

Notice Information: Medical Devices - Warning 26 February 2003

Part 1. Product Information

- a) Title: SC7000 & SC9000 Patient Monitors
- b) Product Name/Type: SC7000 & SC9000 Patient Monitors
- c) Reference: SN2003(03)
- d) Manufacturer/Supplier: Siemens Medical

Part 2. Target Audience

- a) Target Audience: Clinical Engineering Departments; Medical Physics Departments; Equipment Managers; Medical, Nursing and Care Staff; Risk Managers; Lifting and Handling Trainers

Part 3. Problem/Issue

- a) Problem/Issue: Failure of the handle on a patient monitor.

Part 4. Background Information

- a) Background Information: 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.

Part 5. Action to be taken

a) Action to be taken:

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. 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.

Part 6. Enquiries

a) All enquiries should be made to:

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: vigilance@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: +353-1-2162000 Fax: +353-1-2162399
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Part 7. Keywords

a) Keywords:

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