Trust Policy

University Hospitals Plymouth NHS Trust

The Management and Use of Medical Devices Policy

Issue Date	Review Date	Version
May 2021	May 2026	Version 7

Purpose

This is a policy for the effective management of re-usable medical devices from purchase through to disposal. The policy identifies the key duties and responsibilities of staff in respect of the procurement, use, maintenance, repair and disposal of medical devices.

The policy also sets out the requirement for all clinical staff, who use medical devices, to have received training in the use of each device relevant to them; and where necessary, to have been assessed as competent to use them.

Who should read this document?

- All clinical staff, including senior clinicians and senior managers, because they need to be aware of their responsibilities in respect of delivering the safe use of medical devices
- All other staff, who might be required to assist in the use of medical devices, because the same responsibilities and competency requirements apply
- Relevant staff in the Human Resources & Organisational Development Directorate, because they need to be aware of their role in overseeing the provision of training in medical devices

Key Messages

- New medical devices should only be introduced to the Trust through the correct approval and procurement process
- All staff are responsible for ensuring that they are adequately trained and assessed as competent to use any medical device that they are asked to use
- Clinical managers are responsible for ensuring that all staff within their responsibility are suitably and adequately trained in the use of each medical device that they are asked to use
- All medical devices should be kept adequately maintained through a programme of planned maintenance and though prompt identification and repair of faulty devices

Core accountabilities

Owner	J. Applebee
Review	Medical Devices Strategy Group
Ratification	Medical Director / Director of Healthcare Science and Technology
Dissemination (Raising Awareness)	J. Applebee
Compliance	Medical Devices Strategy Group

Links to other policies and procedures

Clinical Engineering Medical Device Users Guide
Medical Device Training Policy
Clinical Risk Classification Scheme for Medical Devices
Management of Contamination Incidents SOP
Decontamination Guidelines and Procedures

Version History

1	Sept 2008	Written M. Webber, C. Stone
2	Oct 2010	Reviewed J. Applebee, C. Stone
3	Jan 2012	Revisions to reflect NHSLA expectations J. Applebee

4	July 2012	Revision of HR&OD Directorate name and Decon Cert version J. Applebee
5	Jan 2013	Revision to incorporate Single Use Policy and LOLER requirements J. Applebee
6	Mar 2017	Reviewed and updated J. Applebee
7	May 2021	Revision to include Information Governance, Medical Devices Regulations and updated J. Applebee

The Trust is committed to creating a fully inclusive and accessible service. Making equality and diversity an integral part of the business will enable us to enhance the services we deliver and better meet the needs of patients and staff. We will treat people with dignity and respect, promote equality and diversity and eliminate all forms of discrimination, regardless of (but not limited to) age, disability, gender reassignment, race, religion or belief, sex, sexual orientation, marriage/civil partnership and pregnancy/maternity.

An electronic version of this document is available on Trust Documents. Larger text, Braille and Audio versions can be made available upon request.

Contents

1 Introduction

Medical devices represent a substantial investment by any NHS trust. University Hospitals Plymouth NHS Trust (the Trust) currently uses over 28,000 medical devices, worth more than £87 million.

Used correctly, they will enhance the quality of care that the trust can offer. However, reliance on medical devices introduces new risks to patients and staff. Medical devices are widely used in the Trust for the diagnosis, monitoring and treatment of patients. It is essential that the use of medical devices meets relevant safety and quality standards; that they are suitable for purpose and represent value for money. Devices in use need to be maintained in a safe working condition and operated competently in accordance with required standards and procedures.

This policy covers the ownership and use of reusable and single use medical devices in the Trust. It addresses the evaluation and procurement of new equipment, training, decontamination, maintenance and repair, and arrangements for monitoring the effectiveness of controls. It applies to devices used in the care of the Trust's patients, whether they are purchased, donated, loaned, hired or leased. Throughout this document, the term medical device will be used to include equipment, apparatus and instruments unless specifically indicated otherwise.

This policy does not cover:

1. Medicines or their use.
2. Pathology / laboratory equipment or its use.
3. Surgical instruments and other equipment that is routinely processed by SDU (although the same management principles for that equipment apply)

Please refer to the appropriate Pharmacy, Pathology or SDU policies and procedures for those items.

2 Purpose, including legal or regulatory background

The Trust recognises its responsibilities as an employer to ensure that staff are competent and safe in the roles that they are performing within their work environment. The Trust has a legal and moral duty to provide adequate training in medical devices in order to minimise the risk of harm to patients, staff and the organisation through the course of its work.

The aim of this policy is to ensure that the benefits to patients from the use of medical devices are maximised and risks minimised; and to ensure that safe and best practice is applied at this Trust in relation to the management and use of medical devices.

Compliance with external regulations

This policy has been written and applied with the aim of enabling the Trust to comply with relevant legislation and guidance and in particular with the Health and Social Care Act 2008, the requirements of the Medicines and Healthcare Product Regulatory Agency (MHRA) document 'Managing Medical Devices – April 2015', IEC 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment' and the 'Medical Devices Regulations 2017' alongside other key references as detailed in Section 15.

In relation to the use of medical devices, the following regulations are also required to be addressed:

- The Provision and Use of Work Equipment (1998) regulations require all equipment to be maintained such that it is safe and regularly inspected to ensure the same.
- The Electricity at Work Regulations (1989) requires that electrical equipment is tested at regular intervals to ensure that it is electrically safe.

3 Definitions

- **Medical device** - any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used in human clinical care 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.

For the purpose of this standard, the term '**Medical device**' should be taken to include:

- active implantable medical devices
- medical devices
- in vitro diagnostic medical devices

- **Reusable medical device** – any medical device that is designed to be used on more than one patient, on more than one occasion. When the term **medical device** is used in this document it refers to **reusable medical devices** unless the term **single-use** is specifically stated.
- **Single patient use medical device** - any medical device intended to be used on an individual patient during a treatment period and then to be discarded.
- **Single use medical device** - any medical device intended to be used on an individual patient during a single procedure and then to be discarded.
- **Maintenance, servicing** – performing planned routine actions which keep the device in working order, or prevent trouble from arising. For the purposes of this policy, this excludes the everyday good practice that device operators should follow to ensure that the device remains in good working order. In this policy, the word **maintenance** is used to include **calibration** and **repair**, unless specifically stated.
- **Calibration** – setting the correctness and magnitude of measurements made by a piece of equipment against a device, or reading with the known or assigned correctness, called the standard.
- **Repair** – performing un-planned actions to make good a device, which is no longer functioning as it should.
- **Medical Equipment Library (MEL)** - implementing NPSA recommendations, a central resource of ready to use general purpose medical equipment accessible 24/7 and

manned during office hours to provide equipment distribution, collection, testing, storage and advice.

4 Overall Duties

Trust Board and Chief Executive

The Board recognises its responsibilities under the Health and Safety at Work Act 1974 and related regulations under this and other related acts for safeguarding the health and safety of its employees.

The Board is required to ensure that staff have access to appropriate education, training and supervision in the operation of medical devices. The Trust also has a duty of care to patients to ensure they are not placed at risk of harm from the inappropriate use of medical devices caused by non-competent practitioners.

Responsibility for gaining assurance that these statutory responsibilities are delivered is delegated to the Safety and Quality Committee.

The Chief Executive is ultimately responsible for ensuring that the Trust maintains adequate procedures for ensuring that, as far as possible, patients and staff are kept safe from the risk of harm from incidents involving medical devices.

Medical Director

Under delegated authorities, the Medical Director is responsible for gaining assurance that adequate arrangements are in place for the management of medical devices across the Trust. The assurance is delivered through monitoring of the record of meetings of the Medical Devices Strategy Group, the Safe Care Group and the Capital Steering Group.

Medical Devices Strategy Group (MDSG)

Reporting to the Medical Director and through the Safe Care Group and the Capital Steering Group, the Medical Devices Strategy Group (MDSG) is a Trust-wide multidisciplinary group which is formed in accordance with MHRA guidance. The key duties of the MDSG are to:

- determine the direction and priorities for current and future medical devices resourcing within the Trust, taking account of reporting from various equipment reference groups and the Trust's Rolling Replacement Programme for medical equipment.
- receive and review clinical governance, risk management and incident review reports, including Clinical Engineering audit reports

Director of Healthcare Science and Technology

Reporting to the Medical Director, is responsible for:

- reviewing the work of Clinical Engineering

Clinical Engineering

Managed by the Head of Clinical Engineering, who has overall responsibility for the service; and reporting to the Director of Healthcare Science and Technology and the MDSG, Clinical Engineering is responsible for ensuring that all medical devices are properly managed within a structured programme.

The Head of Clinical Engineering is responsible for ensuring that Clinical Engineering staff are appropriately trained and competent to provide, or administer maintenance and repair services for medical devices.

The Healthcare Science and Technology (HCST) Quality Management System ensures that all in-house technical and scientific services are accredited to industry-standards for quality management. Clinical Engineering has responsibility for:

- advising the Trust on selection, commissioning, redeployment, safe use, de-commissioning and disposal of medical equipment
- determining appropriate service and support requirements for all medical equipment
- managing the Medical Equipment Library
- providing technical support and advice to users of devices
- investigating and acting upon medical devices alerts and disseminating device related safety information to users
- responding to relevant medical devices alerts and notices, developing action plans
- investigating clinical incidents involving medical devices and reporting to MHRA if required
- contributing to clinical user training
- maintaining a computerised asset register of the Trust's medical devices
- calling upon specialist advice at any stage of the management process from within and outside the Trust as required.

Decontamination Lead

The Decontamination Lead has overall responsibility for the Sterilization and Disinfection Unit (SDU) and reports to the Director of Healthcare Science and Technology for SDU. They also report to the Deputy Chief Executive for Corporate Decontamination strategy and are an essential source of decontamination process advice for all medical devices in the Trust

Medical Devices Safety Officer

This person supports local medical device incident reporting and learning, acts as the main contact for NHS England and the MHRA and medical device manufacturers and is a member of the National Medical Devices Safety Network as required by MHRA and NHS England Patient Safety Alert NHS/PSA/D/2014/006 'Improving medical device incident reporting and learning'. They are also responsible for the reporting of adverse incidents involving medical devices to the MHRA

Patient Safety Manager

Reporting to the Head of Quality Governance, the Patient Safety Manager has responsibility for acting as the link for MHRA information through the DOH-Safety Alerts inbox. This includes distribution of Safety Notices from MHRA, manufactures and suppliers.

Clinical Directors and Department Heads

Are responsible for all relevant aspects of medical device management within their departments.

Ward and Department Managers

Are responsible for:

- ensuring that staff, under their management responsibility, who use medical devices are suitably trained and competent to do so
- informing Clinical Engineering of long term relocation of equipment

- liaising with Clinical Engineering to dispose of equipment in an appropriate manner when it is no longer required.

All Clinical Staff

All Trust clinical staff are responsible for ensuring that medical devices are used appropriately. Staff are responsible for:

- ensuring that they are adequately trained and can demonstrate competence for any medical devices that they use, or are working under direct supervision by a suitably trained person
- ensuring that the medical devices they use are in good working order, clean and safe to use
- equipment is appropriate for the patient, their condition and required treatment and suitable for the purpose (i.e. not using equipment in a manner other than that intended by the manufacturer)
- ensuring that they know where to access advice, user manuals or locally written instructions.
- reporting any incidents involving medical devices through the Trust's (Datix) Incident Reporting system, in accordance with the Trust's risk management policy.

Specific rules apply where a medical device is linked to an adverse incident, as follows:

- the device, including any accessories and consumables, should be removed from service and quarantined. It should not be decontaminated. It should be clearly labelled as being quarantined.
- the incident should be reported to the line manager and Clinical Engineering, as quickly as possible, so that investigation of the cause of the problem can begin as soon as practicable
- Clinical Engineering has initial responsibility for investigating devices involved in adverse incidents. This responsibility may involve reporting to the Medicines and Healthcare Products Regulatory Agency (MHRA) of the Department of Health. For serious adverse incidents an internal investigation will be commissioned in accordance with Trust policy.

5 Duties in Relation to Selection and Procurement of Medical Devices

General Rules

All medical device purchases shall be made in accordance with the Standing Orders and Standing Financial Instructions (SFIs) of University Hospitals Plymouth NHS Trust.

It is considered to be best practice, as far as practicable, to reduce the variety of makes and models of devices that perform the same clinical task to a reasonable minimum. This allows potential economies of scale for equipment purchases and for associated consumable items. This approach:

- reduces the cost of holding spares
- improves flexibility in management of the Trust's medical devices, including transferability of devices and trained staff between teams and departments
- reduces training costs
- reduces the risk to the patient and organisation arising from variation in the application of clinical procedures and the associated difficulties in maintaining competence and

skills

Decisions regarding the selection and procurement of medical devices are determined through the interaction of 3 disciplines fulfilling the essential functions for this process, Clinical Engineering, Procurement and the Clinical Users. Decisions are reported to the MDSG.

Specific duties include:

Clinical Engineering

is responsible for:

- operating the Trust's Rolling Replacement Programme (RRP) and producing regular progress reports for MDSG
- ensuring that all devices purchased are CE (*conformée européenne*) marked.
- Assessing the maintenance requirements of potential new medical devices to help in decision making. This process includes assessment of Pre-Purchase Questionnaires
- seeking advice from the Trust's Infection Control function and Decontamination Lead prior to the procurement of medical devices

MDSG

is responsible for:

- Monitoring and reviewing recommendations from the RRP
- Reporting RRP output to Capital Steering Group
- monitoring and reporting on requisitioning activity, by exception, through reports received from the Procurement Team.
- reviewing reports from devices sub-groups and approving, or rejecting applications for non-standard medical device requisitions

Ward and Department Managers

Are responsible for:

- identifying and prioritising the need for additional medical devices. Clinical users are requested to contact Clinical Engineering for selection advice, ahead of raising requisitions. Good practice is to define the clinical need, draw up a specification and draw up a shortlist of possible suitable equipment
- ensuring that existing and future budgets are sufficient to fund the lifetime of the proposed additional medical devices
- preparing bids for investment and submitting them to Hospital Medical Staff Committee (HMSC) and RRP
- (within their delegated authority) ordering and procuring medical devices.

Procurement

Reporting to the Director of Finance, Procurement and Performance, the Procurement Team, is responsible for:

- purchasing approved medical devices in compliance with the Trust's SFIs and policies and national guidelines
- supporting Clinical Engineering and MDSG in providing initial cost, running cost and contract information of potential new medical devices to help decision making
- safeguarding the financial and clinical impact to the Trust and recording indemnity

records.

- Clinical users are requested to contact Procurement for quotation advice, ahead of raising requisitions.

Specialist Advice

Specialist advice must be obtained to inform purchasing decisions for certain types of medical device, including the following:

- **Ionising Radiation Devices** - Advice should be sought from the Head of Clinical and Radiation Physics or the Head of Radiotherapy Physics as appropriate. Please also refer to the Ionising Radiation Safety Policy and associated procedures.
- **Non-Ionising Radiation Devices** - Advice should be sought from the Head of Clinical Measurement and Innovation
- **Point of Care Testing and Laboratory Equipment** - Advice should be sought from the Point of Care Testing team in Derriford Combined Laboratories.

Medical Devices Rented or Leased by the Trust

Medical devices may be rented to the Trust by an external supplier to fulfil a short term requirement for that device or leased to the Trust as an alternative to direct purchase. The requirement for the device may be identified by Clinical Engineering, Procurement or the clinical users. Liaison of all these parties is important to achieve the most cost effective and clinically appropriate solution to fulfil the device requirement

This includes the following duties:

Clinical Engineering

Is responsible for:

- Advising on appropriate medical devices for rental and assisting with the rental process where required
- carrying out full commissioning checks on leased medical devices
- keeping records of medical devices being leased to the Trust

Procurement

Is responsible for:

- Achieving the most cost effective rental or leasing of medical devices for the Trust
- Processing the rental or leasing requisition and order for medical devices rented or leased by the Trust

Ward and Department Managers

Are responsible for

- checking that leased equipment has been correctly accepted and commissioned before use
- notifying Clinical Engineering and Procurement when rental period has finished
- Assisting with the identification of appropriate medical devices for rent or lease

Medical Devices loaned to or trialled by the Trust

Medical devices may be loaned to the Trust by an external supplier either to fulfil a short term requirement for that device or to trial the equipment as part of a selection procedure leading to purchase.

The need to carry out clinical or user trials of medical equipment in the Trust may be identified by Clinical Engineering, Procurement or the clinical users. However all of these parties must liaise in order that the trial fully achieves its objectives.

This includes the following duties:

Clinical Engineering

Is responsible for:

- carrying out pre-use checks on loaned medical devices
- keeping records of medical devices being trialled in the Trust
- ensuring indemnity is in place before equipment use

Procurement

Is responsible for:

- recording indemnity agreement information relating to medical equipment on trial in the Trust

Ward and Department Managers

Are responsible for

- notifying Clinical Engineering and Procurement when trial or loan period has finished
- checking that equipment has been checked and indemnified before use

Trust Staff agreeing to the loan or trial of devices may find themselves personally liable for losses if they do not follow the above policy

6 Duties in Relation to the Medical Devices Asset Register

Clinical Engineering

Is responsible for:

- maintaining a computerised asset register of all medical devices, that are owned, leased or rented by the Trust, or otherwise used on Trust premises and in accommodation used, but not owned, by the Trust.
- The record will include:-
    - device details; manufacturer, model, serial number
    - financial details; supplier, purchase date, order number, initial value
    - clinical location
    - full service history
    - schedule for in-house and external planned preventative maintenance
    - external maintenance contract arrangements
    - disposal details
- labelling all medical devices recorded on the medical devices asset register with Trust identification and an asset register device number.
- monitoring the accuracy of the asset register, through periodic audits of asset location. Delivery of the role may be delegated.

Ward and Department Managers

Are responsible for (roles may be delegated):

- informing Clinical Engineering of all long-term relocations of medical devices labelled with an asset register device number
- completing an as required medical equipment inventory check in conjunction with Clinical Engineering.

7 Duties in Relation to Acceptance, Commissioning, Installation and Configuration of Medical Devices

Clinical Engineering

Is responsible for:

- taking receipt of all new medical devices received at the Trust
- completing acceptance testing on all new medical devices, in accordance with Managing Medical Devices – April 2015 before they can be put into use. Testing includes:
    - checking the received goods, support and warranties against specification
    - ensuring that devices are functioning correctly, calibrated and electrically safe
    - ensuring that servicing and support arrangements are determined
- recording all new medical devices on the asset register. Labels will be attached to all device that has been through this process to indicate the device number.
- ensuring that permanently installed medical devices are installed in compliance with the Requirements for Electrical Installations BS 7671:2018
- ensuring that devices requiring specialist installation and safety checks are installed in accordance with the relevant regulations. For Ionising Radiation Devices contact Clinical & Radiation Physics or Radiotherapy Physics and refer to the Ionising Radiation Safety Policy and associated procedures as appropriate. For Laser Equipment contact Clinical Measurement and Innovation.
- ensuring that, where devices are installed by a third party, (manufacturer or supplier), it is tested for function and electrical safety to IEC 62353:2014 before being put into use

Ward and Department Managers

Are responsible for:

- ensuring that relevant staff are given adequate training in advance of, or as soon as possible after, installation of the new equipment or introduction of new devices
- ensuring that new medical devices delivered directly to clinical areas are re-directed to Clinical Engineering for acceptance testing before use.

Staff who allow the use of medical devices that have not passed acceptance tests and/or indemnity paperwork may find they are deemed personally liable by the Trust in the event of an adverse incident involving that equipment.

8 Duties in Relation to Clinical Use of Medical Devices

All Medical Device Users

Are responsible for

- ensuring that they are appropriately trained in the clinical use of a medical device before using it on a patient
- ensuring that the appropriate medical device is being used for the clinical treatment prescribed and the device is being used as intended by the manufacturer.
- completing the required pre-testing and preparatory work before using the medical device
- ensuring that single use devices are only used once and disposed of safely after use
- ensuring that single patient use devices are only used for one patient and disposed of safely after use.

Ward and Department Managers

Are responsible for

- ensuring that their staff receive appropriate Medical Device training
- ensuring that there are appropriate medical devices available for use in the ward or department.
- ensuring that medical devices involved in clinical incidents are withdrawn from use, quarantined pending investigation and that the device number is recorded on the incident report

Clinical Education and Training

Please refer to the Trust's Medical Device Training Policy for further detail

9 Duties in Relation to Medical Devices Loaned by the Trust to Another Trust

Clinical Staff

- The requirement for equipment loans to other Trusts will be determined by clinical staff

Clinical Engineering

- All medical devices being loaned to another NHS trust must be loaned via Clinical Engineering
- Clinical Engineering must ensure that the device is safe and in full working order and if applicable decontaminated before hand over. Clinical Engineering should carry out suitable tests.
- Normal practice is for devices to be taken or sent to the equivalent Clinical Engineering team so that they can carry out the pre-use checks and paperwork for their NHS trust.
- A declaration of contamination status is required for medical devices sent via all normal transport routes.
- A service history of the medical device is provided to the receiving Trusts maintenance department at the time of the loan.

10 Duties in Relation to Information Governance of Medical Devices

Clinical Engineering

is responsible for:

- recording and reporting significant events to the device users, MDSG and Information Governance when required e.g. instances where inadequately data-cleansed medical devices are transferred for storage, use, maintenance, repair or relocation.

- for all medical devices capable of storing personal identifiable data, that this capability is recorded in the asset register device record and for each device appropriate controls are in place.

- Ensuring that during medical device disposal any personal identifiable data contained therein is either retained by the Trust or deleted in compliance with the regulations

All Clinical Staff

are responsible for:

- ensuring that they perform good records management within medical devices in relation to personal identifiable information when medical devices are transferred for storage, use, maintenance, repair or relocation

11 Duties in Relation to Decontamination of Medical Devices

Decontamination Lead

is responsibility for:

- ensuring that the decontamination of all reusable medical devices are compliant with manufacturer's instructions and are decontaminated in accordance with the Trust's Decontamination Guidelines and Procedures. This includes ensuring that compliant decontamination has taken place and a certificate of decontamination is issued at the end of life of each medical device before disposal, decommissioning, sale etc.

Clinical Engineering

is responsible for:

- reporting to the equipment users and to MDSG through the audit tool, instances where inadequately cleaned medical devices are transferred for storage, maintenance, repair or relocation

Ward and Department Managers

are responsible for:

- ensuring there is an adequate audit trail process in place for cleaning of devices: when and by whom last cleaned.

All Clinical Staff

are responsible for:

- ensuring that before returning medical devices to the Medical Equipment Library, submitting devices for corrective or preventative maintenance, fault investigation, de-commissioning or any other procedure involving service or technical personnel, the device has been appropriately decontaminated. Devices involved in adverse incidents, however, should not be decontaminated but should be quarantined to await investigation by Clinical Engineering
- ensuring that the devices are adequately cleaned and decontaminated, in accordance with the manufacturer's instructions and the Trust's Decontamination Guidelines and Procedures, before and after use.
- signing and attaching decontamination certificates to the medical device prior to its

transfer to any other location

12 Duties in Relation to Maintenance and Repair of Medical Devices

Clinical Engineering

is responsible for:

- ensuring that all medical devices are subject to an appropriate maintenance programme and that records of this process are kept. Each programme should, as far as is practicable, aim to achieve the standards recommended in the MHRA document Managing Medical Devices – April 2015, subject to an appropriate risk based assessment of the required maintenance frequency, risk profiles and manufacturer's guidance
- managing and delivering a programme of maintenance, servicing and calibration for all medical devices requiring planned preventative maintenance. Delivery of these roles may be contracted out to other service providers, such as the manufacturers, or suppliers of the devices.
- ensuring that external service and maintenance personnel called to work on medical devices are able to prove that they are appropriately trained and accredited
- ensuring appropriate external resources are called in to enable compliance with external regulations and calibration standards such as LOLER (lifting regulations for patient hoists), NAWI (calibration of weighing scales) and relevant British Standards.
- ensuring that unscheduled repairs are carried out to the required standard and in a timely manner by agreeing realistic dates and times, with ward and department managers for the devices to be taken out of commission, whilst the required maintenance is carried out.
- ensuring that before returning to clinical use, all repaired devices undergo functional and electrical safety tests.
- discuss options with department and ward managers in instances where the cost of repair exceeds a predefined level, or the repair history of the device indicates that further repair may not be advisable

Ward and Department Managers

are responsible for:

- ensuring that all equipment, including medical devices are made available for inspection and test annually or at the required frequency.
- planning, with Clinical Engineering, the most effective times for maintenance of devices to be carried out.
- arranging, where required and where possible, for substitute devices to be made available, to reduce the impact of the devices being taken out of commission whilst they are maintained.

All Clinical Staff

are responsible for:

- reporting defects in devices to Clinical Engineering, removing those devices from use and labelling them clearly as defective

Fault Reporting Procedures

Please refer to the Clinical Engineering Medical Device Users Guide for device fault reporting procedures.

13 Duties in relation to Manufacture or Modification of Medical Devices

Requests to manufacture bespoke Medical Devices or modify existing Medical devices may result from innovation or learning during clinical practice. Also modification of Medical Devices is often the action required by a Safety Notice.

Clinical Engineering

is responsible for:

- processing requests for manufacture of bespoke Medical Devices or development /modification of existing Medical Devices
- ensuring that any manufacturing or modification of Medical Devices is compliant with the Medical Devices Regulations (MDR) and associated exemptions
- carrying out or supervising modifications, updates, repairs to Medical Devices which are required by Safety Notices from MHRA or the device manufacturer

Ward and Department Managers

are responsible for:

- ensuring that any requests for manufacture of bespoke medical devices or development/modification of existing Medical Devices are referred to Clinical Engineering.
- Ensuring that Medical Devices that are subject to a Safety Notice are made available to Clinical Engineering to enable repair, modification or other actions required by the Safety Notice to be carried out.

14 Duties in Relation to Decommissioning of Medical Devices

Devices are either condemned or withdrawn because they do not meet current clinical, quality or safety standards; are unserviceable (e.g. spares no longer available); are beyond economic repair; are the subject of a safety notice; clinical procedures have changed; or they have been part of a replacement programme.

Clinical Engineering

For devices included in the medical devices asset register, the Clinical Engineering team are responsible for:

- confirming with the department, or ward manager, or budget holder that the device should be decommissioned
- arranging for appropriate and safe disposal of the device. Where relevant, this process should involve:
    - ensuring personal identifying data is appropriately managed
    - an assessment of whether the device is available for resale, or donation.
    - completion of Trust's Sale Particulars form which absolves the Trust from product liability.
    - disposal of scrap devices through the Trust's Waste Electrical and Electronic Equipment (WEEE) contractor
- updating the medical devices asset register, once disposal has been completed.

15 Overall Responsibility for the Document

The Head of Clinical Engineering is the owner of this document and the Medical Devices Strategy Group are responsible for reviewing it.

16 Consultation and Ratification

The design and process of review and revision of this policy will comply with The Development and Management of Formal Documents.

The review period for this document is set as default of five years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be reviewed by the Medical Devices Strategy Group and ratified by the Medical Director

Non-significant amendments to this document may be made, under delegated authority from the Medical Director, by the nominated owner. These must be ratified by the Medical Director.

Significant reviews and revisions to this document will include a consultation with named groups, or grades across the Trust. For non-significant amendments, informal consultation will be restricted to named groups, or grades who are directly affected by the proposed changes.

17 Dissemination and Implementation

Following approval and ratification, this policy will be published in the Trust's formal documents library and all staff will be notified through the Trust's normal notification process.

Document control arrangements will be in accordance with The Development and Management of Formal Documents.

The document owner will be responsible for agreeing the training requirements associated with the newly ratified document with the Medical Director and for working with the Trust's training function, if required, to arrange for the required training to be delivered.

18 Monitoring Compliance and Effectiveness

The Medical Director is responsible for ensuring that adequate arrangements are in place to monitor and review compliance with this policy; and that the results of these are recorded and reported appropriately.

Clinical Engineering is responsible for monitoring compliance with this policy and for reporting the results of this monitoring, by exception and through Clinical Engineering Key Performance Indicators to the MDSG and to the Medical Director. Compliance will also be subject to annual audit by the Clinical Audit department and the results of these audits reported to the Medical Devices Strategy Group for action.

The inventory of Medical Devices will be monitored each month by Clinical Engineering. additions and deletions will be reported to the Finance Department. This process will be audited by Clinical Engineering through 6 monthly internal audits and annual external audits in accordance with Clinical Engineering ISO9001:2015 Quality System

Monitoring of all aspects of device maintenance will be completed by Clinical Engineering through 6 monthly internal audits and annual external audits in accordance with ISO9001:2015 Quality System, reported through HCST Service Line Board.

Non-compliance with the Quality System will be reported through the Management Review aspects of the Clinical Engineering Operational Management Meetings and any serious non-conformances will be escalated to the Medical Device Strategy Group.

The Board will receive reports by exception.

19 References and Associated Documentation

The following documents are referred to in this policy, or are further information and guidance relevant to management of medical devices

1. Guidance about compliance. Essential standards of quality and safety. Care Quality Commission, March 2010
2. NHSLA Risk Management Handbook, 2011/12. NHS Litigation Authority, February 2011.
3. NHSLA Risk Management Standards for NHS Trusts providing Acute, Community or Mental Health & Learning Disability Services and Independent Sector Providers of NHS Care, 2011/12. NHS Litigation Authority, January 2011.
4. Risk Management Framework, Aug 2012 Version 10, Plymouth Hospitals NHS Trust
5. Clinical Engineering, Medical Device Users' Guide, March 2022 Version 7, University Hospitals Plymouth NHS Trust
6. Medical Devices Training Policy, January 2015 Version 5, Plymouth hospitals NHS Trust
7. Procurement (2006) Guidelines For The Evaluation Of Medical Devices and Technologies Plymouth Hospitals NHS Trust
8. Medical Devices Strategy Group Terms of Reference, Jan 2018, University Hospitals Plymouth NHS Trust
9. BS 7671:2018 Requirements for Electrical Installations
10. Single-Use Medical Devices: Implications and Consequences of Reuse MHRA DB2006(04) v2.0
11. Management of In Vitro Diagnostic Medical Devices MDA DB2002(02) Medical Devices Agency, London
12. Management and use of IVD Point of Care Test Devices MDA DB 2002(03) Medical Devices Agency, London
13. Reporting Adverse Incidents and Disseminating Medical Device Alerts MHRA /2004/001. Medical Devices Agency, London
14. Safeguarding Public Health: The Medical Devices Regulations: Implications on Healthcare and other related Establishments Bulletin 18. Medicines and Healthcare products Regulatory Agency (2003), London
15. Managing Medical Devices: Guidance for healthcare and social services organisations - April 2015 Medicines and Healthcare products Regulatory Agency, London

16. The Management of Medical Equipment in NHS Acute Trusts in England National Audit Office (1999), London
17. For The Record - Managing records in NHS Trusts and Health Authorities HSC 1999/53 1999 NHS Executive
18. Risk Management AS / NZS 4360:1999. Standards Association of Australia. Strathfield NSW
19. The Ionising Radiations Regulations 1999, SI 1999/3232 Stationery Office 1999 ISBN 0 11 085614 7
20. Guidance on the safe use of lasers, IPL systems and LEDs – MHRA DB 2008(03)
21. BS EN 60825-1:2007 Safety of Laser Products – Part 1: Equipment classification and requirements
22. BS EN 60825-8:2006 Safety of Laser Products – Part 8: Guidelines for the safe use of laser beams on humans
23. BS EN 60825-14:2004 Safety of Laser Products – Part 14: A user's guide
24. BS EN 207:1999 Personal Eye-Protection – Filters and eye-protectors against laser radiation (laser eye protectors)
25. BS EN 60601-1:2006 Medical Electrical Equipment, General Requirements for Basic Safety and Essential Performance
26. IEC 62353:2014 'Medical Electrical Equipment – Recurrent test and test after repair of medical electrical equipment',
27. BS EN 60601-2-22:1996 Medical Electrical Equipment Part 2: Particular requirements for safety – Section 2.122 Specification for diagnostic and therapeutic laser equipment
28. Health and Safety at Work Act HMSO 1974 ISBN 0 10 543774 3
29. Safe Use of Work Equipment, Provision and Use of Work Equipment Regulations 1998. Approved Code of Practice and Guidance L22 HSE Books 1998 ISBN 0 7176 1626 6
30. Electricity at Work Regulations 1989 SI 1989/635 HMSO 1989 ISBN 0 11 096635 X
31. UHP NHS Trust Appraisal Process
32. Training Record
33. UHP NHS Trust Incident Reporting Policy
34. Decontamination Certificate and Fault Report, Issue 6 Nov 2019, UHP NHS Trust
35. Combined Laboratories Management of Equipment, SOP M0024, version 1.4 Standard for the Medical Laboratory, Clinical Pathology Accreditation (UK) Ltd Sept 07
36. Pressure Ulcer Prevention and Management Guidance Plymouth Hospitals NHS Trust September 2007
37. Health and Social Care Act 2008 (regulated Activities) Regulations 2009
38. Lifting Operations and Lifting Equipment Regulations (LOLER) 1998
39. The EU Regulation on Medical Devices 2017/745 (MDR)

Dissemination Plan and Review Checklist | Appendix 1

Dissemination Plan	
Document Title	The Management and Use of Medical Devices Policy
Date Finalised	May 2021
Previous Documents	
Action to retrieve old copies	To be managed by the Dissemination Lead

Dissemination Plan

Recipient(s)	When	How	Responsibility
All Trust staff	May 2021	IG StaffNet Page	Information Governance Team

Review Checklist		
Title	Is the title clear and unambiguous?	Yes
	Is it clear whether the document is a policy, procedure, protocol, framework, APN or SOP?	Yes
	Does the style & format comply?	Yes
Rationale	Are reasons for development of the document stated?	Yes
Development Process	Is the method described in brief?	Yes
	Are people involved in the development identified?	Yes
	Has a reasonable attempt has been made to ensure relevant expertise has been used?	Yes
	Is there evidence of consultation with stakeholders and users?	Yes
Content	Is the objective of the document clear?	Yes
	Is the target population clear and unambiguous?	Yes
	Are the intended outcomes described?	Yes
	Are the statements clear and unambiguous?	Yes
Evidence Base	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited and in full?	Yes
	Are supporting documents referenced?	Yes
Approval	Does the document identify which committee/group will review it?	Yes
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A
	Does the document identify which Executive Director will ratify it?	Yes
Dissemination & Implementation	Is there an outline/plan to identify how this will be done?	Yes
	Does the plan include the necessary training/support to ensure compliance?	Yes
Document Control	Does the document identify where it will be held?	Yes
	Have archiving arrangements for superseded documents been addressed?	Yes
Monitoring Compliance & Effectiveness	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes
Review Date	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
Overall Responsibility	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes

Equalities and Human Rights Impact Assessment | Appendix 2

Core Information	
Date	May 2021
Title	The Management and Use of Medical Devices Policy
What are the aims, objectives & projected outcomes?	EIA not required following advice from Equality and Diversity Manager (Service)

Scope of the assessment

Collecting data	
Race	
Religion	
Disability	
Sex	
Gender Identity	
Sexual Orientation	
Age	
Socio-Economic	
Human Rights	
What are the overall trends/patterns in the above data?	
Specific issues and data gaps that may need to be addressed through consultation or further research	

Involving and consulting stakeholders				
Internal involvement and consultation				
External involvement and consultation				
Impact Assessment				
Overall assessment and analysis of the evidence				
Action Plan				
Action	**Owner**	**Risks**	**Completion Date**	**Progress update**