

SAFETY ACTION NOTICE

By arrangement with the Scottish Executive Health Department



MANAGEMENT OF MEDICAL DEVICES, EQUIPMENT AND ACCESSORIES ON LOAN

SAN(SC)02/19

19 JUN 2002

Medical Devices

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SUMMARY

Medical devices, equipment and accessories on loan may not be receiving appropriate maintenance and service. Guidance is provided on responsibilities and local management systems.

BACKGROUND

1. An incident occurred in which a pacing system analyser (PSA) on loan ceased to function during temporary pacing. This caused an hypoxic episode which required patient resuscitation. The cause of the event was identified as damaged battery contacts, which resulted in power supply disconnection.
2. Investigation established that the responsibilities for checking equipment on loan were unclear and that the recommended annual manufacturer's check had not taken place within the previous 5 years. The device was on permanent loan from a manufacturer and the incident could have been prevented if the equipment had been checked and serviced regularly.
3. Other examples of equipment that may be on loan are programmers used with active implantable devices (pacemakers, defibrillators, neurostimulators etc), biopsy guns, ultrasound scanners, X-ray film processors, computed radiography (CR) equipment, syringe drivers, ablation equipment, some surgical instruments and specialist beds. Equipment may be acquired on the basis of loan, rental or trial. It may be provided free of charge, for example, when consumables or drugs are purchased. The equipment may be provided by commercial companies such as manufacturers/suppliers or from another healthcare organisation.
4. Maintenance issues relating to loaned equipment on loan have previously been addressed in Safety Action Notice SAN(SC)00/30 *Handling of Surgical Instruments on Loan from Another Organisation*. In addition, the Medical Devices Agency (MDA) have issued relevant Device Bulletins: DB 9801 *Medical Device and Equipment Management for hospital and Community-based organisations* and DB 2000(02) *Medical Devices and Equipment Management: Repair and Maintenance Provision*.

ACTION

5. This notice should be brought to the attention of all appropriate managers, staff and users.
6. Management systems and procedures should exist for equipment on loan, including:

<i>Suggested Distribution</i>	All wards, patient areas and departments		Accident & Emergency
Cardiology	Care Home Services	Coronary Care Units	Dental
Device Managers	District Nursing	Estates/Facilities	General Dental Practitioners
General Medical Practitioners	Gynaecology	Health Centres	Hospices
Infection Control Staff	Intensive Therapy Units	Managers (all specialties)	Maternity
Medical Physics	Nursing	Operating Departments	Orthopaedics
Out-Patients (all specialties)	Paediatrics	Pharmacy	Physiotherapy
Radiology / Imaging	Risk Management	Safety Officers	Sterile Supplies Departments
Supplies	Sterilising & Disinfection Units		



SCOTTISH HEALTHCARE SUPPLIES

Gyle Square Edinburgh EH12 9EB

A Division of the National Service Scotland for NHSScotland

This notice was obtained from the INCIDENT REPORTING & INVESTIGATION CENTRE (public) website

http://www.nhsscotland.com/shs/hazards_safety/adverse_p.html

FAX: 0131 314 0722

E-MAIL: iric@shs.csa.scot.nhs.uk

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- a) Liaison with purchasing departments when the acquisition of equipment on loan is anticipated, including the signing of indemnity agreements and definition of the Trust/Board's liability in the event of loss or damage to the device.
 - b) Registration detailing ownership, service history, current location, service responsibility and instructions for use.
 - c) Initial acceptance checks prior to putting into service, in accordance with manufacturers' instructions.
 - d) Issue of instructions for use (and updates) for end users.
 - e) Periodic checks for functionality, safety and repair in accordance with manufacturers' instructions, whether by the hospital, owner/manufacture or a third party.
 - f) Clear definition of responsibilities for the maintenance, repair and regular safety checks including identifying the person(s) responsible for initiating the testing of the equipment (e.g. user) and those responsible for performing the testing (e.g. Medical Physics, supplier).
 - g) Adequate instructions regarding decontamination/sterilisation of re-usable equipment and availability of appropriate equipment/facilities to carry out the process by the hospital (see Safety Action Notice SAN(SC)00/30).
 - h) Identification and withdrawal or return of unwanted or obsolete equipment on loan.
7. Equipment management departments such as Medical Physics should be advised/informed whenever equipment is received on loan, trial, free of charge, etc.
8. Signed indemnity agreements should be obtained for equipment on loan, rent etc. before being put into service. The supplier should indemnify and hold each NHS body harmless against all liability in respect of personal injury or death of any person, except liability resulting from the negligence or fault of any NHS employee or agent. Where this is not written in the terms and conditions of a formal contract (e.g. rental or purchase) an Indemnity Form should be completed by the supplier.
9. Scottish Healthcare Supplies has a portfolio of Master Indemnity Agreements with various companies. (See Guidance Notes in the Annexe on page 3 for mechanisms for use of this Agreement.) Further information regarding Master Indemnity Agreements can be obtained from the Scottish Healthcare Supplies website at <http://www.show.scot.nhs.uk/shs/MIA/MIA.htm> or by contacting:

Name: John Slater
Tel: 0131 551 8796
Fax: 0131 559 3927
E-mail: john.slater@shs.csa.scot.nhs.uk



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ANNEXE

MASTER INDEMNITY AGREEMENT - GUIDANCE NOTES

The Master Indemnity Agreement (MIA) is intended as an umbrella agreement to encompass the requirements of NHS Bodies in respect of equipment and other goods supplied:

- i. On Loan for Trial and Testing
- ii. On Loan (Not for Trial and Testing)
- iii. Free Issues

Combined into a single document, the MIA is intended for signature by suppliers who deal regularly with the NHS Scotland and who do not wish to have to sign, at a senior level, separate indemnity forms every time they provide 'free' equipment.

Provision has been made to cover use by university employees at teaching hospitals. However the MIA will not cover equipment supplied to the university directly (i.e. delivery note signed by University staff). The indemnity will not cover use of equipment by Trust employees supplied to the University.

Mechanisms for use:

1. A request will be made by Scottish Healthcare Supplies (SHS) to companies requiring an MIA, to sign the Indemnity Agreement at board level and provide proof of insurance cover.
2. Each MIA will be assigned a supplier specific reference number, which will be advised to the supplier.
3. A register will be compiled, by SHS, of suppliers possessing an MIA including their reference number. Copies of the register will be distributed to participating NHS Bodies and up-dated on a regular basis as new Agreements are concluded.
4. When goods are provided on loan/free issue, it should be ascertained by staff whether the Supplier has an MIA either by:-
 - i. reference to the register, or
 - ii. telephoning a nominated point of contact within SHS, or
 - iii. requesting the supplier to quote his MIA reference number.
5. Suppliers with an MIA need only sign a simple delivery note when providing goods. The delivery note to be countersigned by the appropriate person at the Trust and a copy retained as a record.
6. Suppliers without an MIA should be requested by staff to sign any relevant local Indemnity Agreement prior to provision of equipment/goods and/or directed to Scottish Healthcare Supplies for inclusion, if appropriate, in the central register.



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