

**AN (NI) 2001/07**

**DATE: 26 October 2001**

**For Attention and Action by:  
Chief Executive of each HSS Trust  
General Manager/Chief Executive of each HSS Board  
Chief Executive of each Agency**



**HEALTH ESTATES  
ESTATE POLICY**

**NORTHERN  
IRELAND  
ADVERSE  
INCIDENT  
CENTRE**

**TITLE:**

**Recall of Baxter A and AF Series Dialysers**

**MANUFACTURER/SUPPLIER**

Baxter Healthcare Ltd

**PROBLEM**

Baxter Healthcare Ltd have initiated a precautionary global recall of A and AF series dialysers pending the outcome of investigations of adverse incidents.

**DISTRIBUTION**

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Medical Directors
- Executive Directors
- Nurse Directors
- Medical, Nursing Staff in Hospital and Community Settings
- Dialysis Units
- Intensive Care Units
- Renal Physicians
- Renal Technicians
- Home Haemodialysis Patients
- Registration Inspection Units
- General Medical Practitioners
- Practice Nurses
- Private Hospitals and Clinics

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

**ACTION**

All providers of haemodialysis treatment should be made aware that Baxter are recalling all A and AF series dialysers. Baxter issued the Recall Notice on 18 October 2001 shown in Appendix 1.

All clinical areas should be checked to ensure that none of the implicated dialysers are available for use. Trusts should also inform home haemodialysis patients of the recall. If any are found, they should be quarantined and returned to Baxter.

**ADVICE**

**NOTICE**

## BACKGROUND

Baxter Healthcare A and AF series dialysers cover models designated:

A15, A18, A22 (237015, 237018, 237022)  
AF150, AF180, AF220 (238015, 238018, 238022)

All lots of the above product codes should be withdrawn.

Unexpected deaths have occurred with patients receiving haemodialysis treatment involving Baxter A and AF series dialysers. The deaths are reported to have occurred in Spain, Croatia and the USA.

Investigations by the relevant authorities are ongoing and so far, no casual link has been established between the dialysers and the deaths. As a precaution, Baxter Healthcare has decided to initiate a global recall of the implicated dialysers and has issued the Recall Notice shown in Appendix 1.

NIAIC have been informed that there are no A and AF dialysers in service in Northern Ireland. However, because they have been supplied in the UK in the past, users are advised to check existing stocks of dialysers to ensure that none are held. If any A and AF dialysers are found, they should be removed from clinical areas and returned to Baxter Healthcare.

## ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Ms Pat Dargan  
Regulatory QA (d) Associate  
Baxter Healthcare Ltd  
Caxton Way  
Thetford  
Norfolk  
IP24 3SE  
Tel: 01842 767 000  
Fax: 01842 767 099

Enquires to the NIAIC should quote the reference number AN (NI) 2001/07 and be addressed to:

Northern Ireland Adverse Incident Centre (NIAIC)  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast BT16 1US  
Marked for the attention of Mr Brian Godfrey

Tel: 02890 523714  
Fax: 02890 523900  
Email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

Brian Godfrey  
NIAIC 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 Safety Notice SN (NI) 2000/NIAIC. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety  
Áisíneacht Feidhmeannach don Roinn Sláinte. Serbhíst Sóisialta agus Sábháilteacht Phoiblí*



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