

## Policy for the Management of Medical Devices and Equipment

<b>Document Reference No:</b>	PTHB / CDP 002	
<b>Version No:</b>	6	
<b>Issue Date:</b>	July 2021	
<b>Review Date:</b>	July 2025	
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<b>Approved By:</b>	Medical Devices Group & Clinical Policy Group	
<b>Approval Date:</b>	July 2021	
<b>Document Type:</b>	Policy	
<b>Scope:</b>	PTHB	Clinical

The latest version will be accessible via the intranet.  
If the review date has passed please contact the Author for advice.

### Disclaimer

Powys Teaching Health Board is the operational name of Powys Teaching Local Health Board  
Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

### Version Control

Version	Summary of Changes/Amendments	Issue Date
1	Initial Issue	Dec 2004
2	Reviewed and Merged with CP 015.	Dec 2007
3	Reviewed and updated to reflect changes in management & procedure	Jul 2008
4	Complete revision of policy	May 2012
5	Complete revision of policy Coding amended by Corporate Governance from CP 017 to CDP 002	Aug 2017 Nov 2017
6	<ul style="list-style-type: none"> <li>Reviewed to reflect changes to Executive Director Portfolios and minor updates to reflect role changes and process improvements</li> <li>Updated following consultation with Medical Devices Group</li> </ul>	Jan 2021 June 2021
6	<p>Deputy Director of Therapies and Health Sciences agreed to extend the review date of this policy by 12 months to July 2025, no changes made to Policy.</p> <p>The work on the medical device maintenance service contract document is specification development in liaison with NWSSP in preparation for contract going out to tender in September-October 2024 as the Avensys contract expires in March 2025.</p>	19/07/2025

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## ENGAGEMENT & CONSULTATION

### Key Individuals/Groups Involved in Developing this Document

Role / Designation
Assistant Director Therapies & Health Science Medical Devices and Point of Care Testing Manager Environment & Sustainability Manager Administration Assistant - Medical Devices and Point of Care Testing Manager

### Circulated to the following for Consultation

Date	Role / Designation
18/03/2021	Medical Devices Group

Evidence Base
<p><b>Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area?</b></p> <p>Documented in the following sections: 25. Legislation &amp; Guidance 26. Associated Health Board Policies</p>

## IMPACT ASSESSMENTS

Equality Impact Assessment Summary					
	No impact	Adverse	Differential	Positive	Statement
<b>Age</b>	X				<p>An Equality Impact Assessment has been undertaken for the review of this document. Assessment included obtaining advice from the Service Improvement Manager – Welsh Language &amp; Equality.</p> <p>Managers must ensure staff are supported in relation to protected characteristics. For example, appropriate size font for instructions for use manuals.</p>
<b>Disability</b>	X				
<b>Gender</b>	X				
<b>Race</b>	X				
<b>Religion/ Belief</b>	X				
<b>Sexual Orientation</b>	X				
<b>Welsh Language</b>	X				
<b>Human Rights</b>	X				
Risk Assessment Summary					
<p><b>Have you identified any risks arising from the implementation of this policy / procedure / written control document?</b></p> <p>Where risk assessments are referred to throughout the document the following standard Risk Assessment Template must be used:</p> <p><a href="#">HS Risk Assessment Template v2 2021 Link.docx</a></p>					
<p><b>Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document?</b></p>					
<p><b>Have you identified any training and / or resource implications as a result of implementing this?</b></p> <p>Capacity &amp; resource limitations to process, manage and progress improvements at pace across all areas.</p>					

## 1. Policy Statement

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 procured, 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 patients.

This Policy ensures the health board has a systematic and planned process in place to:

- Comply with all relevant legislation and guidance for purchase, use and disposal of all medical devices and equipment.
- Promote the safe and effective use of medical devices and equipment.
- Identify the risks associated with the prescribing, purchasing, commissioning, training, operating, storage, maintenance, servicing, disposal and documentation of medical devices and reduce these risks as far as is reasonably practicable.
- Comply with the Medicines and Healthcare products Regulatory Agency (MHRA) 'Managing Medical Devices' – Guidance for healthcare and social services organisations January 2021.
- Comply with Health and Care Standards 2015: Standard 2.9 Medical Devices, Equipment and Diagnostic Systems.
- Embed environmental sustainability into procurement processed in line with the health boards Environment and Sustainability Management System.
- Where possible reduce the environmental impacts of medical device use and disposal.

## 2. Objective

The policy covers the management of medical devices and equipment and their associated systems. It refers to all medical devices and equipment used for the care and treatment of patients throughout the health board.

Staff understanding and adhering to the policy will ensure that all medical devices and equipment 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

- Included on an asset register/inventory for planned equipment maintenance and replacement
- Managed to reduce environmental impacts and to ensure safe and compliant disposal

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 hospital and community setting.

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.

### **3. Scope of the Policy**

The term 'Medical Devices and Equipment' covers a broad range of products and 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.

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 and maintenance 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 being aware of their responsibilities.
- The safe effective use of medical equipment - trained, competent professional users, technical supervisors and end users.
- 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.
- Opportunities for continual improvement identified by annual audit.

### **4. Indemnity**

The health board is required to have management and governance arrangements in place to ensure effective risk management in respect of medical devices and equipment.

The Scope of Risk Pooling Arrangements (Welsh Risk Pool, 2020) provides information on the provision of reimbursement from the WRP funds for equipment and outlines the process for organisations to submit claims for consideration. The Welsh Risk Pool (WRP) will only consider indemnity for loss or damage sustained to equipment, supplies or consumables within the scope of their arrangements under exceptional circumstances, and where considered is subject to an excess of £50,000.

Exceptional circumstances is not fully prescribed but does include factors such as flood, storm and other weather damage. Other losses are subject to consideration on a case by case basis by the WRP Committee who will consider the impact the loss has on service delivery; the foreseeability of the loss and what precautions have been taken by the health body to limit or prevent the loss.

The WRP will determine the level of reimbursement due based on the age and depreciation of equipment.

In the event of any claims to the WRP, the health board must evidence the equipment has been reasonably maintained and, where appropriate, that all legal inspections were undertaken.

## **5. Responsibilities**

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

### **5.1 Chief Executive**

The Chief Executive Officer (CEO) is ultimately accountable for all premises, appointment of personnel, and the allocation of resources in relation to medical devices.

### **5.2 The Board**

The Board will receive annual reports from the Quality Governance Group assuring them of the health board's compliance with this policy.

### **5.3 Executive Director of Therapies and Health Science**

PTHB must ensure there is clear and effective management at Board level of all aspects of medical device and equipment management. This responsibility has been delegated to the Executive Director of Therapies & Health Science.

### **5.4 Assistant Director of Therapies and Health Science**

Will lead the improvement of safe systems ensuring processes for medical devices are robust, reporting to the Executive Director of Therapies & Health Science.

## **5.5 Medical Devices and Point of Care Testing Manager**

Reporting to the Assistant Director of Therapies and Health Science, the Medical Devices and Point of Care Testing Manager's responsibilities include:

- To lead and coordinate the delivery of medical devices, ensuring systems and processes for medical devices are robust; promoting best practice in relation to medical devices.
- To develop policies/procedures for medical devices that reflect best practice and provide advice and support to the service directorates in the implementation of policies locally.
- Working in close liaison, where applicable, with theatre staff, ward staff, Senior Infection Prevention & Control Nurse, Senior Health & Safety Officer, Environment & Sustainability Manager and directorate leads to achieve effective medical device management, to ensure that all parties have clear roles and responsibilities as outlined in policies and procedures.
- To collaborate with others and /or develop and present written and verbal reports on progress against action plans, audits and standards in relation to medical devices.
- To manage the e-Quip information system in relation to medical devices, ensuring regular reports on compliance.
- 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 by the relevant staff or service groups.
- Ensuring that MHRA Alerts and Internal alerts are disseminated across the health board, targeting specific staff as necessary.
- Ensuring that nominated staff take responsibility for key devices and equipment.
- Leading on relevant projects involving the implementation of new medical devices e.g. infusion devices.
- Reviewing and updating the Management of Medical Devices and Equipment Policy in line with current legislation guidance and best practice.

## **5.6 Directorate Leads, Heads of Service, Community Service Managers and Professional Leads**

It is the responsibility of senior staff and leads to ensure that the appropriate systems are in place to identify needs analysis and business planning according to local processes.

Providing professional leadership and advice on best practice, to all areas and departments of the health board.

Senior Managers are accountable, via their relevant executive director, to the Chief Executive Officer for ensuring all staff under their remit, act according to the Management of Medical Devices and Equipment Policy.

They must 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 must have a nominated person(s) responsible for coordinating and ensuring the updating of the training records for the directorate via the ESR system).
- Risk assessments relating to medical devices are completed and incorporated into the Directorate/Department risk registers.
- Incidents involving medical devices and MHRA alerts are promptly and correctly reported, investigated and acted upon according to Policy.
- All medical equipment is recorded on the Medical Devices Asset Management System (e-Quip) and entered onto a planned replacement programme where appropriate. Each Directorate must have a nominated person(s) responsible for ensuring that records for the directorate are up to date.
- Robust maintenance and servicing processes are in place for all medical devices and equipment.
- Lifecycle revenue costs have been identified and budgeted for.
- External devolved maintenance contracts for equipment within the Directorate are their responsibility and must be requisitioned and agreed through the NHS Wales Shared Services Partnership (NWSSP) Procurement Services.
- Each Directorate participates in the audit of relevant medical equipment and ownership of the resulting action plans to maintain continuous improvement. Link to audit form: <https://forms.office.com/Pages/ResponsePage.aspx?id=uChWuyjjgkCoVkm8ntyProdAyVg2bL9CssqUykYvcu1UN0VVVE1XTUFJRVPNRlpDS1c4OVRHMVRyNy4u>
- The Equipment and Devices Ordering Form (EDOF) process must be adhered to for all medical devices and equipment purchases.
- All equipment is purchased according to Financial Control Procedures, Standing Financial Instructions and other relevant financial procedures. <http://nww.powysthb.wales.nhs.uk/document/430806>  
<http://nww.powysthb.wales.nhs.uk/financial-control-procedures>
- Justification for the need to purchase a medical device and business objectives in relation to medical devices are determined and met.
- Obtaining quotations for new or updated equipment through NWSSP Procurement
- If the purchase of medical devices is a development of the service this

must be made clear as part of the (Equipment and Devices Ordering Form) EDOF process.

- Equipment replacements are to be prioritised by consultation between appropriate managers and clinical users.

## **5.7 Ward and Departmental Managers**

Ward/Department Managers are responsible for ensuring:

- Medical equipment and devices are acquired following Procurement Procedures and the PTHB EDOF Process.
- Identification of medical equipment and devices where user training is required.
- Staff are trained in use of medical devices and the training undertaken is documented, both locally and via the ESR system.
- Medical equipment is stored and managed safely and effectively.
- Devices have a documented risk assessment.
- That all equipment owned by their ward or department is serviced and maintained on a regular basis
- Bank and locum staff are supervised and trained appropriately when using medical devices.
- To work with the Medical Devices and Point of Care Testing Manager to update the asset register (e-Quip) regarding medical devices and equipment for their ward or department.
- 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 implemented following an adverse incident involving a medical device.
- Medical device alerts are responded to appropriately.
- That staff are competent to safely operate equipment.
- Ensure Medical Device and Point of Care Testing Administration Assistant is informed of any service location changes to ensure the asset register is kept up-to-date.

Random audits must be carried out on all elements of maintenance, repair, record generation and storage to ensure that the correct procedures are in place and being adhered to.

Audits must be carried out by staff with appropriate knowledge and experience of managing medical devices on a six-monthly basis.

Link to audit form:

<https://forms.office.com/Pages/ResponsePage.aspx?id=uChWuyjjgkCoVkM8ntyProdAyVg2bL9CssqUykYvcu1UN0VVVE1XTUFJRVpNRlpDS1c4OVRHMVRYNy4u>

## **5.8 All Staff Using Medical Equipment**

All staff are responsible and accountable for their practice and for their use of medical devices and equipment. Staff are responsible for:

- Ensuring that they are competent to use an item of medical equipment before using.
- That, where indicated, they have received appropriate training in the use of the device and have documentary evidence available.
- If there is any doubt on how to operate a piece of equipment, the individual concerned must consult their manager and report their training needs.
- Undertake a visual check of the equipment before use, *pay particular attention to electrical wires for wear and tear*
- Referring to manufacturers' directions for use before using devices.
- Bringing to the attention of their line manager any concerns they have regarding the devices.
- Report incidents involving medical devices, including loss, damage, failures, faults or breakdowns to their Line Manager and complete an Incident Report on the Once for Wales Incident Reporting System for investigation and action.
- Ensuring that medical devices and equipment are stored securely, appropriately and safely.
- Ensuring that accurate and consistent record keeping is undertaken including relevant tracking documentation for specific medical devices. For example, syringe drivers.
- Ensuring that all equipment is cleaned and/or decontaminated appropriately following use.
- MHRA alerts and internal medical devices alerts are appropriately responded to and acted upon in conjunction relevant policies
- Ensuring all devices and equipment when in use or storage do not present trip hazards to other members of staff, patients or public.

## **5.9 Local Responsible Officer**

Directorates will have identified local responsible officers who will be the lead contact with regards to any queries relating to the purchase of a medical device. When a need has been identified for a new piece of equipment, the local responsible officer will ensure the EDOF process is adhered to and all applicable sections of the EDOFs are completed prior to submission. On receipt of new equipment, the local responsible officer must ensure a MDF3 form and is completed and sent to the Medical Devices and Point of Care Testing Manager via the medical devices email ([medical.devices.POW@wales.nhs.uk](mailto:medical.devices.POW@wales.nhs.uk)) for adding to central medical equipment register (e-Quip)

## **5.10 Medical Device and Point of Care Administration Assistant**

They are be responsible for supporting the functions of Medical Device and Point of Care Testing Managements. In particular the data input into the e-Quip Medical Devices Asset Management System in accordance with the following Key Performance Indicators:

Indicator	Target	Description
New items (MDF3)	7 working days from receipt of MDF3 Form	Items to be added to e-Quip asset register
Inspection Reports	14 working days from receipt of Inspection Reports	Reports following routine service
Condemned/Disposed Items	7 working days from receipt of notification from service	Items to be removed from asset register
Validation of equipment lists with services	Every 6 months	Review of lists by ward/department
Maintenance Contracts	Within 7 days of contract start date	Maintenance contracts entered onto e-Quip - either new or renewed
EDOF Requests Actioned	7 working days from receipt of EDOF Form	EDOF requests responded to - approval or request for further information where required.

### 5.11 Estates and Property

Estates and Property must be involved in the purchase and commissioning of medical equipment such as washer disinfectors, dental sterilisers, macerators, gas regulators, flow meters, wall suction units, and gas air operated equipment to ensure the infrastructure is appropriate to support such equipment and/or determine if any required adjustments to the environment can be implemented.

### 5.12 Procurement NHS Wales Shared Services Partnership (NWSSP) Procurement Services

All purchases of medical devices must be made through relevant procurement processes in conjunction with NWSSP, adhering to procurement policies and standing financial orders.

<http://nww.sharedservicespartnership.wales.nhs.uk/home>

NWSSP will provide support to the health board in relation to the purchase of equipment and the arrangement of maintenance contracts. Their support will include:

- The selection and purchase of equipment in line with procurement policies.
- Identifying the costs of purchasing medical equipment which must, in addition to the initial financial outlay, include the cost of ongoing associated consumables and maintenance to keep revenue costs to a minimum.
- Ensuring alternative options are considered in relation to purchasing, i.e. leasing, long term loans.

- Ensuring procurement policies and procedures are up to date with national tendering guidelines.
- Ensuring all purchase requisitions and contracts raised through procurement are authorised by a designated signatory and have a unique EDOF number that confirms the correct processes have been followed.
- 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.
- Ensuring safeguards are in place to prevent unauthorised downloading, uploading or modification of data in computer controlled medical equipment/systems.
- Ensuring 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.
- Ensuring 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.
- Ensuring indemnity processes are adhered to before any device is accepted on loan into the organisation, Indemnity forms must be completed. 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 processes must be undertaken in conjunction All Wales Policy on insurance, NHS Indemnity and related risk management for potential losses and special payments and the Welsh Risk Pool Scope of Risk Pooling Arrangement.

### **5.13 Medical Devices Group**

The Medical Devices Group (MDG) is chaired by the Assistant Director Therapies and Health Service and is accountable to the Quality Governance Group. The purpose of the group is to monitor the use of medical devices with emphasis on quality, effectiveness, risk management, product safety, standardisation, training needs, service contracts, capital and consumables cost and cost containment.

In addition, the Medical Devices Group is responsible for the evaluation of new medical devices and equipment and inclusion of any new or replacement medical devices onto PTHB's preferred equipment list.

The Medical Devices Group will engage other groups of staff when necessary to give them expert advice. Further details can be found in the Terms of Reference for the Group.

### **5.14 The Resuscitation Committee**

PTHB's Resuscitation Committee has the responsibility for developing operational policies governing Cardio Pulmonary Resuscitation (CPR) practice

throughout the health board. This should consider national CPR guidelines and standards.

### **5.15 Health and Safety Officer & Manual Handling Advisors**

The Manual Handling Advisors will be responsible for co-ordinating training of staff when using the medical equipment such as hoists for lifting, lowering and moving patients and for ensuring manual handling training is provided and documented on ESR. The Health and Safety Team will also offer advice and guidance in relation to specific health and safety legislation.

### **5.16 Senior Nurse Infection Prevention and Control**

The Senior Nurse Infection Prevention and Control will provide advice to the Medical Device Group on equipment purchase and decontamination.

### **5.17 Environment and Sustainability Manager**

The Environment and Sustainability Team will support the Medical Devices Group and the procurement process to embed a circular economy and lifecycle analysis principle. The Environment and Sustainability Manager is Responsible for supporting waste managers to ensure end of life equipment is responsibly handled and disposed of in accordance with legislation and the health boards Sustainable Waste Management Procedure.

### **5.18 End Users**

For devices used in the community, users or carers must be provided with adequate training by the relevant staff on the safe use of the device as appropriate. Training must be documented in the end users notes.

Patients and Carers must be informed that it is their responsibility to advise a health professional if they are unsure how to use a particular medical device so that relevant training and information can be provided for them.

Patients and Carers must be provided with the contact details of a health professional who will deal with any problems relating to the medical device.

### **5.19 Community Equipment Service**

The Community Equipment Service (CES) provides equipment for use in the Community for residents of Powys. The services will be provided by the approved service provider in accordance with the agreed service specification.

### **5.20 Manufacturers of Medical Equipment and Devices**

Organisations that manufacture medical devices but do not place them on the market (i.e. they are used only within the organisation or legal entity) must, as a matter of best practice, ensure that those devices are

manufactured in accordance with the UK Medical Device Regulations.

## **5.21 Medical Gases Governance Group**

Liquid Nitrogen Gas is classified by the MHRA as a Class IIA Medical Device. The health board has taken the decision to exclude Liquid Nitrogen from the Medical Gases Policy, implementing a Standard Operating Procedure as an alternative to ensuring its safe management. Whilst Liquid Nitrogen is included in the remit of the Medical Gases Governance Group, it also figures within that of the Medical Devices Group.

## **6. Acquisition and Selection of Devices**

All selection and purchase of equipment must be in conjunction with the NHS Wales Shared Services Partnership Procurement Services, considering all available guidelines in compliance with the user needs, compatibility with existing equipment and Medicines and Healthcare Products Regulatory Agency guidelines (MHRA).

When a need has been identified for a new piece of equipment the EDOF process must be adhered to. The following criteria will need to be considered:

- Case of need and risk assessment?
- Fitness for purpose?
- Do devices already exist within the unit, ward or department
- Have you liaised with or consulted all relevant specialists or leads?
- Is the device a replacement or additional to existing equipment?
- Does the device appear on the list of health board's preferred equipment list?
- 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?
- Planned preventative maintenance put in place.
- Devices, which are complicated or require commissioning, must be installed in collaboration with EBME, the supplier and the staff.
- The health board meets current statutory requirements on ionisation and radiation equipment. The Radiation Protection Committee will provide expert advice.
- The environmental and sustainability impact of the selection of devices or equipment shall be assessed and recorded. The Environment & Sustainability Manager must be contacted should professional advice be sought.
- The social value of any new device, equipment or maintenance option must be considered whenever alternative or new schemes are appraised.

## **7. Standardisation of Equipment and the Preferred Equipment List**

In order to reduce and prevent risks associated with medical devices the organisation aims to standardise medical devices where appropriate. Safety, Environment and Sustainability must 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 the device.
- Cost benefits in terms of purchase of consumables.
- Cost reduction if equipment is to be placed on contract.
- Rapid exchange of equipment in the event of a major failure.

To ease the above process the organisation holds a Preferred Equipment List, which has been approved by the Medical Devices Group. This preferred equipment list is available to all staff on the [medical devices page](#) of the PTHB Intranet.

## **8. Training, Awareness & Competency**

Directorate Leads, Community Service Managers, Lead Therapists and Professional Heads must ensure that their staff are suitably trained and competent to use all medical devices and equipment necessary within the scope of their practice.

They are also responsible for documenting evidence of training taking place and in addition, evidencing of regular competency assessments.

This information must be recorded onto the Electronic Staff Record (ESR) in conjunction with Workforce and Organisational Development (WOD) Team.

Training will ensure that:

- Staff understand the purpose and function of medical device to be used, and where appropriate, explain to the end user what the device does and why it is being used
- Staff fully understand the operation and controls of the device and understand what must be done if a medical device fails its pre-use checks
- Staff are trained to connect the device to the end user referring to the directions for use where appropriate
- Staff understand the purpose of any alarms and can respond to such alarms appropriately.
- Staff are familiar with the operational malfunctions that may occur and are able to take appropriate action in the event of device failure.
- Staff are aware of PTHB's incident reporting procedure.

## **9. Training for New Devices to the Organisation**

When a new medical device is purchased into the organisation, the supplier must provide training to key clinical staff and be available to support staff. This must be specified and agreed in the initial contract. However, any subsequent training may need to be negotiated and this may incur additional costs.

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

## **10. Instructions for Use**

Manufacturer's instructions must accompany any piece of medical equipment. A digital copy of the manufacturer's equipment manual and instructions must be saved by the Local Responsible Officer and stored electronically.

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. This may be in the form of a Standard Operating Procedure (SOP).

Evidence that suitable instructions and training were provided will be needed, should a legal case be brought. Details of training must also be recorded. A simple test at the end of training to check that the information has been understood must also be included.

## **11. Maintenance and Repair**

### **11.1 Planned Preventative Maintenance (PPM)**

Planned Preventative Maintenance is carried out by technical staff and must follow regulatory requirements & manufacturers' guidance on test procedures.

This will include portable appliance testing (PAT) as and when required. This would be carried out by a service contractor authorised by PTHB.

Managers must ensure appropriate service contracts are in place for all devices. Procurement NHS Wales Partnership Shared Services will provide support to Managers in allocating service contracts, considering frequency, level of contract cover required and costs.

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.

Details of service contract providers for all devices must be recorded in e-Quip. The Service Lead must ensure copies of such contracts are shared with the Medical Devices and Point of Care Testing Manager and that the following essential details are included:

- Name of Company
- Contract Reference number
- Company Service Number
- Length of contract
- Date of last service
- Date of next service

### **11.2 Broken or Faulty Equipment**

To ensure that breakdowns are dealt with in a timely and appropriate manner the relevant maintenance service contractor must be contacted as soon as possible.

Breakdowns can be dealt with in one of two ways, by substituting an equivalent device or by rapid repair. In both cases planning is needed to ensure suitable replacement devices are available and that maintenance contracts specify adequately short response times.

The faulty device must be set aside, labelled "Do Not Use" and stored separately and securely from the equipment that is in regular use, until such time as the repair has been completed or the equipment is disposed of.

Staff reporting faulty equipment must give a description of the faulty symptoms or breakage to assist the process of repair. Remember to report on Once for Wales Incident Reporting System, include the breakdown and repair details. This will support decision making when planning for replacement devices.

### **12. Decontamination**

All reusable medical devices must be effectively decontaminated prior to use and the risks associated with decontamination processes well-managed. Please refer to the health board Decontamination Policies and procedures for further details.

Items subject to inspection, maintenance, repair or disposal, either on site or at external premises, must be decontaminated beforehand.

Any loaned items being returned to a manufacturer or supplier must be decontaminated.

Devices intended for single-use only do not require decontamination, except where they are implicated in an adverse incident and may need to

be sent to the manufacturer for investigation. In this situation, the manufacturer will need to be contacted to find out the most appropriate method of decontamination.

Medical devices must be decontaminated and stored in accordance with legislation and best practice requirements, whilst following validated procedures.

The following table identifies classification of infection risk associated with the decontamination of medical devices:

<b>Risk</b>	<b>Application of Item</b>	<b>Recommendation</b>
High	<ul style="list-style-type: none"><li>• In close contact with broken skin or broken mucous membrane</li><li>• Introduced into sterile body areas</li></ul>	Cleaning followed by sterilization.
Medium	<ul style="list-style-type: none"><li>• In contact with mucous membranes.</li><li>• Contaminated with particularly virulent or readily transmissible organisms.</li><li>• Before use on immunocompromised patients.</li></ul>	Cleaning followed by sterilization or disinfection.  NB: Where sterilization will damage equipment, cleaning followed by high level disinfection may be used as an alternative.
Low	<ul style="list-style-type: none"><li>• In contact with healthy skin</li><li>• Not in contact with patient</li></ul>	Cleaning.

Once decontamination has been completed, a Declaration of Contamination Status form must be attached to the equipment. No transportation or collection of equipment can take place without this form being attached.

### **13. Decommissioning**

Decommissioning aims to make devices safe and unusable, while minimising damage to the environment. Any device deemed unfit for use must be decommissioned.

Decommissioning must include decontamination, making safe and making unusable. This is to ensure that an inappropriate person does not use the device and expose themselves and/or others to hazards.

Decommissioning of larger installations often involves removal from purpose-built room or surroundings. Decommissioning of devices incorporating radioactive sources must be carried out in accordance with the Ionising Radiations Regulations.

If a device stores patient identifiable data, this must be certified as securely erased to an appropriate standard, such as BS ISO/IEC 1540 before disposal.

When the decision has been made that an item of equipment is to be replaced and therefore condemned, a condemnation form must be completed.

## **14. Disposal of Equipment & Devices**

The health board's Environment and Sustainability Manager, along with the manufacturer, must be consulted for the best methods of waste disposal.

Some products need specialised disposal. Examples include:

- Wastes containing certain metals (e.g. thermometers above 3%, some batteries)
- Oil wastes (including polychlorinated biphenyls – PCBs)
- Wastes from coolants
- Radioactive waste
- Healthcare wastes from human or animal origin
- Human waste from natal care, diagnosis, treatment or prevention of disease.

Equipment and devices must be cleaned &/or decontaminated before disposal or transfer to a third part and supplied with a certificate of decontamination.

### [Waste and Surplus Equipment Process](#)

When returning medical devices to the manufacturer at end of life, or when transporting devices, care must be taken to ensure they are appropriately packaged and secured. Issues that must be addressed include: strength of packing materials, protecting sharp edges and ensuring the device is not damaged in transit.

Legislation applies to the transport of goods:

- The Carriage of Dangerous Goods by Road Regulations
- The Carriage of Dangerous Goods by Rail Regulations
- Chemicals (Hazard Information and Packaging for supply) Regulations
- The Radioactive Material (Road Transport) (Great Britain) Regulations

## **15. Sale or Transfer of Ownership**

Consideration must be given to the resale of any decommissioned devices. This will provide an opportunity for the health board to receive income generation as opposed to potential disposal costs.

The following must be supplied for all items resold or transfer of ownership:

- When being sold, a statement stating that the device is being resold must accompany the device
- Contamination Status Certificate
- User manuals/manufacturers' instructions
- Training requirements (if applicable)
- Service History of that device
- Service manual where applicable
- Quality assurance tests
- Disposal costs versus revenue generation potential
- Changes in clinical recommendations or standards
- New equipment technologies and/or technological obsolescence
- Changes in service provision
- Necessity to withdraw from use because of a Hazard warning issued by the MHRA

## **16. Equipment on Loan**

There are several different routes through which equipment may be loaned:

- Equipment loaned by suppliers
- Equipment loaned to other health board or hospital sites
- Loans within departments in the same hospital
- Equipment loaned by an external company but on long term loan to the health board

It is important that full documentation is retained recording to whom it is loaned and by whom. Records must include make, model, and serial number. Manufacturers' instructions must accompany any piece of medical equipment on loan.

Indemnity processes must be adhered to via the All Wales Policy on insurance, NHS Indemnity and related risk management for potential losses and special payments and the Welsh Risk Pool Services Scope of Risk Pooling Arrangement.

Indemnity forms are required for any equipment loaned.

## **17. Equipment on Trial**

Where staff wish to trial a new device or equipment, it is essential to complete the necessary process and to obtain approval for senior managers.

As with equipment on loan, an indemnity form must accompany the trial equipment. This may be provided by the Manufacturer or Company providing the equipment or trial but must be reviewed by NWSSP Procurement colleagues to ensure it provides adequate cover.

Documentation must be retained. In addition to the indemnity, records must include make, model, and serial number. Manufacturers' instructions must accompany any piece of medical equipment on loan.

Staff trialing equipment must liaise with the Medical Devices and Point of Care Testing Manager. At the end of the trial period, an evaluation form must be completed and submitted to the Medical Devices and Point of Care Testing Manager for audit purposes.

Should staff wish to purchase equipment the standard EDOF process must be followed and the evaluation form will provide robust support in the approval to purchase.

## **18. Lending PTHB Medical Devices between PTHB Wards, Departments or PTHB Community Hospitals**

When a medical device is moved between departments the head of the owning department, Team Leader or Ward manager is responsible for informing the Medical Devices and Point of Care Testing Manager of the loan so the e-Quip Medical Devices Asset Management System can be updated accordingly.

Maintenance and servicing (in accordance with the manufacturer's instructions) will remain the responsibility of the department that owns the device.

## **19. Storage of Medical Equipment**

- Appropriate safe and clean storage will prolong the life of a medical device when it is not in use.
- Where central or shared storage facilities are available the whereabouts of equipment must be accurately documented.
- All medical equipment **must** be decontaminated prior to return to the central or shared storage area.
- Manufacturer's instructions must be followed for all devices e.g. catheters must be stored in their boxes to prevent deterioration.

## **20. Medical Devices Asset Register (e-Quip)**

The MHRA recommends healthcare organisations establish an inventory of all medical devices purchased, excluding consumables.

All purchased medical devices must have a unique asset barcode number.

The inventory must identify following:

- Device Name
- Asset Number
- Location of Device
- Type and Model of device
- Maintenance service provider details
- Date device put in use
- Dates of maintenance carried out
- Dates maintenance due

- 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.

## **21. Single Use Medical Devices**

### **21.1 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.

### **21.2 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.
- Once that patient no longer requires that device, it must be discarded according to the manufacturer's instructions.
- It must not be used on any other patient/end user.

## **22. Incident Reporting**

Incidents relating to medical devices must be reported following the health board's incident reporting processes Once for Wales Incident Reporting System and where necessary to the MHRA.

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 Medical Device and Point of Care Testing Manager must be informed of any incident relating to faulty, broken or lost medical devices.

The Assistant Director Therapies & Health Science and Medical Device and Point of Care Testing Manager are responsible for ensuring that the MHRA

Alert, Hazard and Safety Warning Notices relating to medical devices are distributed to all the Clinical Service Directorates.

### **22.1. Risk Assessment / Clinical Audit**

Risk assessments or clinical audits may need to be carried out after a reported medical device incident or event, as part of the action or recommendations, in order to determine a more comprehensive picture of the risks. The standard health and safety risk assessment tool must be used:

[HS Risk Assessment Template v2 2021 Link.docx](#)

### **22.2 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.

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 must be recorded in the patient's notes.

## **24. Monitoring Compliance, Audit & Review**

Regular audit is a key part of the policy implementation. An annual audit programme shall be completed. The results of any audit undertaken shall be presented at the Medical Devices Group.

Specific audits may need to be undertaken once a medical device incident or event has taken place as part of the action required.

This policy will be reviewed every three years or earlier should audit results or changes to legislation/ practice within the health board indicate otherwise.

## **25. Legislation and Guidance**

- [MHRA - Managing Medical Devices - Guidance for health and social care organisations January 2021](#)
- [Health and Care Standards 2015, specifically Standard 2.9: Medical Devices, Equipment and Diagnostic Systems](#)
- [Lifting Operations & Lifting Equipment Regulations \(LOLER\) 1998](#)
- [Provision & Use of Work Equipment Regulations \(PUWER\) 1998](#)

- MHRA DB 9702 Electromagnetic Compatibility of Medical Devices with Mobile Communications
- 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 \(COSHH\) Regulations](#)
- Provision and Use of Workplace Equipment Regulations 1998 ACOP and Guidance Notice
- [Manual Handling Operations Regulations 1992 Guidance on Regulations](#)
- [WHC \(2015\) 050 Decontamination of Medical Devices](#)
- [National Audit Office \(1999\) The Management of Medical Equipment in NHS Acute Health Board organisations 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](#)
- [The Carriage of Dangerous Goods by Road Regulations 1996](#)
- [The Carriage of Dangerous Goods by Rail Regulations 1996](#)
- [The Carriage of Dangerous Goods \(Amendment\) Regulations 2019](#)
- [Chemicals \(Hazard Information and Packaging for supply\) Regulations 2009](#) This has been replaced with [Classification, Labelling and Packaging Regulations \(CLP\)](#)
- [The Radioactive Material \(Road Transport\) \(Great Britain\) Regulations 1996](#)
- Dangerous Substances and Explosive Atmospheres Regulations 2002
- The Public Services (Social Value) Act, 2012
- All Wales Policy on insurance, NHS Indemnity and related risk management for potential losses and special payments

### **Associated Health Board Policies**

- CP 023 Management and Distribution of Alerts and Safety Notices
- [FCP 021 Budgetary Control](#)
- [FTP 002 Sustainable Waste Management Procedure](#)
- [GNP 026 Prevention and Management of Pressure Damage Guidelines](#)
- [GNP 052 Subcutaneous Infusion in Adult Patients via McKinley T34 Syringe Driver](#) Updated
- [HSP 003 Manual Handling Policy](#)
- [ICP 004 Decontamination of Reusable Medical Devices](#)
- [ICP 022 Decontamination of Flexible Endoscopes SOP](#)
- [IGP 008 Records Management Policy](#)
- [CDP 004 Resuscitation Policy](#)
- [MMP 010 Safe and Secure Storage of Refrigerated Medicines and Vaccines](#)
- [RAD 002 Ionising Radiation Safety Policy](#)
- [Standing Financial Instructions](#)
- FTP008 – Environment & Sustainability Policy

## **26. Resources**

- [Medical Devices Intranet Page](#)
- [Medicines and Healthcare products Regulatory Agency \(MHRA\)](#)

## **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
- Implantable – 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 (e.g. loop systems, hearing aids)
- Environmental controls
- Orthotic and prosthetic appliances
- Patient hoists
- Pressure relief equipment
- Special support seating

- 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
- Prescribed 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 (IUD's)

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?**

- Ambulances
- General workshop equipment such as power or machine tools

- General purpose laboratory equipment
- Prefilled devices e.g. drug inhalers, syringes and certain other drug/device combinations also fall into this category