# Medical Device Alert

**Immediate action**

Ref: MDA/2010/020 Issued: 10 March 2010 at 11:00

## Device

Hansen type coloured connectors on dialysis fluid lines used on Dialysis and Haemodiafiltration machines.
All manufacturers.

## Problem

Potential for the red and blue Hansen type dialysis fluid line connectors to be incorrectly configured (interchanged) resulting in a significantly less efficient dialysis.

## Action by

Renal units, renal technologists and renal unit nursing staff.

## CAS deadlines

Action underway: 17 March 2010
Action complete: 24 March 2010

## Action

Renal technologists should:

- not rely solely on the colour of the Hansen type connectors to ensure that dialysis fluid flows in the opposite direction to the blood.
- check local unit policy regarding the colour configuration of dialysis fluid lines/Hansen type connectors to ensure that all machines are configured correctly and consistently within your unit.
- set up systems to ensure that the same checks are undertaken on all machines used in the home care setting, and provide advice to home users on how to do this.

# Problem

The MHRA is aware that the colour coding of the dialysis fluid line connectors of dialysis machines can be in either of the two configurations in the table below. The configuration will depend on manufacturer and local practice in renal units. Therefore, the coloured Hansen type connectors cannot be relied on to indicate the direction of the fluid flow through the dialyser.

| | Configuration 1 connector colour | Configuration 2 connector colour |
|---|---|---|
| Dialysis fluid **supply** to the dialyser | Blue | Red |
| Dialysis fluid **return** to the dialyser | Red | Blue |

There have been occurrences where machines in a unit (or a patient's home) were set up with the red and blue Hansen type connectors transposed. This led to inefficient dialysis being performed until the discrepancy was discovered.

A system that uses a dialysis adequacy monitor will show an incorrect clearance value if the machine has not been set up with the dialysis fluid and blood flowing in opposite directions.

**Note: the failsafe way to identify the dialysis fluid lines/correct configuration is to note that the dialysis fluid supply line is always connected to the venous side of the dialyser.**

# Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC)
- 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:

- Adult intensive care units
- EBME departments
- Haemodialysis nurses
- Haemodialysis units
- Health and safety managers
- In-house maintenance staff
- Medical directors
- Nursing executive directors
- Paediatric intensive care units
- Renal medicine, directors of
- Renal Technicians
- Renal Units
- Special care baby units
- Staff supporting patients receiving haemodialysis at home

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

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent dialysis centres

### Primary care trusts to:

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

- District nurses

## England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/020 or 2010/001/011/081/013**

**Technical aspects**
Grace Walker or Roopa Prabhakar
Medicines & Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
London SW8 5NQ

Tel: 020 7084 3397/3293

Fax: 020 7084 3209

E-mail: grace.walker@mhra.gsi.gov.uk
roopa.prabhakar@mhra.gsi.gov.uk

**Clinical aspects**
Jonathan 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

### 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 (NIAIC)
Health Estates Investment Group
Room 17, Annex 6
Castle Buildings
Stormont Estate
Dundonald
Belfast BT4 3SQ

Tel : 02890 523 704
Fax: 02890 523 900

E-mail: 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.iric@nhs.net

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

## 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