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Reference Number: UHB 082		Review Date: 31 Mar 2023
Version Number: 5		Date of Publication: 01 December 2022
 <p>Bwrdd Iechyd Prifysgol Caerdydd a'r Fro Cardiff and Vale University Health Board</p>		<p>Reference Number: UHB 082 Version Number: 5 Date of Next Review: 31 Mar 2023 Previous LHB Reference Number: UHB 082</p>
MEDICAL EQUIPMENT MANAGEMENT POLICY		

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Policy Statement

Cardiff and Vale University Health Board is required to set out a Policy for the management of Medical Equipment it deploys in the care of its patients and services users. This requirement is established by a number of national standards and regulatory bodies including the Medicines and Healthcare Products Regulatory Agency (MHRA) and is necessary to assure compliance with the Medical Device Regulations 2002 (as subsequently amended) and other relevant legislation.

The Medical Equipment Management Policy establishes a clear governance framework for the management of Medical Equipment used in the care of UHB patients and service users. The Policy and associated Procedures covers the life cycle management of all Medical Equipment in use in the UHB. It establishes a minimum set of quality standards which are applicable to all Medical Equipment irrespective of whether the Medical Equipment is owned, loaned, leased or used by commissioned external service providers.

The Medical Equipment Group (MEG) is responsible for maintaining and reviewing the Medical Equipment Management Policy and its associated Procedures. The MEG will oversee a network of Medical Device Safety Officers (MDSOs) who will have delegated responsibility for the implementation of the standards for the management of Medical Equipment contained within the Medical Equipment Management Policy and its associated Procedures.

Equipment management encompasses the whole life cycle process that applies to all equipment from critical evaluation, selection / in-house design, procurement / in-house manufacture, commissioning, training, use, maintenance, repair, upgrade, decommissioning through to final disposal. Inappropriate management of Medical Equipment at any stage of its life will lead to increased risks (unintended harm to patients, harm to professional users, statutory regulatory non-compliance, Welsh Risk Pool indemnity etc.) and poor value for money.

Cardiff and Vale UHB aims to provide the most effective Medical Equipment to support the delivery of high quality patient care and deliver the best possible health and financial outcomes. This is to be achieved by managing Medical Equipment effectively and efficiently in order to reduce risk, meet all statutory regulatory requirements, ensure that all staff and, where appropriate, patients know how to operate the equipment safely and ensure that equipment is maintained to its optimum standard. To this end, the following 15 principles will be applied:

1. Medical Equipment must be selected taking account of the following factors:
 - fitness for purpose as judged against a duly considered specification which references, where appropriate, NICE and other national evidence based standards,
 - future proofing in terms of both predicated demand and technology evolution including the impact of known disruptive technologies in that clinical sector,
 - prudent healthcare principles; Medical Equipment must be selected to support the minimum appropriate intervention agreed on the patient pathway,
 - strategic alignment including national, regional and local clinical service planning where the selection and procurement of Medical Equipment may be a strategic enabler for change,
 - known risks to sustainable delivery of high quality and affordable clinical services,
 - best life cycle value for money including whole life revenue costs (consumables, maintenance, training etc.)

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- demonstrable clinical benefits to deliver outcomes which matter to patients and service users,
- standardisation with other similar types of equipment already in use,
- the training needs of users of the equipment,
- the needs of the UHB as a teaching / training organisation and a leading research and development organisation, to include needs highlighted by strategic partnerships,
- maintenance implications, i.e. cost of maintenance, warranty terms, availability of in- house technical support, quality of support from the supplier etc.
- reliability, based on experience in this UHB and other organisations,
- any need for decontamination of the equipment and the availability of suitable decontamination facilities at the UHB,
- any implications for the UHB's IT infrastructure,
- any Estates enabling works,
- Medicines and Healthcare Products Regulatory Agency (MHRA) safety alerts, safety standards, Health & Safety Regulations and other relevant regulatory requirements and external quality accreditation standards and guidance,
- the UHB's Standing Orders, Policies and Procedures.

2. In planning for the replacement of Medical Equipment the following equipment criteria should be considered. Is the existing Medical Equipment:

- worn out beyond economic repair,
- damaged beyond economic repair,
- unreliable,
- clinically or technologically obsolete,
- supported on 'best endeavours' as spare parts are no longer available,
- unable to be cleaned effectively prior to disinfection/sterilisation.

If replacement needs are identified then the availability of better alternatives on a regional or national network level should be considered rather than 'like for like' replacement. This may also enable health system level pathway or service redesign.

3. Procurement of Medical Equipment will be undertaken via NHS Wales Shared Services Partnership (NWSSP) Procurement Services, in collaboration with the Medical Equipment users, the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to the Artificial Limb and Appliance Service (ALAS)), the Health & Safety Department, the Estates Department and others as required.

4. There must be a site visit and survey carried out before any item of Medical Equipment that will be fixed to the floor, ceiling or to a wall is ordered to ensure that there is sufficient space to use and maintain the equipment in a safe and effective manner, and that all necessary enabling works can be undertaken. This site visit must be undertaken in collaboration with the UHB's Estates Department.

5. Certain types of Medical Equipment, as designated from time to time by the Medical Equipment Group (MEG), will be 'owned' and managed corporately through the Medical Equipment Loan Service.

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<p>6. Before submitting a requisition for Medical Equipment of capital or revenue value, Directorates and Clinical Boards must seek advice from the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to the Artificial Limb and Appliance Service (ALAS)) to confirm that all aspects of clinical risk, standardisation, technical specifications and maintenance arrangements are taken into account at the start of the procurement process.</p> <p>7. Medical Equipment (whether purchased or on loan) must not be put into clinical use until it has been commissioned by the appropriate technical department or, in approved cases, by the supplier. Specific provisions apply for equipment manufactured, modified or repaired in-house (please refer to the UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure).</p> <p>8. Appropriate maintenance arrangements must be considered and agreed before Medical Equipment is put into clinical use. Where appropriate, external maintenance contracts will be technically monitored by the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to the Artificial Limb and Appliance Service (ALAS)).</p> <p>9. Professional Users must have received appropriate training and be competent, before Medical Equipment is put into clinical use.</p> <p>10. End Users of Medical Equipment must be appropriately trained and given suitable written instructions before equipment is issued to them.</p> <p>11. Records of all Medical Equipment as designated from time to time by the Medical Equipment Group (MEG), will be kept on a database held and maintained by the UHB's Clinical Engineering Department.</p> <p>12. The Clinical Engineering Department will hold a database of all Medical Equipment prioritised by risk to inform the UHB's Medical Equipment replacement programmes.</p> <p>13. Disposal of Medical Equipment must be done in consultation with the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to the Artificial Limb and Appliance Service (ALAS)) and adhere to UHB waste disposal policies and protocols.</p> <p>14. The Policy and Procedures apply to all acquisitions of Medical Equipment from whatever source, e.g. directorate budgets, capital allocation, capital schemes, Welsh Government, National Service Frameworks, lease, loan, voluntary organisations, endowment funds, charitable funding allocation, in-house manufacture, etc.</p> <p>15. This liability extends to all Medical Equipment brought onto UHB premises by external contractors. The same level of assurance must be provided through contractual arrangements for Medical Equipment used to deliver subcontracted or hosted clinical services for the population served by the UHB.</p> <p>16. The Medical Equipment Group (MEG) will maintain overarching governance of all Medical Equipment (and Devices) within the Health Board. The MEG will be chaired by the Executive(s) that is responsible for Medical Equipment (and Devices) as part of their portfolio. Ultrasound Medical Equipment will be primarily overseen by the Ultrasound Clinical Governance Group (USCGG) with any governance issues escalated to the MEG when necessary.</p>		

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Policy Commitment

Cardiff and Vale UHB is committed to adopting a standard, evidence based and systematic approach to the specification, acquisition/in-house manufacture, deployment, maintenance (preventive maintenance and performance assurance), repair and disposal of medical devices (noting that software used to inform clinical decision making may also be a medical device under relevant legislation) and Medical Equipment training.

The aim of the policy is to ensure that Cardiff and Vale UHB provides the most effective Medical Equipment support the delivery of high quality patient care and deliver the best possible health and financial outcomes and to assure compliance with relevant legislation. It sets minimum standards which are applicable across all sectors of the UHB's healthcare services and includes equipment which is deployed by partner organisations and contractors to care the UHB's patients. It also enshrines through Medical Equipment selection criteria strong alignment to UHB started and the overarching principles of prudent healthcare.

The Medical Equipment Management Policy establishes a clear framework within which the UHB can;

- Effectively and actively manage its Medical Equipment so as to reduce risk,
- Meet its legal obligations to comply with legislation,
- Meet its governance obligations, both clinical and financial,
- To the requirements of the relevant Health and Care Standards,
- Demonstrate that it is taking account of MHRA guidance,
- Meet external accrediting body quality standards covering Medical Equipment
- Report medical device adverse incidents in line with MHRA Yellow Card reporting

Supporting Procedures and Written Control Documents

This Policy, the Medical Equipment Management Procedure and the In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure describe how the UHB will discharge its duties in respect of statutory legislation and its obligations to meet external quality standards set out by health service accreditation bodies.

Other supporting documents are:

- Cardiff and Vale UHB Policies:
 - Decontamination of Reusable Medical Devices Policy
 - Safe Use of Ionising Radiation Policy
 - Safe Use of Non-Ionising Radiation Policy
 - Waste Disposal Policy
 - Ultrasound Clinical Governance and Risk Policy
- Provision and Use of Work Equipment Regulations (PUWER), 1998
- Medical Device Regulations 2002 (as subsequently amended).
- Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, January 2021.
- Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021)
- [Yellow Card | Making medicines and medical devices safer \(mhra.gov.uk\)](https://www.mhra.gov.uk/yellowcard)

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Scope

This policy applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It applies to all Medical Equipment used by Cardiff and Vale UHB services irrespective of whether the Medical Equipment is owned, loaned, leased or used by commissioned external service providers.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be a positive impact.
Health Impact Assessment	A Health Impact Assessment is not required for this policy.
Policy Approved by	Quality, Safety and Experience Committee
Group with authority to approve procedures written to explain how this policy will be implemented	Medical Equipment Group
Accountable Executive or Clinical Board Director	Director of Therapies and Health Science.

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the [Governance Directorate](#).

Summary of reviews/amendments			
Version Number	Date Review Approved	Date Published	Summary of Amendments
1			
2	15 Sep 2015	25 Sep 2015	UHB policy reviewed and updated to reflect new organisational structures and life cycle management framework for medical equipment. This is in response to the rapidly evolving regulatory landscape in which medical equipment is now used, and to keep pace with innovative, novel and emergent medical technologies. The Policy and Procedure are now contained in separate documents.
	18 April 2019	01 Jul 2019	Outcome of the review by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure that the content should remain unchanged at this time and a new review date set at 31.03.20 in order that the policy / procedure may be revised

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			in response to updated MHRA guidance due to be published in the next few months
3	25 Mar 2020	15 April 2020	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure in response to likely delay of publication of updated MHRA guidance until after the MDR 2017 full implementation date of 26 th May 2020. The Policy and Procedures will be further updated following publication of pending updated MHRA guidance.
4	17 Mar 2021	4 April 2021	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure in response to the publication of Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021) and likely introduction of Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 during 2021.
5	02 March 2022	14 April 2022	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure pending the outcome of the MHRA consultation on medical device regulation in the UK and subsequent introduction of new legislation.