**Aneurin Bevan University Health Board**

# Management of Medical Equipment and Devices Policy

*N.B. Staff should be discouraged from printing this document. This is to avoid the risk of out of date printed versions of the document. The Intranet should be referred to for the current version of the document.*

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# 1. Executive Summary

Medical devices and equipment represent a substantial Health Board asset, and have a significant impact on patient care. It is essential that all medical devices and equipment are stored and maintained in a safe and reliable manner, are suitable for the intended purpose and that staff are appropriately trained in their use. Inadequate decontamination, faulty equipment, inappropriate use or poorly trained staff can have major repercussions for patient/client safety.

This Policy ensures the Health Board has a systematic and planned process in place to:

- Promote the safe and effective use of Medical Equipment and Devices.
- Identify the risks associated with the prescribing, purchasing, commissioning, implementation, training, operating, storage, maintenance, servicing, disposal and documentation of medical devices and reduce them as far as is reasonably practicable.
- Comply with the Medicines and Healthcare products Regulatory Agency, Managing Medical Devices, Guidance for healthcare and social service organisations, April 2015.
- Comply with Health and Care Standards 2.9 Medical Devices, Equipment and Diagnostic Systems

## 1.1 Scope of the policy

This Policy applies to all Health Board Managers, clinically trained, technically trained, hospital or community staff who are involved in the prescription, purchase, use, storage, maintenance and supervision of medical devices in the hospital and community setting.

**Addendum**

Student nurses (*Aligned to ABUHB partner universities*) **in Part 2 and Part 3** of their nurse education programme may participate in this procedure under the direct supervision of a registered Health Care Professional/Health Board Employee who is competent in this aspect of care and in the supervisory role, with the consent of the patient /carer/service user.

***Please note***
***Direct supervision (Alongside the student):*** *the student is observed by a competent health care professional who takes accountability for the student's actions throughout the procedure.*

The policy applies to all medical devices and equipment used within the Health Board. This includes equipment purchased through capital or revenue funds, lease, operating lease, hire, consumable deals, free gifts, private funding, donations by voluntary organisations, and public donations.
The term Medical Devices and Equipment covers a broad range of products including an instrument, apparatus, appliance, material or healthcare product.

A medical device is defined as 'any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means'

There are a range of products used within the Health Board that are regulated as medical devices rather than licensed medicinal products. These are products where the principal intended action is typically fulfilled by physical means rather than a pharmacological, metabolic or immunological action. Examples include artificial tears, non-medicated dermatological products, nebulised saline, and artificial saliva. Whilst such products are medical devices they will not form part of this policy and will be considered under existing Medicines policies.

Medical Devices and Equipment can be defined as instrument, apparatus, appliance, material or healthcare product*, (excluding drugs)* used for, or by a patient or service user. For examples of Medical Devices and Equipment see Appendix 1.

## 2 Aims

The policy covers the management of medical equipment and devices and their associated systems.

It refers to all medical equipment and devices used for the care and treatment of patients throughout Aneurin Bevan University Health Board. The policy will ensure that all medical equipment and devices are:

- Suitable for the intended purpose
- Properly understood by the trained, professional and end users
- Maintained and stored in a safe and reliable condition
- Appropriately decontaminated
- Offers compatibility with current clinical practice
- Operates in a safe and serviceable condition
- Complies with Safety and Quality standards
- Identifies revenue consequences for budgetary purposes
- Where necessary is included on an asset register / inventory for planned equipment maintenance and replacement

## 3 Policy Statement

This policy reflects relevant legislation; it is designed to promote best practice throughout the Health Board and to assist anyone who has responsibility for the management of medical devices. This will be achieved by:

- A partnership approach with all stakeholders.
- Compliance with relevant legislation.
- Clear lines of accountability between senior management, professional, technical, clinical staff and the Board.
- Good communication between these elements and free access of information to all.
- Professional users and end users aware of their responsibilities.
- The safe effective use of Medical Equipment by trained, competent professional users, technical supervisors, end users, and staff.
- A well organised planned preventive maintenance programme.
- Accurate and consistent documentation of devices in use, to validate service history and enable the Health Board to track a device in the event of recall, due to defects or patient contamination such as CJD.
- Opportunities for continual improvement identified by annual audit.

## 4 Responsibilities

It is important that all staff, patients and carers understand their roles and responsibilities in relation to the management of medical devices within the Health Board.

### 4.1 Chief Executive

The Chief Executive through the Board is ultimately accountable for all premises, appointment of personnel, and the allocation of resources in relation to medical devices.

### 4.2 Medical Director

The Medical Director has been delegated Board responsibility for the overall management of medical equipment within the Health Board. The post holder reports to the Chief Executive and will ensure that an appropriate policy is developed, updated and implemented effectively.

### 4.3 Divisional Directors, Divisional Nurses, Lead Clinical Directors, and Senior Managers

It is the responsibility of Divisional Directors, Divisional Nurses, Lead Clinical Directors and Senior Managers to ensure that the appropriate systems are in place to identify needs analysis and business planning according to local processes.
Divisional Directors, Divisional Nurses, Lead Clinical Directors and Senior Managers are accountable to the Chief Executive for ensuring all staff under their control act according to the Management of Medical Equipment and Devices Policy.

They will ensure that:

- Staff comply with the implementation of this policy.
- That manufacturer's directions for use are available to staff.
- That staff have the appropriate knowledge and skills to use any medical devices required. Staff training is updated and documented (each Directorate should have a nominated person(s) responsible for co-ordinating and ensuring the updating of the training records for the directorate locally and/or via the ESR system).
- Risk assessments relating to medical devices are completed and incorporated into the Directorates/Departments risk register.
- Incidents involving medical devices and MHRA alerts are promptly and correctly reported, investigated and acted upon (Policy and procedure for the Management and Distribution of Alerts ABUHB/Corporate/0415).
- All designated Medical equipment should be detailed on the appropriate Directorate and/or Divisional asset register/ inventory and entered onto a planned replacement programme, where appropriate, (each Directorate must have a nominated person(s)

responsible for co-ordinating and updating the medical device inventory register and ensuring that records for the directorate are up to date).
- Ensuring the provision of maintenance and servicing of equipment for the Health Board.
- Lifecycle revenue costs have been identified and budgeted for.
- External devolved maintenance contracts for equipment within the Directorate are the responsibility of the Directorate and must be requisitioned and agreed through the Procurement department.
- Each Directorate participates in the audit of relevant Medical Equipment and ownership of the resulting action plans to maintain continual improvement.
  - All equipment is purchased according to Procurement Financial Control Procedure/6203 and other relevant financial procedures.
  - Justification for the need to purchase a medical device and Business objectives in relation to medical devices are determined and met.
  - Equipment replacements are to be prioritised by consultation between appropriate managers and clinical users using a pre-purchase questionnaire (see Procurement Financial Control Procedure).
  - If the purchase of medical devices is a development of the service the information in the pre-purchase questionnaire must be considered when formulating a business plan.

The detail of the plan will depend upon the proposed clinical procedure, complexity of the device and its cost. The following criteria will need to be taken into account:

- Case of need and risk assessment?
- Fitness for purpose?
- Do devices already exist within the unit, ward or department?
- Have Procurement, EBME, Risk Manager- Patient Safety and/or Decontamination Manager been consulted?
- Is the device a replacement or additional to existing equipment?
- Where the device is used across the Health Board does it appear on the list of Health Board's approved devices e.g. Infusion devices?
- Does the device meet the safety requirements for its type?
- Technological advances may mean more recently designed models are software driven. Have the IT department been consulted about compatibility with Health Board main frame computer?
- Have storage Facilities been assessed?

- Devices will be entered onto the departmental asset register.
- Planned preventative maintenance put in place.
- Devices, which are complicated or require commissioning, must be installed in collaboration with works and estates, the supplier and the staff.
- The Health Board meets current statutory requirements on ionisation and radiation equipment. The Health Board radiation committee will provide expert advice.

- Where new equipment is to be purchased an implementation plan is developed that ensures that the equipment will be used, stored and maintained appropriately and that a minimum of 70% of staff are trained prior to the equipment being put into use (see section 6 Training).

### 4.4 Risk Manager- Patient Safety

Risk Manager- Patient Safety is accountable to the Assistant Director Quality and Patient Safety and is responsible for:

- Keeping the Health Board up to date with Medical Device Legislation, regulations, guidance and best practice.
- Ensuring incidents involving medical devices are promptly and correctly reported, investigated and acted upon.
- Ensuring that MHRA Alerts and Internal alerts are disseminated across the Health Board targeting specific staff if necessary.
- Ensuring that nominated staff take responsibility for key devices and equipment.
- Providing professional leadership and advice on best practice, to all areas and departments of the Health Board.
- Leading on relevant projects involving the implementation of new medical devices for use across the Health Board e.g. Infusion devices.
- Working in close liaison with theatre staff, ward staff, infection control staff, health and safety managers, sterile services manager, directorate managers and divisional managers to progressively reduce patient risk.
- Reviewing and updating the Management of Medical Devices and Equipment Policy in line with current legislation guidance and best practice.

### 4.5 Decontamination Manager

The Decontamination Manager will be responsible for:

- Providing professional leadership across the Health Board in the identification and management of risk issues relating to the decontamination of reusable medical devices.
- Developing and supporting the implementation of a robust strategy for the effective decontamination of reusable medical devices and its ongoing review.
- Ensuring government initiatives in relation to decontamination of reusable medical devices are addressed within the strategy and brought to the attention of appropriate staff.
- Identify and address risk issues relating to the decontamination of reusable medical devices ensuring directorates have risk systems and processes in place.
- Working with key departments to ensure appropriate decontamination standards are maintained in the procurement of and decontamination of reusable medical devices.

### 4.6 Works and Estates / EBME Department

Works and Estates / EBME Department must be involved in the purchase and commissioning of Medical equipment such as Infusion devices, portable suction systems, washer disinfectors, gas regulators; flow meters, wall suction units and gas operated equipment along with any large fixed installations such as Theatre Operating Lights and wall mounted monitoring systems.

The Health Board acceptance procedure is mandatory and no re-usable medical device, whether bought, leased, loaned, gifted or on trial may be attached to a patient without having first been formally accepted as fit for use by the relevant Health Board technical staff. Where the ownership and management of the device remain with the supplier, such as enteral feeding pumps, the manufacturer's pre-dispatch tests combined with simple pre-use checks by those responsible for the care of the end user in the community (e.g. community nurse) should provide adequate safety assurance (MHRA Managing Medical Devices April 2015).

#### 4.6.1 Head of Estates, Maintenance & Operation

The Head of Estates, Maintenance & Operation in conjunction with the EBME Manager

**Is responsible for:**

- The Central Maintenance budget to which all in-house and external maintenance contracts associated with current medical equipment service is identified within existing budget managed by Works & Estates are charged. This budget is reviewed and amended annually through cost pressure proposals.
- Ensuring the provision of maintenance and servicing of equipment for the Health Board which falls within the Works & Estates remit.
- Monitoring the application and implementation of the policy by maintaining a computerised equipment management system for all medical equipment detailing
  acceptance testing and commissioning of all new equipment.
- Ensuring equipment is logged on to the departments inventory and Health Boards asset register.
- Identifying all items of capital value at the point of acceptance and passed to the Financial Asset Register system for capital charging purposes.
- Maintaining an equipment service history programme e.g. Insurance testing.
- Ensuring technical staff are appropriately trained and competent to work on medical equipment.
- Ensuring incidents involving medical devices and MHRA alerts are promptly and correctly reported, investigated and acted upon (Appendix 3).
- Ensuring staff performing technical maintenance on critical items of medical equipment (such as defibrillators, ventilators, infusion devices etc) receive formal training in the maintenance of that equipment.

### 4.6.2 The Electro Biomedical Engineering (EBME) Manager

Is responsible for:

- Registering all patient connected equipment onto the EBME Department computerised equipment management database giving each piece of equipment a unique equipment inventory number. This identifies its location, owner, purchasing details, service history, maintenance schedules, breakdown records, general equipment history and equipment contracted to external contractors.

- Maintaining and updating the data base information on a regular basis. The information on this database is available to managers and printouts can be obtained by contacting the EBME Manager.

- Equipment Trials. Patient connected device trials should be referred to the EBME manager by procurement. If the EBME Manager considers that there are significant areas of non-conformity with safety standards and the Health Board is not meeting its statutory requirements, he will advise the Procurement Manager and the user not to evaluate or purchase the equipment on safety grounds.

- Ensuring all trials carried out are on the suppliers' indemnity; a list of companies signed to the NHS Wales Master Indemnity List is available from the EBME Department and Procurement. If the supplier is not listed then they must complete an indemnity form before trials can continue.

- Registering Equipment onto the EBME Departments Loan Equipment register before trials are carried out to ensure it is traceable, is suitable for its intended purpose and that an electrical safety check is carried out.

### 4.7 Procurement

All selection and purchase of equipment must be via the Procurement Department following the Health Board's Procurement Policy, Standing orders and Standing Financial instructions taking account of all available guidelines in compliance with the user needs, compatibility with existing equipment and Medicines and Healthcare Products Regulatory Agency guidelines.

#### 4.7.1 Head of Procurement Services

The Head of Procurement Services is responsible for managing the procurement process and ensuring that:

- Equipment users play a major role in determining the generic specification and choice of Medical Equipment acquired is purchased in line with Procurement Policies and Health Board Standing Orders and Financial Instructions

- The cost of purchasing medical equipment should, in addition to the initial financial outlay, include the cost of ongoing associated consumables and maintenance to keep revenue costs to a minimum.

- Other options are considered in relation to purchasing, i.e. leasing, long term loans.

- Procurement policies and procedures are up to date with national tendering guidelines.

- All purchase requisitions and contracts raised through procurement are authorised by a designated signatory.

- Equipment acquired and used on the Health Board's behalf complies with recommended standards particularly those relating to safety are delivered to the appropriate department for testing, validation and commissioning.

- To adhere to all current legislation on Ionising Radiation in line with Department of Health (DOH), Welsh Good Practice Guidance and Health Board guidelines.

- Safeguards are in place to prevent unauthorised downloading, uploading or modification of data in PC controlled medical equipment/systems.

- A standardisation of common types of equipment is achieved in order to lessen the risk and possible confusion of operation and to facilitate ease of training and equipment availability.

- The Health Board has a single point of contact with suppliers for the purpose of organising Medical Equipment trials, ensuring adequate levels of indemnity are in place and discussing/negotiating costs.

- To co-ordinate indemnity forms.

## 4.8 Ward and Departmental Managers

Ward/Department Managers are responsible for ensuring:

- Identification of medical equipment and devices where user training is required.

- Staff are trained in use of medical devices, and the training documented both locally and via the ESR system.
- Medical Equipment is managed safely and effectively.
- Staff are aware of the processes for storage of and obtaining medical equipment stored centrally.
- Devices have a documented risk assessment.
- Report incidents involving medical devices and MHRA alerts promptly and correctly and are also investigated and acted upon where necessary.
- Take part in the audit of Medical Equipment and ownership of the relevant points in the resulting action plans to maintain continual improvement.
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- That all equipment owned by their ward/department is serviced and maintained on a regular basis.
- Bank and locum staff are supervised and trained appropriately when using medical devices.
- New Medical Devices are checked prior to installation and documentation of delivery is completed, including operators and technical manuals and checks for damage in transit and appropriate safety and calibration tests have been completed.
- Staff are aware of the procedure to be followed following an adverse incident involving a medical device.
- Medical Device alerts are responded to appropriately.
- That staff are competent to safely operate equipment borrowed from other areas.
- When equipment is loaned to other departments a record is maintained, so that the location of equipment is known. Records to include make, model, and serial number.

**No electrical equipment, whether purchased, loaned or leased, will be put into use until it has undergone the relevant testing and safety checks by Works and Estates. This is a Health and Safety legal requirement. This also applies to Electro Medical – Patient Connected devices which are tested by EBME.**

## 4.9 Staff Prescribing Medical Devices and Equipment

The prescription of equipment is the responsibility of the prescribing professionals and should only be undertaken by suitably qualified and experienced staff e.g. Doctors, Nurses, Physiotherapists & Occupational Therapists who will:

- Comply with relevant policies e.g. the Safe use of Infusion Devices.
- Document details in the patient's health record of the medical device prescribed to enable easy tracking e.g. date of insertion for implantable devices.

## 4.10 All Staff Using Medical Equipment

All staff are responsible and accountable for their practice. In addition, all staff have the following responsibility if using a medical device:

- Referring to manufacturers' directions for use before using devices.
- That, where indicated, they have received appropriate training in the use of the device and have documentary evidence available.
- Ensuring that they are competent to use an item of medical equipment before they attempt to use it.
- If there is any doubt on how to operate a piece of equipment, the individual concerned should consult their manager and report their training needs.
- Ensure that all medical equipment and devices are serviced and maintained so that they are fit for purpose.
- Bring to the attention of their line manager any concerns they have regarding the devices. This includes concerns around the

appropriateness of the device, maintenance or storage concerns or training issues.

- Report to their manager and document all failures, faults or breakdowns.
- Ensure that devices are stored appropriately, for example clean or sterile instruments.
- Ensure that accurate and consistent record keeping is undertaken including relevant tracking documentation for specific medical devices e.g.syringe drivers
- Ensure that all equipment is decontaminated following use.
- Completing the checklist for patients discharged from hospital with a Medical Device (Appendix 2).
- Incidents involving medical devices and MHRA alerts are promptly and correctly reported, investigated and acted upon.

### 4.11 Nurse Bank and Locum Agency

The Nurse Bank and Locum Agency are responsible for checking and documenting staff qualifications prior to employment.

### 4.12 Equipment Library/Store

The managers of the equipment libraries are responsible for ensuring:

- That all equipment owned by the Library/store is serviced and maintained on a regular basis.
- Accurate documentation of the whereabouts of equipment managed by the equipment library/store.
- Appropriate processes are in place for staff to obtain equipment when required and the procedure for return of equipment.

### 4.13 Back Care Advisors

The back care advisors will be responsible for:

- Co-ordinating training of staff when using medical equipment such as hoists for lifting, lowering and moving patients.

- Ensuring Manual handling training is provided and documented on ESR.

### 4.14 Manufacturers of medical equipment and devices

From June 2002, under the Medical Devices Regulations (2002/618) all medical devices placed on the market must conform to 'essential requirements' including safety – required by law and bear a CE marking as a sign of that conformity.

### 4.15 Gwent Wide Integrated Community Equipment Service (GWICES)

GWICES provides equipment for use in the Community for the residents of Blaenau Gwent, Caerphilly, Newport, Monmouthshire and Torfaen Boroughs. The GWICES service will be provided by the Approved Service Provider. The Approved Service Provider will take the responsibility for ensuring:

- Records of purchase, loan, decontamination and maintenance/repair are kept and up to date.
- The loan equipment maintenance schedule status is compatible with the loan.
- That the device has been fully tested to confirm full functionality and fitness for purpose.
- The Medical Device Regulations require that each device must be accompanied by the information to use it safely. Instructions for use should be included, wherever possible, in the packaging of every device.
- That the patients /carers know where to obtain help and advice.
- That the patients /carers have a point of contact for the Health Board for any queries, to return the device when it is no longer required or in emergencies.

### 4.16 **Infection Control** to provide advice on:

Decontamination of equipment.
Compatibility of intended purchase to Health Board decontamination systems.

## 5. Implementation of new equipment

- All selection and purchase of equipment must be via the Procurement Department following the Health Board's Procurement Policy, Standing orders and Standing Financial instructions taking account of all available guidelines in compliance with the user needs, compatibility with existing equipment and Medicines and Healthcare Products Regulatory Agency guidelines.

- All new electronic patient connected medical equipment purchases must in the first instance be delivered direct to the **EBME Department, Delivery Point Code: 321166** to ensure appropriate commissioning, assembling and acceptance testing prior to delivery to end users. Where it is inappropriate for EBME to take delivery of much larger items of medical equipment, it still needs to be informed, to enable on site commissioning checks to be carried out, as well as updating its Equipment Inventory.

- All new equipment must be registered on a Divisional, Directorate or Health Board wide inventory register indicating date of purchase, location and storage requirements, training and service and maintenance arrangements.

- An implementation plan must be developed that ensures that the equipment will be used, stored and maintained appropriately and that a minimum of 70% of staff are trained prior to the equipment being put into use. This includes the appropriate purchase, storage and management of any necessary consumables.

## 6. Training

### 6.1 Training, awareness and competence

All employees using medical devices must:

- Act in accordance with their professional code of conduct ensuring the safety of the patients, visitors and staff.

- Where necessary have documentary evidence of training and evidence of being assessed as competent on an ongoing basis.

- Be aware of their responsibilities and consequences of departure from operating procedures.

- Staff to undertake further updates and training as required ensuring that changes in practice and technology are incorporated into practice.

## 6.2 Training for new equipment

When new equipment is purchased an identified nominated lead must be responsible for ensuring that a minimum of 70% of users have been trained and assessed as competent prior to the device being available for use. The supplier must provide training to key clinical staff and be available to provide ongoing support to staff. This should be specified and agreed in the contract.

On-going training may need to be negotiated with the manufacturer which may incur a financial cost. A sustainable process must be in place for new staff and for updating purposes.

All staff are responsible for ensuring that they are appropriately trained and assessed as competent prior to using any new device. If there are any issues about training or competence the user must refrain from using the device and discuss further training and/or support with their line manager.

If the end user of the medical device is a patient or a patient's carer, record of training and assessing them as competent to use the medical device must be recorded in the patient's notes.

## 6.3 Instructions for the use of medical equipment

Manufacturers' instructions must accompany any piece of medical equipment.

Professional users and end users must have access to the manufacturers' instructions. The information in the instructions must be explained and expanded during training.

It may be necessary to consider adding to manufacturers' instructions.

In the event of any incident there should be documentary evidence that written and/or oral instructions were given.

# 7 Further Information

## 7.1 Gifts, Donations

Equipment, which is donated, or presented as a gift from whatever source, must still meet the requirements of this policy.
It must be purchased through the Health Boards Procurement process prior to being accepted by the ward or department.

This will ensure it meets current Health and Safety legislation and is logged on to the Departments inventory and Health Board's asset and risk register and to ensure that it is serviced/maintained to the manufacturer's specification.

## 7.2 Standardisation of equipment

In order to reduce and prevent risk associated with the use of medical devices the Health Board aims to standardise medical equipment where appropriate. Safety must always be an overriding consideration; this ensures that unless there are valid clinical and technical reasons, similar and up to date models of equipment are purchased from a single supplier in order to ensure:

- Ease of user training.
- Reduction in risk due to users being familiar with type of equipment.
- Availability of in-house expertise and ease of servicing.
- Cost benefits in terms of purchase of consumables e.g. IV giving sets.
- Cost reduction if equipment is to be placed on contract.
- Rapid exchange of equipment from a low usage area or equipment library in the event of a major failure.

There are several categories of equipment that it is of particular benefit to the Health Board to standardise Health Board wide due to the risk. Examples are:

- Infusion Devices

- Defibrillators
- Lasers
- Ventilators
- Anaesthetic Equipment
- Diathermy Equipment
- Home loans Equipment
- Consumables

This list is not exhaustive and there may be equipment used by specialist areas which still need to be standardised across the Health Board.

EBME should be consulted for advice prior to any medical equipment purchase to ensure standardisation is retained wherever possible. This is most relevant for all patient connected medical equipment & devices such as infusion devices, portable suction pumps, defibrillators and vital sign monitoring systems.

## 7.3 Life Cycle Replacement

When purchasing medical equipment, particularly electro-medical equipment it is important to establish how long the manufacturers will support maintenance, service of parts. This information should be documented and kept with the asset register.
Replacement programmes should be implemented for all Medical Devices that have a specified life.

## 7.4 Loan/Hire/ on trial/free

There are several different routes that equipment may be loaned between departments in the Health Board:

- Equipment loaned by suppliers, often for trial periods.
- Equipment loaned to other Health Board Hospital sites.
- Loans within departments in the same hospital.
- Equipment loaned by an external company but on long term loan to the Health Board.

Equipment which is on loan, hire or on trial from whatever source, must still meet the requirements of this policy.

It is important that this is fully documented to whom it is loaned and by whom. Records should include make, model, and serial number.

Manufacturers' instructions must accompany any piece of medical equipment on loan.

## 7.5 Indemnity Forms

Indemnity forms are required for any equipment loaned. This includes equipment on trial, courtesy equipment covering equipment being sent for repair, loan or as a free issue by a supplier. Indemnity cover must be discussed with the Procurement Department who will arrange for the Indemnity forms to be completed.

## 7.6 Decontamination

Prior to purchasing any Medical equipment it should be ensured that it can be decontaminated according to Infection Control Guidelines and Decontamination of Reusable Medical Devices Policy (ABHB/Clinical/0103).

## 7.7 Single use medical devices

### *7.7.1. Single use only*

Equipment is to be used on an individual patient for a single use and then discarded. Equipment must not be reprocessed and used on other patients.
The single use symbol indicates that the manufacturer considers the device is not suitable for use on more than one occasion and has evidence to confirm that reuse would be unsafe.

### *7.7.2 Single patient use*

The MHRA defines 'single patient use' as more than one episode of use on the same patient only. The device may undergo some reprocessing. Manufacturers' instructions must be followed.

## 7.8 Storage of Medical Equipment

Appropriate clean storage will prolong the life of a medical device when it is not in use.
Electro-medical devices should be stored plugged into an AC power supply to recharge internal batteries.
Where central storage facilities are available the whereabouts of equipment must be accurately documented

All reusable medical equipment **must** be decontaminated prior to return to the central storage area.

Manufacturer instructions should be followed for all devices e.g. catheters should be stored in their boxes to prevent deterioration.

## 7.9 Inventory/Asset Register

MHRA Managing Medical Devices, April 2015 recommends that Healthcare organisations establish an inventory of all medical devices purchased excluding consumables, on to an equipment inventory. All previously purchased medical devices should have an asset barcode number and also newly purchased medical devices should be given one at the time of purchase.

The inventory should identify some of the following:

Total assets register
Type of contract
Servicing dates
Location of equipment
Reports on recurring faults
Life of the equipment
Users
Training records (training needs analysis)

The inventory is essential to have in place for addressing any MHRA Alert, Hazard and Safety Warning Notices to enable the Health Board to have a tracking system in place.

## 7.10 Replacement Programmes

Medical equipment can have a life expectancy from 5-15 years. The life cycle of medical devices must be monitored on the departmental/directorate asset register to identify the equipment that will need replacement.

## 7.11 Maintenance and Repair

### *7.11.1 Servicing*

Managers in consultation with the Procurement department, works and estates and EBME should decide whether it would be cost effective and

efficient for a device to be managed internally. By identifying cost and availability of specialist tools, availability of spares, service manuals etc…or externally, terms and conditions, frequency and cost of service contract, number of devices in the Health Board, location.

### *7.11.2 Broken or Faulty Equipment*

All broken or faulty equipment, which includes any equipment, deemed to have been cannibalised, where serviceable parts from one device are utilised to repair or upgrade another device, should be clearly labelled to avoid continued use. The faulty device must be set aside and stored separately from the equipment that is in regular use.

The service organisation responsible for maintaining the medical device must be contacted. This will be Medical Electronics (EBME) for general electro-medical equipment, and appropriate departments for non-electronic medical devices. Where a department has a service contract with the manufacturer or third party service provider, they must contact the relevant company. Contract maintained equipment must be identified with a company label giving a contact phone number and equipment identifier code.

Staff reporting faulty equipment should give a description of the faulty symptoms or breakage to assist the process of repair.

## 7.12 Decontamination Status

All broken devices whether put aside for collection or sent for repair should have a Declaration of Contamination Status Form attached (MHRA DB2003 [05] June 2003). Forms are available via the Intranet in the infection control manual, labels are available from Procurement, EBME and the IT department.

The ward/department manager should keep a record of the device going for repair and when the item is returned from repair, keep a copy of the service report.

## 7.13 Risk Management

In 2003 the Medicines and Health products Regulatory Agency (MHRA) replaced the agencies known as the Medical Devices Agency and the

Medicines Control Agency. This Agency issues guidance on the management of Medical Devices and incidents relating to medical devices.

Incidents relating to Medical Devices must be reported following the Health Board Incident Reporting Policy and if necessary to the MHRA.

*7.13.1 Incident Reporting*

Incidents relating to Medical Devices that must be reported are:

- Malfunction of a medical devices while in use resulting in either harm or
  significant potential harm to patient or staff.
- Significant Risk that is likely to cause potential harm to patient or staff.
- Misuse of medical devices.
- Training issues.

The Risk Manager-Patient Safety and Medical Electronics (EBME) must be informed of any incident relating to a faulty or broken medical device.

The Health Board Risk Manager- Patient Safety is responsible for ensuring that the MHRA Alert, Hazard and Safety Warning Notices relating to medical devices are distributed to all the Clinical Service Directorates (Procedure for the handling of Medical Device Alerts).

*7.13.2 Risk Assessment / Clinical Audit*

Risk Assessments or Clinical Audits may need to be carried out after a reported Medical Device Incident/event as part of the action or recommendations, in order to determine a more comprehensive picture of the risks (contact the Risk Manager- Patient Safety for advice).

## 7.14 Alarms

Medical devices with alarms have an important role in the care of dependent patients.

They are an adjunct to, but not a substitute for, well-developed sensitive and rigorous observations of the patient made by qualified professional

staff. The appropriate use of such devices, when planning care and interpreting changes in a patient's condition, is the responsibility of health care professionals.

- Checking Alarms
  Medical equipment alarms must be switched on. Staff accountable for the care of the patient must ensure they check the alarm situation at each shift hand over, and when setting up the device: If the alarms are suspended or silenced for any reason it should be recorded in the patient's notes.

- Mobile Phones
  It is the recommendation of the Health Board that Mobile "cell" phones should always be switched off and staff portable hand radios should not be operated on speak mode in all areas where sensitive devices may be used e.g. infusion devices, monitoring equipment, mechanical ventilators, defibrillators and pulse oximeters. This reflects the recommendations made by the Medical Devices Agency in Device Bulletin MDA DB 9702.

## 7.15 Condemning and disposal of medical devices

When equipment is condemned it should be removed from the equipment inventory and the appropriate condemning forms should be completed. (Forms to be obtained from Medical Electronics (EBME) for general electro-medical equipment and Works and Estates for Medical Devices).

Reasons for condemning equipment:

- Obsolete
- Clinically, electrically or mechanically unsafe
- Worn out beyond economic repair
- Spare parts unavailable
- Necessity to withdraw from use because of a Hazard warning issued by the MHRA
- Unreliable operation *(check service history)*
- Contaminated internally with body fluids or other obnoxious substances
- More cost effective or clinically effective devices have become available on the market

Prior to disposal all patient identifiable data must be professionally deleted by Information Technology Services from the equipment where necessary.

Where equipment is listed on an asset register this must be updated to show the details of the equipment disposed of and the date of disposal. Where equipment can be re sold this must be undertaken by Procurement Services using an approved Auction Facility

The final decision for condemning equipment rests with the appropriate Health Board technical staff. This will be Medical Electronics (EBME) for general electro-medical equipment and Works and Estates for Medical Devices.

## 8 References

MHRA DB 9702 Electromagnetic Compatibility of Medical Devices with Mobile Communications

MHRA Managing Medical Devices, Guidance for healthcare and social services organisations, April 2015 .

MHRA DB 2009 (01) Reporting Adverse Incidents and Disseminating Medical Device Alerts

Health and Safety at Work Act 1974

Health and Safety Executive

Management of Health and Safety at Work Regulations 1999

Health & Safety Commission – 2002 Control of Substances Hazardous to Health Regulations

Provision and Use of Workplace Equipment Regulations 1998 ACOP and Guidance Notice

Manual Handling Operations Regulations 1992 Guidance on Regulations

Medicines and Healthcare products Regulatory Agency website (www.medical-devices.gov.uk)

WHC (99) 158 – Variant Creutzfeldt-Jakob Disease (vCJD): Minimising the risk of transmission

WHC (2001) 004 Decontamination of Medical Devices

National Audit Office (1999) The Management of Medical Equipment in NHS Acute Health Boardorganisations in England

National Patient Safety Agency (2004) Standardising and centralising infusion devices – a project to develop safety solutions for NHS organisations: Full Evaluation Report NPSA, London

## Associated Health Board Policies

### Clinical Policies

Pre-Operative Checking and Regular Maintenance of Anaesthetic and other Theatre Equipment – Ref: 0021
Check List for Anaesthetic Apparatus – Ref: 0032
Equipment Maintenance, Repairs and Tracking – Ref: 0028
Patient Monitoring – Ref: 0011
Protocol for the Supervision of Doctors in Training – Ref: 0026
Creutzfeldt-Jakob Disease Policy – Ref: GHT/Clinical Policy/5014
The Safe Use of Infusion Devices – Ref: 4003
Resuscitation Policy – Ref: 0036
External Defibrillation Policy Ref 4030
Policy for the Use of Subcutaneous Infusions via a Syringe Driver in Adult Patients

### Organisational Policies

Policy for Minimal Manual Handling – Ref: 0011
Risk Management Policy and Strategy – Ref: 0002
Secure Disposal and Re-use of IT Equipment Procedure – Ref: 0055
Incident Reporting Policy and Procedure – Ref: 0015
Procedure for the handling of Medical Device Alerts Ref: 0047
Guide to Good Records and Record Keeping – Ref: 1001
Policy on the Prevention and Management of Latex Allergy – Ref: 0020
Retention and Destruction of Health Records Policy - Ref: 0074
Risk Management Policy Ref:0002

### Finance Policies

Procurement Policy – Ref 0010
Financial Control Procedure : Capital Assets and Charges – Ref: GHT/Finance Procedure/6207

Budgetary Control Policy
Capital Procedures and Guidance
Financial Control Procedure : Ordering of Goods and Services
Financial Control Procedure :Stores and Stocks
Standing Orders, Tendering and Contract Procedures and Standing Financial Instructions

**Personnel Policies**

Training Policy – Ref: 2823
Supervision and Training of Students – Ref: 2829

**Community**

Gwent Wide Integrated Community Equipment Service

# 9 Appendices

## Appendix 1

What is a medical device?
Equipment used for the diagnosis or treatment of disease, or for monitoring of patients.
Some examples are given below (this is not an exhaustive list):
Anaesthetic equipment
Blood warming cabinets
Catheters (e.g. urinary, cardiac)
Chiropody equipment
Dental equipment and materials
Dressings
Endoscopes
Examination gloves
Implants - powered and non-powered (e.g.
Implantable defibrillators, pacemakers, heart
Valves, orthopaedic prostheses, bone cements)
IV administration sets and pumps
Ophthalmic equipment
Patient monitoring equipment (e.g. cardiac monitors)
Physiotherapy equipment
Radiotherapy equipment (brachytherapy, external beam)
Sphygmomanometers
Surgical instruments and equipment
Syringes and needles
Thermometers
Vaginal specula
X-ray systems, ultrasound imagers and CT/MR scanners
For critical care:
Defibrillators
Resuscitators
Ventilators
And all other technical equipment that may be prescribed as necessary by the Critical Care Consultant to support therapeutic interventions.
For people with a disability:
Communication aids
Environmental controls
Orthotic and prosthetic appliances
Patient hoists
Pressure relief equipment
Walking aids

Wheelchairs and special support seating
For patient transportation or moving (but *not* including ambulance vehicles themselves):
Carry chairs
Lifting aids
Stretchers and trolleys
For daily living:
Bathing and showering equipment
Commodes
Hearing aids
Incontinence products
Prescribable footwear
Special chairs
Urine drainage systems
Medical devices and equipment also include the following in vitro diagnostic
medical devices and their accessories:
Blood gas analysers
Devices for blood glucose measurement
Hepatitis and HIV test kits
Pregnancy test kits
Specimen collection tubes
Urine test strips
Also included are:
Condoms
Contact lenses and care products
Intra-uterine devices (IUDs)

Products which, whilst not themselves medical devices are used closely in conjunction with these devices: and included in the remit as such.
Bench top sterilizers
Endoscope reprocessors
Blood and tissue storage systems
Chemical and biological indicators used in sterilization processes
Disinfecting and sterilizing equipment
What is *not* a medical device?
Medical devices do not include ambulances, general workshop equipment such as power
or machine tools, or general-purpose laboratory equipment.
Pre-filled devices e.g. drug
inhalers, syringes and certain other drug/device combinations also fall into this category

## Appendix 2

## Checklist for Patients Discharged from Hospital with a Medical Device

General Considerations

- ☐Is the device suitable for home use (have, for example, robustness, back-up systems, alarms been considered if appropriate, modifications needed, patient care and instructions)?
- ☐Has the person responsible for the use of the device been identified, i.e. is it patient and/or carer?
- ☐Is the loan equipment schedule maintenance status compatible with the loan?
- ☐Has the device been fully tested with confirmed full functionality and fitness for purpose?

Patient/Carer Instructions

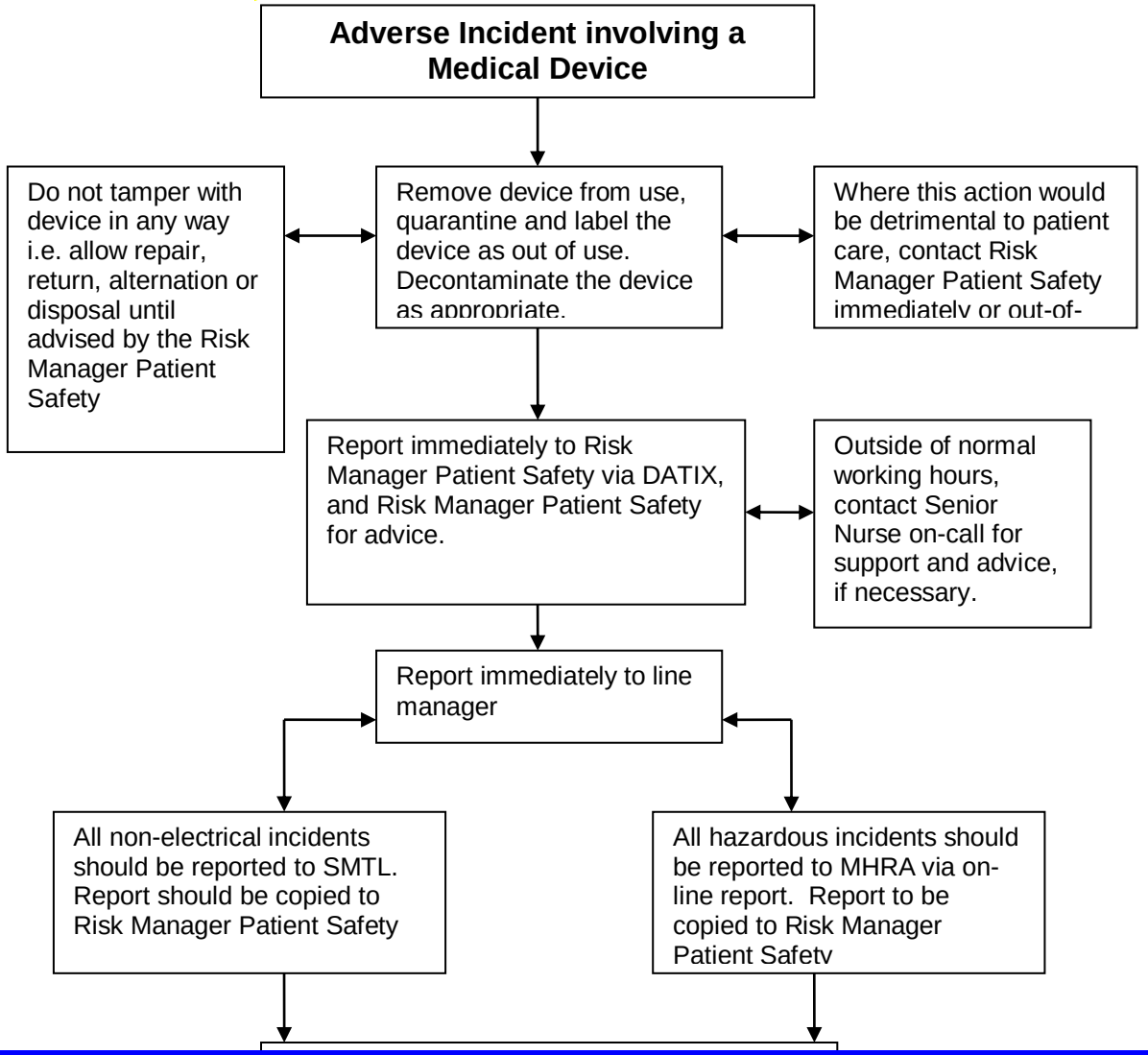
- Does the patient/carer know the name of the device?
- Does the patient/carer know how to set up the device in the home?
- Has the patient/carer been trained in the use and functions of the device?
- Has the patient/carer been provided with written instructions specifically about the device?
- Has the patient/carer been trained in how to deal with fail-safe features, e.g.
- alarms?
- Has the patient/carer been trained in the care of the device?
- Does the patient/carer require accessories? If so, does the patient/carer know
- where to obtain these and how often?
- Is maintenance required? If so, is the patient/carer aware and in possession of
- instructions about how this will be achieved?
- Does the patient/carer have a point of contact in the Health Board for any queries?
- If relevant, does the patient/carer have a contact point in case of emergency?

Return

- Does the patient/carer know when to return the device?
- Does the patient/carer know where to return the device once treatment is complete, to whom and at what time?

**Appendix 3**

## IN THE EVENT OF AN ADVERSE INCIDENT INVOLVING A MEDICAL DEVICE PLEASE FOLLOW THE DIAGRAM BELOW




**For further information please see the:**

The Policy for the Management of Medical Devices

**Which is located on the Intranet**

**IF YOU HAVE ANY QUERIES PLEASE CONTACT:**

**Susan Hallybone, Risk Manager Patient Safety on 01633 623585**