Bag valve mask (BVM) manual resuscitation system – risk of damage to lungs by delivery of excessive pressure

## Summary

Manufactured by Intersurgical – Valves may be incorrectly oriented, resulting in overpressure of the bag.

## Action

- Identify and immediately quarantine affected devices (see [Field Safety Notice \(FSN\)](#) for model and lot numbers).
- Replace with an alternative device where available.
- If no alternative is available, check the orientation is correct for all valves on quarantined devices before releasing them from quarantine (see Problem). This can be done without opening the packaging. Do not use if the orientation of the valve is incorrect.
- Follow the instructions in the manufacturer's [FSN](#) to return affected devices. Return the response form to Intersurgical, even if you don't have affected devices left in stock.

### Action by

All healthcare professionals involved in the use of these devices.

### Deadlines for actions

Actions underway: 23 March 2018

Actions complete: 17 April 2018

**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

Specific lot numbers from the following models are affected. See [FSN](#) for lot numbers.

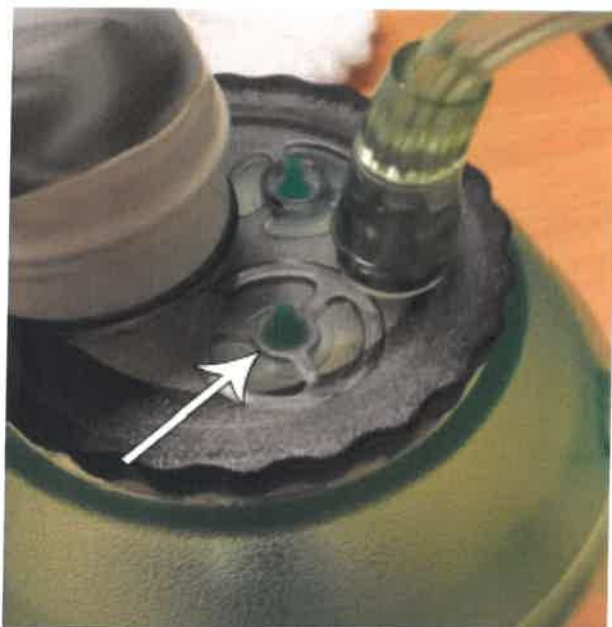
Intersurgical Code	UDI No.	NHSSC Code (England only)
7150000	5030267073238	FDE656
7151000	5030267073245	N/A
7152000	5030267073252	FDE658
7152005	5030267102259	N/A
7152006	5030267105632	N/A
7152007	5030267104901	N/A
7152012	5030267143061	N/A
7153000	5030267073276	FDD4288
7153008	5030267124473	N/A
7154000	5030267073283	FDE660

## Problem

The images below show the incorrect and correct orientation of the directional valves.

The green nipples on the valves should **not** point in the same direction.

### Incorrect orientation of directional valve



### Correct orientation of directional valves



## Manufacturer contacts

Intersurgical

Tel: 0118 9656 362

Email: [priority@intersurgical.co.uk](mailto:priority@intersurgical.co.uk)

## 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 directors
- 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
- Cardiologists
- Cardiology departments
- Cardiology nurses
- Cardiothoracic departments
- Cardiothoracic surgeons
- Chief pharmacists
- Clinical perfusionists
- Colposcopy departments
- Community children's nurses
- Community defibrillation officers
- Community dental practices
- Community hospitals
- Community nurses
- Coronary care departments
- Coronary care nurses
- Day surgery units
- Dental departments
- District nurses
- ENT departments
- ENT medical staff
- Equipment stores
- Gastroenterology departments
- General surgery
- General surgical units, directors of
- Gynaecology departments
- Haemodialysis units

- Hospital at home units
- Intensive care medical staff/paediatrics
- Intensive care nursing staff (adult)
- Intensive care nursing staff (paediatric)
- Intensive care units
- Intensive care, directors of
- Minor injury units
- Maternity units
- Medical directors
- Midwifery departments
- Neonatal nurse specialists
- Neonatology departments
- NHS walk-in centres
- Obstetrics and gynaecology departments
- Obstetrics departments
- Operating department practitioners
- Outpatient clinics
- 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
- Paramedics
- Patient transport managers
- Peritoneal dialysis units
- Renal medicine departments
- Resuscitation officers and trainers
- Risk managers
- School nurses
- Special care baby units
- Supplies managers
- Theatre managers
- Theatre nurses
- Theatres
- Urology departments
- Walk-in centres

### **NHS England area teams**

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

- General practitioners
- General practice nurses

### **Social services**

Liaison officers for onward distribution to all relevant staff including:

- Care at home staff
- Community care staff
- Day centres (older people, learning disabilities, mental health, physical disabilities, respite care, autistic services)

- Education departments for equipment held in schools
- In-house domiciliary care providers (personal care services in the home)
- In-house residential care homes

### ***Independent distribution***

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

- Care homes providing nursing care (adults)
- Care homes providing personal care (adults)
- Clinics
- Domiciliary care providers
- Further education colleges registered as care homes
- Hospices
- Hospitals in the independent sector
- Independent treatment centres
- Nursing agencies
- Private medical practitioners

#### **Establishments registered with OFSTED**

- Children's services
- Educational establishments with beds for children
- Residential special schools

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/2018/009** or 2017/012/022/291/023

### **Technical aspects**

Emma Rooke or Sophie Clewlow, MHRA

Tel: 020 3080 6609 or 6871

Email: [emma.rooke@mhra.gov.uk](mailto:emma.rooke@mhra.gov.uk) and [sophie.clewlow@mhra.gov.uk](mailto:sophie.clewlow@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 \(Wales\)](#).

MHRA is a centre of the Medicines and Healthcare products Regulatory Agency, an executive agency of the Department of Health  
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