

# Medical Device Alert

## Immediate action

Ref: MDA/2010/026 Issued: 08 April 2010 at 11:00

### Device

PediCap 6 paediatric end-tidal CO<sub>2</sub> detector manufactured by Covidien (part of Tyco Healthcare).  
Specific lot numbers.



Problem	Action
<p>A modification to the indicator paper in the detector may result in:</p> <ul style="list-style-type: none"> <li>increased resistance to airflow</li> <li>inadequate sensing of carbon dioxide (CO<sub>2</sub>), as the indicator does not change colour</li> <li>delay in detection of an incorrectly placed breathing tube.</li> </ul>	<ul style="list-style-type: none"> <li>Identify and quarantine affected devices, as listed in the manufacturer's <a href="#">Field Safety Notice</a>.</li> <li>Contact Covidien to arrange return of, and receive credit for, the affected devices.</li> </ul>
Action by	
All those who use or distribute these devices	
CAS deadlines	Contact
<p>Action underway: 15 April 2010 Action complete: 22 April 2010</p>	<p><b>Manufacturer</b> Mr B Cole Covidien Tel: 07710 597 649 Fax: 0203 027 1758 E-mail: <a href="mailto:ben.cole@covidien.com">ben.cole@covidien.com</a></p>

## Device

The recall applies to the following 80 lot numbers:

8294199	8301112	8301113	8315189	8315190	8319262	8319263	8322181	8322182	8326251
8326252	8326253	8326254	8329072	8329073	8330001	8333183	8350018	8350019	8354221
8354224	8357021	8357022	8361153	9005011	9005012	9012058	9012059	9026042	9026043
9033128	9033129	9040067	9040068	9047127	9047128	9054110	9054111	9061066	9061067
9065209	9068061	9068062	9072281	9075059	9075060	9079160	9082376	9082377	9086312
9089126	9089127	9103038	9103039	9110481	9110482	9117039	9117040	9124134	9124135
9131188	9131189	9138084	9138085	9138226	9145088	9145089	9152238	9152239	9159128
9159129	9170191	9170192	9170197	9176471	9176477	9184145	9191233	9191234	9204128

## Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)
- NHS boards and trusts in Wales (Chief Executives)
- Primary care trusts in England (Chief Executives)

### Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

#### Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- A&E departments
- All wards
- Ambulance staff
- Anaesthetic nursing staff
- Anaesthetists
- Day surgery units
- EBME departments
- Equipment stores
- High dependency units
- Intensive care units
- Maternity units
- Medical physics departments
- Midwifery departments
- Operating department practitioners
- Paediatric intensive care units
- Paediatric outpatients
- Paediatric wards
- Paramedics
- Resuscitation officers and trainers
- Risk managers
- Special care baby units
- Theatres

#### Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres

#### Primary care trusts to:

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

- Resuscitation officers

## Contacts

### Manufacturer

Mr B Cole  
Covidien

Tel: 07710 597 649

Fax: 0203 027 1758

E-mail: [ben.cole@covidien.com](mailto:ben.cole@covidien.com)

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/026** or **2009/008/025/081/024**.

### Technical aspects

Mr J Lefever or Dr C Blake  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3262/3219

Fax: 020 7084 3209

E-mail: [jim.lefever@mhra.gsi.gov.uk](mailto:jim.lefever@mhra.gsi.gov.uk)  
[catriona.blake@mhra.gsi.gov.uk](mailto:catriona.blake@mhra.gsi.gov.uk)

### Clinical aspects

Mr J Plumb  
Medicines & Healthcare products Regulatory Agency  
Market Towers  
1 Nine Elms Lane  
London SW8 5NQ

Tel: 020 7084 3128

Fax: 020 7084 3111

E-mail: [jonathan.plumb@mhra.gsi.gov.uk](mailto:jonathan.plumb@mhra.gsi.gov.uk)

## How to report adverse incidents

Please report via our website <http://www.mhra.gov.uk>

Further information about **CAS** can be found at <https://www.cas.dh.gov.uk/Home.aspx>

## Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

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

Northern Ireland Adverse Incident Centre

Health Estates Investment Group

Room 17

Annex 6

Castle Buildings

Stormont Estate

Dundonald BT4 3SQ

Tel: 02890 523 704

Fax: 02890 523 900

E-mail: [NIAIC@dhsspsni.gov.uk](mailto:NIAIC@dhsspsni.gov.uk)

<http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

### How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website <http://www.dhsspsni.gov.uk/niaic>

Further information about **SABS** can be found at <http://sabs.dhsspsni.gov.uk/>

## Scotland

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

Incident Reporting and Investigation Centre

Health Facilities Scotland

NHS National Services Scotland

Gyle Square

1 South Gyle Crescent

Edinburgh EH12 9EB

Tel: 0131 275 7575

Fax: 0131 314 0722

E-mail: [nss.irc@nhs.net](mailto:nss.irc@nhs.net)

<http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-irc/>

## Wales

Enquiries in Wales should be addressed to:

Dr Sara Hayes

Senior Medical Officer

Medical Device Alerts

Welsh Assembly Government

Cathays Park

Cardiff CF10 3NQ

Tel: 029 2082 3922

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