IRISH MEDICINES BOARD

MEDICAL DEVICE
SAFETY NOTICE

Equipment Management

Guidance for the Maintenance and Timely Replacement of Medical Equipment

IMB Safety Notice: SN2003(08)

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MANUFACTURER / SUPPLIER

Various

TARGET GROUPS

This notice has been written as a guide for those people who are responsible for purchasing, installation, commissioning, schedule maintenance and repair of medical devices in hospitals. It is targeted particularly at:

Chief Executive Officers
Clinical Engineering Personnel
Medical Physics Personnel
Purchasing Managers
Risk Managers

ISSUE

Continued use of equipment that has surpassed its recommended life span may result in undesirable effects e.g. adverse incidents or near incidents.

BACKGROUND

The factors that have the greatest impact on device safety are **training** and **maintenance**. Training needs to be timely and effective and include procedures for day-to-day routine maintenance of devices by the user. Planned preventative maintenance carried out following manufacturers guidance is a key element in helping ensure devices are safe and reliable.

Given today's economic and financial climate, equipment will more than likely have an extended operational life span as funds may not be

available to replace the device as originally planned. Due to the extended lifespan it is all the more important to ensure that that there is regular maintenance of hospital medical device equipment. If a proper maintenance programme is not in place, then the use of poorly maintained equipment will greatly increase the risk of adverse incidents or near incidents e.g. loss of patient records, disruptions to patient treatment, delays to patient treatment, increased or multiple treatments – all potentially impacting on the general health of the patient.

ACTION OR RECOMMENDATIONS

The user organisation should take all reasonable steps to ensure that medical devices are repaired and maintained appropriately. The liability for the repair and maintenance of the device or item of equipment will vary depending on the person who effects the service and how the repair or maintenance is undertaken.

If a device malfunctions following repair and / or maintenance and leads to the death or serious injury of a patient or user there is a greater likelihood of the user organisation and the service provider being held liable for injuries caused if the device was not repaired / maintained in accordance with the manufacturer's instructions.

Those healthcare managers with responsibility for medical equipment need, therefore, to review and take decisions about the appropriate strategy for repair and planned preventative maintenance. This may involve the use of an in-house engineering department, a third party servicing organisation or manufacturers servicing facilities. In any case, the equipment management process must be overseen and verified as appropriate by healthcare managers.

Any organisation carrying out the servicing of medical device equipment must have properly trained staff, the correct manuals and tools, access to spare parts approved by the manufacturer and an adequate quality control system.

Professional users and end users are responsible for day-to-day **routine maintenance** – regular cleaning, preparation for use and checking of devices in their use.

Planned preventative maintenance should involve following the manufacturers guidance both in those procedures recommended and in the qualifications / training of the personnel /staff carrying out the work.

Each medical device should have the expected economic life stated on it or on its accompanying documentation. For equipment that is used beyond this economical life, an annual risk assessment should be conducted to allow for its continued use. In some instances it will be very clear that the device should be replaced, for example:

- Worn out beyond economic repair
- Damaged beyond economic repair
- Unreliable

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In other instances it may not be so clear, for example:

- Spare parts no longer available
- More cost effective and clinically effective devices have become available

This risk assessment should be documented and should include an assessment of the use of alternative spare parts if OEM (Original Equipment Manufacturers) parts are not available.

ROUTINE MAINTENANCE AND DEVICE MANAGEMENT FOR PROFESSIONAL USERS

When	Action
Device Malfunction	▪ Obtain technical advice ▪ Withdraw from service if necessary ▪ Note problems that occurred and the actions taken
Before Initial Use	▪ Conduct an acceptance test ▪ Check leads, probes, ancillary pipework are in good order and properly installed ▪ Check reassembly if the device has been dismantled for cleaning or decontamination ▪ Do relevant functional and calibration checks, noting results ▪ Check settings and controls ▪ Check storage requirement ▪ Document all the above information on a device inventory record
At Specified Intervals	▪ Inspect, check known problem areas ▪ Note results ▪ Remove from service if tests fail

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After use and before releasing for servicing	▪ Clean ▪ Decontaminate ▪ Safely discard single use devices or other accessories, which cannot be reused. ▪ Ensure that devices designed for single use are not reused
When sending a device for repair	▪ Include all probes, leads and any other necessary parts that are needed for the operation of the device ▪ Ensure proper decontamination before sending the device for repair ▪ Enclose a full account of any possible problems
When a device has undergone maintenance	In addition to the standard “before use” checks: ▪ Check the output levels where relevant ▪ Check the appropriate programs have been selected
When a serious adverse incident has occurred	First take the necessary steps for the well-being of the patient and /or staff then: ▪ Avoid altering the setting, switching off the equipment, or removing patient leads, infusion sets, ventilator tubing ▪ Leave any fluid in the device ▪ Note the details of all medical equipment connected to the patient, e.g. device type, make, model and serial number ▪ Retain packaging for details of consumables ▪ Note all displays that are displaying information ▪ Note settings of controls and limits for alarms ▪ Record the contents of the computer memory log for devices which have them ▪ Contact the manufacturer / IMB before dismantling the equipment ▪ All adverse incident must be reported to the manufacturer and the IMB in line with IMB guidance

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The above list does not purport to be a definitive list but should serve as guidance.

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

ANNEX I: DEFINITIONS

Professional User:	Qualified user using the device as a tool.
End User:	The person using the device as defined by the manufacturer. The end user may be either a professional user or a member of the public depending on the device.
Routine Maintenance:	Inspection and device-care operations carried out by the end user and professional users

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ANNEX II: Medical Devices Equipment Management

All organisations involved in the use and management medical equipment must ensure that:

- The repair and maintenance of a device is considered at the purchase stage.
- All the information necessary to undertake a repair or to maintain a device safely is made available.
- They have a system in place to bring any changes to repair and maintenance methods to the attention of the repairer.
- The repairers are appropriately trained and up-to-date with their knowledge of repair and maintenance methods.
- The instructions used should be as specified by the manufacturer.
- The use of alternative instructions, methods and parts should be demonstrated to be equivalent and take into account all risks to patients and users and fully documented.
- All replacement spare parts and critical components used in a repair or maintenance are traceable.
- All associated repair and test equipment is suitable for its purpose and is appropriately maintained and calibrated.
- They have a system in place to manage device repair and maintenance activities.
- The device itself remains identifiable.
- All records relating to the repair and maintenance of any device are accurate, detailed and readily accessible.
- They undertake regular audit and review and maintenance process, taking any action necessary.
- The service provider report conditions that have the potential to cause a device failure or otherwise compromise the clinical outcome to the manufacturer and other appropriate bodies.
- They report device adverse incidents to the IMB.
- They always have a contract with the repairer defining responsibilities for repair and maintenance.
- They are aware of their legal responsibilities in respect of device repair and maintenance.
- All devices intended for repair or maintenance are safe to handle (equipment decontamination).

The above listing is based on some of the information provided in the IMB Medical Devices Newsletter vol. 1 no. 3 and the MDA device Bulletin DB2000(02) Medical Devices Equipment Management: Repair and Maintenance Provision.

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