IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

Haemodialysis Equipment
IMB Safety Notice: SN2004(07)

MANUFACTURER/SUPPLIER

Various

TARGET GROUPS

Haemodialysis Unit Managers
Haemodialysis Nurses
Engineering Departments
Risk Managers

ISSUE

Blood contamination of the pressure monitoring lines of haemodialysis equipment

BACKGROUND

The Irish Medicines Board has received a vigilance report relating to blood contamination of the pressure monitoring lines of a haemodialysis unit.

The investigation has indicated that contamination may have occurred during a haemodialysis treatment where the pressure and the resulting blood levels in the blood reservoir exceeded the normal level. This led to the blood rising through the transducer protector into the internal tubing of the device.

The exact time when the contamination occurred is not known as it was discovered during an inspection of the device.

Following such events where the blood levels rises to such a level that it comes in contact with the transducer protector, the device should be removed from service. The engineer responsible for the device should be contacted and ask to conduct a contamination assessment or disinfection of the device before it is used on another patient.

In cases where contamination has occurred, the risk of blood in the

SAFETY NOTICE

internal pressure monitoring lines of the device coming in contact with the subsequent patient's blood is minimal. Nevertheless, it is good practice to ensure that the internal pressure monitoring lines are clean at all times.

ACTION OR RECOMMENDATIONS

- Ensure that all appropriate staff is advised of this notice.
- Arrange for a qualified person to inspect all haemodialysis devices in your service to ensure that there is no evidence contamination. Ensure that the inspection includes an examination of the pressure tubing sets and pressure sensing ports.
- If contamination has occurred, ensure that the device(s) is decontaminated before further use.
- Ensure that regular inspections are carried our on all devices.
- Ensure that staff take the following action following any treatments that they **suspect** may have resulted in contamination to the inner lines (e.g. treatments during which the blood levels rise to a significant level in the blood reservoir and where the transducer protector is stained):
  - Remove the device from service
  - Arrange for a qualified person to inspect the device
  - Arrange for the device to be decontaminated (if required)

ENQUIRIES

All adverse incidents relating to a medical device should be reported to the:

Medical Devices Department
Irish Medicines Board
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6767836
Email: medicaldevices@imb.ie
Website: www.imb.ie

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