

MEDICAL DEVICE
SAFETY NOTICE

**SC7000 & SC9000 Patient
Monitors**
IMB Safety Notice: SN2003(03)

MANUFACTURER/SUPPLIER

Siemens Medical

TARGET GROUPS

Clinical Engineering Departments
Medical Physics Departments
Equipment Managers
Medical, Nursing and Care Staff
Risk Managers
Lifting and Handling Trainers

ISSUE

Failure of the handle on a patient monitor.

BACKGROUND

When a monitor was being removed from over a patient's bed (in the USA) the handle broke resulting in the monitor hitting the patient's head. The impact resulted in serious head injuries and death.

The manufacturer of the device has implemented a corrective action, advising all users of the product of the potential problem and replacing the handles on those devices manufactured before August 2000.

Precautions should be taken when lifting all equipment to ensure that there is not risk to either staff or patient.

ACTION OR RECOMMENDATIONS

- Determine if you have these devices in use in your centre.
- Ensure that you have received the Advisory Notice that was circulated by the manufacturer.

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- Ensure the manufacturer replaces the handles on the device.
- **Ensure that all staff is advised of the potential problem with handling of heavy equipment.**
- **Ensure that local procedures emphasise the importance of care when lifting heavy equipment, particularly indicating not to lift heavy items over patients.**

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: 00 353 1 6764971
Fax: 00 353 1 6767836
Email: medicaldevices@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Gerard O'Brien
Siemens Limited
8 Raglan Road
Dublin 4

Telephone: 00 353 1 2162000
Fax: 00 353 1 2162399

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