Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

POLICY NAME:	**MEDICAL EQUIPMENT MANAGEMENT POLICY**
POLICY ID NUMBER:	**TW10-051**
VERSION NUMBER:	**8**
APPROVING COMMITTEE:	**ESTATES AND FACILITIES DQEC**
DATE THIS VERSION APPROVED:	**November 2024**
RATIFYING COMMITTEE	**PARG (Policy Approval and Ratification Group)**
DATE THIS VERSION RATIFIED:	
AUTHOR (S) (JOB TITLE)	**MEDICAL EQUIPMENT MANAGER**
DIVISION/DIRECTORATE:	**ESTATES AND FACILITIES**
LINKS TO ANY OTHER POLICIES/PROCEDURES:	**MHRA Guidance on Managing Medical Devices (Jan 2021).** **TW10-025 Medical Devices Policy** **Medical Equipment SOP's 1 - 10**
CONSULTED WITH:	**Minor changes only – previous consultation with all divisions and relevant persons (as per policy responsibility sections).**

DATES PREVIOUS VERSION(s) APPROVED	**Version:** 3 4 5 6 7 8	**Date**: January 2011 June 2012 February 2015 August 2018 October 2021 November 2024
NEXT REVIEW DATE:		
MANAGER RESPONSIBLE FOR REVIEW (Must be Authors Line Manager)	**Head of Operational Estates**	

VERSION CONTROL

Version	Date	Amendment
8	05/12/2024	Clarifications made to existing processes: • Throughout CE amended to CE/UKCA • 4.3.5 – Appendix 1: Acceptance Certificate added. • 4.6.1.8, 4.6.2.8, 4.6.3.6, 4.6.3.12, 4.8.1.9, 8.8, 8.9 – All Added

CONTENTS PAGE

1 INTRODUCTION

1.1 The purpose of this Policy is to put systems in place which ensure that all risks associated with the acquisition and use of Medical Devices are controlled and minimised by ensuring that all devices are: -

1.1.1 Suitable for their intended purpose.

1.1.2 Properly understood by the user, so that they may be used and managed safely and effectively.

1.1.3 Maintained in a safe and reliable condition.

1.1.4 Used only for their intended purpose.

1.1.5 Procured in such a way which affords best (qualitative and quantitative) value for Wrightington, Wigan and Leigh Teaching Hospitals NHS Foundation Trust, taking whole-life costs into account.

1.2 The Trust intends to work in accordance with the guidance laid down in the Medicines and Healthcare products Regulatory Agency (MHRA) bulletin “MHRA Guidance on Managing Medical Devices (Jan 2021)”, which will be referred to in order to resolve any complex issues relating to medical devices use and management.

2 POLICY STATEMENT

2.1 The Trust attaches great importance to the health, safety and wellbeing of its staff, patients and visitors whilst fulfilling its statutory obligations within Health and Safety law.

2.2 As a means of fulfilling its obligations, the Trust and its employees have responsibility for ensuring that all medical devices owned by or loaned to the Trust comply with the appropriate codes and standards and are operated and maintained to meet the requirements of the Health and Safety at Work Act etc., MHRA Guidance on Managing Medical Devices (Jan 2021) and other MHRA documents.

2.3 The Chief Executive is the person ultimately responsible for the management of all medical devices used within the Trust and is required to establish policies and responsibilities for ensuring the appropriate management of all medical devices.

2.4 The Chief Executive has appointed the Director of Operations and Performance who has the delegated responsibility for Management of Medical Devices in the Trust.

2.5 All staff shall comply with this Management of Medical Devices Policy for the use of medical devices to the benefit of patients and staff.

2.6 This policy defines how Users and others are to act on the management of medical devices, including procurement, replacement, selection, maintenance, record keeping, training and loan of devices between departments, Users and End Users in the community. It seeks to ensure that the risk to patients and staff is kept to a minimum level possible.

2.7 It will act as the enabling Document for a range of detailed procedures with Trust wide application for the management of Medical Devices.

2.8 The Director of Operations and Performance will have direct access to the Chief Executive for matters where there may be conflict of advice and be of sufficient seniority and proficiency to be able to carry out the whole range of duties effectively.

3 KEY PRINCIPLES

3.1 The policy will apply to all medical devices whether:
- 3.1.1 Obtained via direct procurement by the Trust;
- 3.1.2 Made available by gift or loan;
- 3.1.3 When sent for repair to the Original Equipment Manufacturer, third Party agent or in-house.

3.2 The Trust requires that there be consistent and manageable approach in respect of medical devices.

3.3 The content of this policy is based on legislation and associated guidance (MHRA Guidance on Managing Medical Devices (Jan 2021); therefore, this policy is mandatory and applies to all areas of the Trust where medical devices are in use.

3.4 All Trust employees are required to adhere to the content of this policy.

4 RESPONSIBILITIES

4.1 Trust Board

- 4.1.1 The Director of Operations and Performance is the person ultimately responsible for the appropriate management of all medical devices used within the Trust and are required to establish policies, SOPs and work instructions and responsibilities for ensuring the appropriate management of all medical devices.
- 4.1.2 In view of the wide range of activities associated with effective management of medical equipment the Chief Finance Officer delegates these responsibilities to the Director of Estates and Facilities (Dir E&F).
- 4.1.3 The Decontamination Manager reports directly to the Head of Decontamination.
- 4.1.4 This provides clear and effective oversight of all aspects of medical equipment within the Trust and ensures that operational aspects of the medical devices' strategy are in place.

4.2 Director of Estates and Facilities

- 4.2.1 Chairs the Medical Equipment Management Group (MEMG) ensuring that the roles and responsibilities of the group are adhered to (Section 5.0).4.2.2 Ensures that systems are in place for the selection, procurement and record keeping of medical devices within the Trust.
- 4.2.3 Co-ordinates, with the Chief Finance Officer, regarding User submissions for funding consideration at the Capital Medical Equipment Group.
- 4.2.4 Ensures that systems are in place within Sterile Services Decontamination Unit (SSDU) for the selection, procurement and repairs of re-usable surgical medical devices. The SSDU is accredited as a Medical Device Manufacturer, and as such the Director of Estates & Facilities ensures the unit maintains and retains its accreditation with the Notified Body under the Medical Device Regulations.

4.3 Medical Equipment Manager (MEM)

- 4.3.1 Provides a technical advisory service to the Medical Devices Management Group, and all device Users, and evaluates Pre-Acquisition Questionnaires (PAQ) form.
- 4.3.2 Acts upon Medical Device Alerts from the MHRA, and the DOH guidance material.
- 4.3.3 Processes correspondence from the Health and Safety Executive in respect of medical devices.

4.3.4 Ensures written protocols for the use of each type or broad category of medical device are available for reference within the medical electronics department.

4.3.5 Arranges commissioning and undertaking of acceptance testing of all identified new medical devices (refer to TW10-051 SOP 3, Appendix 1: Acceptance Certificate).

4.3.6 Provides an emergency breakdown service throughout the Trust.

4.3.7 Acts on relevant Medical Device Alerts and guidance from the MHRA.

4.3.8 Ensures that all identified medical devices are regularly maintained by either in-house staff or external service contractors.

4.3.9 Maintains an inventory of medical devices, together with records of breakdowns, modifications etc.

4.3.10 Arranges, in accordance with TW10-051 SOP 1 (Disposal - Transfer of Ownership) the condemning and safe disposal of medical devices no longer required.

4.3.11 Ensures Medical Electronics Department in-house service personnel are appropriately trained and qualified.

4.4 **The Decontamination Manager (SSDU)**

4.4.1 Provides a technical advisory service to all reusable surgical medical device Users.

4.4.2 Acts upon Medical Device Alerts from the MHRA, and the DOH guidance material.

4.4.3 Ensures all reusable medical devices are processed in accordance with the manufacturer's guidance and work instructions.

4.4.4 Ensures written work instructions and Quality System Procedures are in place and audited for compliance.

4.5 **Procurement Department**

4.5.1 Obtain tenders and quotations in accordance with the Trusts' Standing Orders.

4.5.2 Obtain PPQ (Pre-Purchase Questionnaire) forms from potential suppliers prior to purchase and to liaise with the Medical Equipment Manager for technical evaluation.

4.5.3 Obtain assurance from respective divisions that adequate funding has been made available for the maintenance of medical equipment purchased.

4.5.4 Notify the Medical Equipment Manager of all medical devices purchased to ensure the device is made available for acceptance testing before it is introduced into service.

4.5.5 Ensure that all Medical Devices are appropriately CE/UKCA marked prior to purchase.

4.6 **User**

There are three categories of User as designated by the Chief Finance Officer who is responsible for the safe use of medical devices:

4.6.1 **Divisional Directors of Performance**

Are ultimately responsible for medical devices management and use within their division. In particular, the Chief Finance Officer is required to:

4.6.1.1 Ensure that adequate resources are made available for the procurement of medical devices and that appropriate levels of maintenance are appointed to each device. This should include maintenance contracts as appropriate.

4.6.1.2 Liaise with the Medical Equipment Manager in maintaining their internal inventories and records, as well as service contracts.

4.6.1.3 Ensure that arrangements are in place to prevent new devices being used before they have been acceptance tested/commissioned through the Medical Electronics department.

4.6.1.4 Ensure that their staff and End Users receive appropriate training in the use and day-to-day maintenance of devices supported by risk assessments and that only competent operators are allowed to use devices;

4.6.1.5 Ensure that their departments/wards maintain an inventory of the medical devices that are stored and used within those areas;

4.6.1.6 Ensure that written protocols and manufacturer's instructions are available for the use of each type of medical device and are held on the ward or department.

4.6.1.7 Ensure that the Trust has indemnity for any Loan Equipment purchased for use within the Trust. https://www.gov.uk/government/publications/master-indemnity-agreement-mia

4.6.1.8 Monitor the full life cycle of the device working together with MEM and ensure that a replacement strategy is in place for all medical equipment.

4.6.2 **Medical Device Safety Officer (MDSO)**

Is a nominated Health Care professional appointed to coordinate all aspects of medical devices incidents within the Trust that are reportable to the MHRA. The staff appointed into the role should be registered with the MHRA. The Medical Device Safety Officer role will normally be undertaken by the Medical Equipment Nurse Specialist (Quality Improvement Team) with the support of the wider Medical Equipment Management Group. The MDSO will be expected to fulfil the following duties: -

4.6.2.1 Lead and provide expert advice upon medical device management.

4.6.2.2 Support local medical device reporting across the Trust.

4.6.2.3 Ensure that lessons are learned, and Trust procedures are updated based upon evidence gathered from reported incidents.

4.6.2.4 Act as the Trust's main contact for NHS England.

4.6.2.5 Medical Device training will generally be facilitated by the Medical Device Safety Officer.

4.6.2.6 The Trust's nominated person for receiving MHRA CAS Alerts will be the Patient Safety Manager employed within Corporate Governance. All CAS Alert receipts and responses should therefore be channelled via Corporate Governance.

4.6.2.7 Report adverse incidents or suspected faults in line with Trust guidance on Managing Medical Devices (Jan 2021).

4.6.2.8 Develop and maintain a system that ensures all members of staff are competent to use medical devices appropriate to their clinical areas, including training requirements. (TW10-025)

4.6.3 **Operator**

The operator of a device is a person who has the necessary qualifications and competencies to operate and use medical devices for patient care. The Operator is required to:

4.6.3.1 Ensure that each time a device is used the identification of the operator, the device type, Equipment number and device setting is added to the patient record.
4.6.3.2 Ensure that new device settings are added to the patient's record.
4.6.3.3 Operate in accordance with approved standards and practices.
4.6.3.4 Ensure medical devices are cleaned in accordance with the Trusts' Decontamination SOP prior to sending it for service or repair.
4.6.3.5 Undertake day-to-day care and maintenance of medical devices.
4.6.3.6 Report medical equipment malfunction or any unsatisfactory performance to the Medical Electronics via Medusa Task Ordering (Fault notification) via the intranet Medusa Login. The equipment should be properly identified as faulty, removed from the clinical area, and made accessible for repair in a clean environment.
4.6.3.7 Report adverse incidents, near misses or serious untoward incidents involving medical devices to the Medical Electronics department and complete a Datix web incident report in compliance with Trust's incident reporting and investigation policy.
4.6.3.8 Make medical devices available for Planned Preventative Maintenance (PPM) on time and in a clean condition.
4.6.3.9 Keep records of devices loaned between departments,
4.6.3.10 Check device functionality, including that of alarms, and record details, whenever the device is switched on.
4.6.3.11 Only operate and carry out day-to-day maintenance of medical devices when required to do so.
4.6.3.12 Any configuration modifications or changes to the medical device are logged and reported to MEM and MDSO.

4.7 All Staff

4.7.1 All staff, but in particular managers, have responsibilities for developing strategies to foster the safe use and management of medical devices to ensure all equipment is used in accordance with the principles laid down in the MHRA guidance document "Managing Medical Devices (Jan 2021)"
4.7.2 All staff shall comply with the Medical Devices Management Policy for the use of medical devices to the benefit of patients and staff.

4.8 End User

4.8.1 End user needs to understand the intended use and normal functioning of the device in order to use it effectively and safely. And where relevant, know also,
4.8.1.1 Any limitations on use.
4.8.1.2 How to fit accessories and to be aware of how they may increase or limit the use of the medical device.
4.8.1.3 How to use controls appropriately.
4.8.1.4 The meaning of any displays, indicators, alarms etc., and how to respond to them.
4.8.1.5 Requirements for maintenance and decontamination, including cleaning.

4.8.1.6 Recognise when the device is not working properly and know what to do about it.
4.8.1.7 Understand the known pitfalls in the use of the device, including those identified in safety advice from the MHRA, manufacturers and other relevant bodies.
4.8.1.8 Understand the importance of reporting device-related adverse incidents to the MHRA.
4.8.1.9 Ensure the device has an in-date service label attached prior to use.

4.9 **Medical Equipment Management Group (MEMG)**
The scope of the Medical Equipment Management Group is to assist the Trust to deliver high quality healthcare in an effective and efficient manner by promoting systems and procedures that ensure the availability and safe use of adequate, appropriate medical equipment.

5 THE MANAGEMENT OF MEDICAL DEVICES

5.1 This section of the policy relates principally to complex, re-useable medical devices.

5.2 All managers involved in the procurement process will ensure that:
5.2.1 All new devices are CE/UKCA marked.
5.2.2 All devices are purchased with due consideration of all the issues detailed in in the (MHRA Guidance on Managing Medical Devices (Jan 2021) regarding the Equipment Life Cycle Planning.
5.2.3 All devices have practical benefits for the patients and the Trust.
5.2.4 All devices are economically sound and offer value for money.
5.2.5 All devices meet the needs of professional users.
5.2.6 All devices avoid exposing the persons or the Trust to undue or unacceptable levels of risk.

5.3 Full option appraisals for any new devices will be carried out by completing a Risk Assessment Template that relates to the safe use of work equipment, including medical equipment and devices, as required under the Provision and Use of Work Equipment Regulations (PUWER) 1998 (Refer to the Risk Assessment Template).

6 EQUIPMENT PROCUREMENT AND REPLACEMENT

6.1 The Procurement department should be the first point of contact for all new/replacement goods or services coming into the trust.

6.2 The Trust Standing Financial Instructions should be adhered to ensure compliance with EU Procurement Directives and the Trusts internal regulations.

7 EQUIPMENT PROCUREMENT AND REPLACEMENT STRATEGY

7.1 Each division will develop a three-year outline business plan (rolling programme) for the purchase of new and replacement equipment.

7.2 The Business Plan should be presented for discussion at the Capital Equipment Management Group meeting in order to develop a co-ordinated purchasing strategy and to strengthen our procurement practice.

7.3 Regardless of whether purchases are funded centrally or divisionally they will, in most cases, be centrally coordinated to ensure standardisation, quality, safety and best value.

7.4 Divisional representatives will be invited to participate in evaluations at the Medical Equipment Management Group which represents all Divisions to agree on the result.

7.5 Once suppliers/products have been selected via this route, only those products will be purchased by the Trust.

7.6 The priority replacement scoring tool as shown in Appendix 4 will assist managers to determine priorities for equipment replacement.

7.7 Items which have been placed on the Divisional or Corporate Risk Register will be considered by the Capital Equipment Management Group for purchase from funds specifically allocated for risk reduction.

7.8 Priority will be given to equipment issues which present the highest risks to the Trust and where the purchase of new/replacement equipment will significantly reduce the risks.

8 LOAN EQUIPMENT

8.1 The Trust will receive loan equipment from various routes. Long term (consignment) stock will be held within the Trust and used as appropriate with Equipment Manufacturers' instructions for use etc.

8.2 Short term loans will also be received by the Trust, where the item will be used, decontaminated, and returned to the Manufacturer.

8.3 Any items for demonstration or for loan must be accompanied with a Decontamination certificate upon arrival at the Trust, as well as upon dispatch from the Trust.

8.4 Any ex-demonstration and/or loan equipment must also be supported by documented evidence of previous servicing and maintenance performed on that item in the last 12 months.

8.5 All loan equipment must be accompanied with full instructions for use and for reprocessing.

8.6 For any equipment being loaned or prescribed to a patient to be used outside the Trust premises, please refer to Appendix 1a in Standard Operating Procedure TW10-051 SOP 2 and Section 5 - External Loans/Prescriptions to Patients/Carers.

8.7 The Trust must maintain records of devices that are loaned and must include the following information and held securely to prevent unauthorised viewing:

8.7.1 Patients details – name, address, hospital reference, telephone number and

held securely

8.7.2 Device details – device description, model number, serial number, inventory number, date loaned, date to be returned for service/replacement records of loans must be completed on the Equipment Loaned to Patients Form.

8.8 All loan equipment must be acceptance tested by the medical electronics department before being used in clinical settings.

8.9 A copy of the MIA call of agreement should be attached to all short- and long-term loan equipment on Medusa, as well as end-user files.

9 FUNDING

9.1 The budgetary responsibility for replacement of non-capital equipment (items under £5k) lies with the Divisions or Departments where the equipment will be used. Recognising however a backlog of risk related equipment replacements, a central budget may be allocated through the Capital Medical Equipment Group annually to supplement divisional capital medical equipment replacement budget schemes. Based on divisional priorities and risk assessment co-ordinated by the Capital Medical Equipment Group will determine how the funds may be spent each year. Funding of items not earmarked for central funding via this route remains the responsibility of the Division or Department where the equipment is used.

9.2 It should not be assumed that particular types of equipment will always be centrally funded, and others will always be divisionally funded. It may for example be that the Capital Medical Equipment Group agrees to fund the replacement of one or all items of a particular model which have been determined to be high risk but that thereafter routine replacement would revert to the relevant Divisions.

9.3 Where additional new items are purchased, the appropriate revenue funding for ongoing decontamination and maintenance must be identified and noted on the purchase of new equipment Risk assessment template, the Provision and Use of Work Equipment Regulations (PUWER) 1998

10 SCORING MECHANISM TO DETERMINE REPLACEMENT PRIORITIES FOR MEDICAL EQUIPMENT

All equipment can fail at any time, but the tables shown in Appendix 4 can be used to try and assess priorities for equipment replacement based on its value to the Trust and the likelihood of failure.

11 PURCHASE OF NEW EQUIPMENT - RISK ASSESSMENT TEMPLATE

The law requires the Trust to develop risk assessments for work equipment. A copy of the risk assessment template can be found alongside this Policy on the Trust's Intranet Policy Library together with guidance on how to complete it.

12 HUMAN RIGHTS ACT

Implications of the Human Rights Act have been considered in the formulation of this document and they have, where appropriate, been fully reflected in its wording.

13 INCLUSION AND DIVERSITY

The document has been assessed against the Equality Impact Assessment Form from the Trust's Equality Impact Assessment Guidance and, as far as we are aware, there is no impact on any protected characteristics.

14 MONITORING AND REVIEW

14.1 Audit: The arrangements for the monitoring and Audit of this policy and the processes therein are contained within the Monitoring and Audit Template at Appendices 6

14.2 Monitoring: The results of audits undertaken will be monitored via the Medical Equipment Management Group and provided as a report to the E&F Divisional Quality Executive Committee.

14.3 Review: This Policy will be reviewed as per the review date highlighted on the front sheet of this document or as and when changes which affect the process are introduced.

15 ACCESSIBILITY STATEMENT

This document can be made available in a range of alternative formats e.g. large print, Braille and audio cd.
For more details, please contact the HR Department on 01942 77 3766 or email equalityanddiversity@wwl.nhs.uk

Appendix 1

REFERENCES AND FURTHER INFORMATION:

Pertinent Legislation

- Health and Safety at Work etc. Act 1974
- Medical Device Regulations
- Management of Health and Safety at Work Regulations 19929 (as amended)
- Provision and Use of Work Equipment Regulations (PUWER) 1998 (as amended)
- Lifting Operations and Lifting Equipment 1998
- Workplace (Health Safety and Welfare) Regulations 1992
- Manual Handling Operations Regulations 1992
- MHRA Guidance on Managing Medical Devices (Jan 2021)
  Medicine and Healthcare Products Regulatory Agency
  Department of Health
  London
- Numerous MHRA safety notices for medical equipment and devices MHRA Safety Notices.
- MHRA Guidance - Devices in Practice a Guide for Health and Social Care Professionals
- MRHA Guidance - Equipped to Care
- MHRA Document - MDA/2007/001 Reporting Medical Device Adverse Incidents and Disseminating Medical Device Alerts
- The Clothier Report - The Allitt Inquiry

Associated Policies:

- Health and Safety Policy
- Risk Management Strategy
- Resuscitation Training Policy

Appendix 2

GLOSSARY OF TERMS

MHRA	Medicines and Healthcare products Regulatory Agency
CQC	Care Quality Commission
MEMG	Medical Equipment Management Group
MEM	Medical Equipment Manager
PPQ	Pre-purchase Questionnaire Form
DoH	Department of Health
EU	European Union
TAPs	Trainee Assistant Practitioners

DEFINITION AND EXAMPLES OF RE-USABLE MEDICAL DEVICES

The term medical device, (as legally defined in the Medical Devices Regulations), encompasses a broad range of equipment which would be too numerous to list in a document of this nature and can be defined as any instrument, apparatus, appliance, material or healthcare product, excluding drugs, used for a patient or client for the purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, or alleviation of, or compensation for, an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process
- Control of conception

The following is by no means an exhaustive list, but gives examples to illustrate the breadth of equipment covered:

Function	Examples (not definitive)
Diagnosis or treatment of disease	X-Ray machines, surgical instruments, anaesthetic machines, scanners, diagnostic laboratory equipment, glucose meters, sphygmomanometers, infusion devices, laryngoscopes, operating theatre tables.
Monitoring of patients	BP monitors, ECG monitors, pulse oximeter
Critical care	Baby incubators, blood-gas analysers, defibrillators, ventilators, haemofilters,
Improve function and independence of people with physical impairments	Hearing aids, assistive speech technology, walking aids, environmental controls, hoists, supportive seating and pressure care, wheelchairs, prosthetic appliances, spectacles, external pacemaker boxes
General and community based healthcare	Oxygen therapy equipment, pressure care systems, thermometer
Emergency services	Stretchers, patient trolleys, defibrillators, resuscitation trolley equipment

Appendix 4

SCORING MECHANISM TO DETERMINE REPLACEMENT PRIORITIES FOR MEDICAL EQUIPMENT

Value of device to the Trust /Impact of its loss (Consequence)		
Score	**Description**	**Guidelines**
5	Catastrophic	Department cannot function effectively without this equipment
4	Major	Essential tasks cannot be carried out without this equipment
3	Moderate	Important tasks may be hindered or delayed without this equipment
2	Minor	Some beneficial but non-essential tasks may be hindered or delayed without this equipment.
1	Negligible	Equipment is not or rarely used or is used only for low impact tasks.

Likelihood of permanent failure /inadvisable to continue use		
Score	**Description**	**Guidelines**
5	Almost Certain	(i) Equipment is in very poor condition and there is no possibility of repair should it fail. (ii) Equipment has been superseded by new technology and Trust is in serious contravention of accepted clinical guidelines by using this device. (iii) Equipment has been superseded by new technology that is considerably more cost-effective.
4	Likely	(i) Equipment is in reasonable condition but if it should fail there would be no possibility of cost-effective repair. (ii) Equipment can still be repaired but service history shows this device to be either no longer clinically effective or cost effective. (iii) Equipment has been superseded by new technology and new clinical guidelines are expected which will render device obsolete.
3	Possible	Equipment is very old but it might still be cost-effectively repaired, but some parts might not be cost-effective to replace should it fail.
2	Unlikely	Equipment is in good condition and should it fail cost-effective repairs are available.
1	Rare	Equipment is new.

Each piece of equipment should be given a score from each table and then the scores multiplied. Those with the highest score are the devices that should be replaced first.

E.G. if equipment is deemed important and likely to fail score would be 5 x 4 = 20

Appendix 5

NHS
Wrightington, Wigan and Leigh Teaching Hospitals
NHS Foundation Trust

Medical Equipment Inspection

Audit of Monitoring and Review Arrangements

Hospital Site: _____
Ward/ Dept being inspected: _____
Checklist Completed by: _____
Job Title: _____
Date of Completion: _____
Proposed date for review: _____

Ward Manager to sign on completion of the document:

Ward Manager Name: _____
Ward manager Signature: _____
Date: _____

Ward Safety Inspection Checklist **Appendix 6**

	YES	NO	N/A	Comments/remedial action required:	Action monitored and completed by:	Date of Completion:
1. Inventory list						
a) Do you have an equipment inventory showing all the devices being used on the ward?						
b) Do all the medical devices have an inventory reference number label attached?						
c) Do all the medical devices show an 'in-date' service label attached. ▪ **"Next Due Date"** Service date? ▪ Shows the Servicer? ▪ In-date electrical safety test label?						
2. Repairs Process						
2.1 Fault reporting system:						
a) Do you have a record of the reported faulty medical devices that is away for repair? ▪ To Medical Electronics workshop ▪ To an External Service contractor						
b) Do you have a record of a fault notification number issued by the medical equipment database based at Medical Electronics department?						
c) Do you have a decontamination requisition booklet?						

	YES	NO	N/A	Comments/remedial action required:	Action monitored and completed by:	Date of Completion:
• Do you know that you have to safely clean and decontaminate each medical device before releasing it for repair or service to the technicians? • In-house? • External service contractor?						
3. Routine Service (PPM) Process:						
a) Are you aware that you are responsible for identifying medical devices that require a maintenance regime on your unit, If so, do you: • Keep a record of all the equipment that is on contract? • Check to see if the medical device in use on your unit has an in-date service label attached? • Report all the out-of-date medical devices to Medical Electronics for attention? • Check to see if the equipment on contract does get serviced?						
b) Are you aware that you are expected to ensure that all work described in the maintenance schedule (PPM) gets carried out and monitored for quality If so, do you: • Retain and keep a copy of the service report for each medical device, on contract, that gets serviced?						

	YES	NO	N/A	Comments/remedial action required:	Action monitored and completed by:	Date of Completion:
4. Loan Equipment Process						
4.1 Equipment on Loan (on Trial or Demonstration)						
a) Do you always arrange with Medical Electronics dept. before bringing onto your unit an on-loan medical device ?						
b) Have you recently brought in an on-loan medical device onto your unit without having the medical device checked by the medical electronics dept • Trial? • Demonstration?						
4.2 Equipment on Loan to other Wards/Department						
a) Do you keep a log of all the medical device that go out on loan to other wards?						
b) If yes, could you please show us the log book?						
5. Disposal of Equipment						
a) Do you always make sure that medical devices that cannot be repaired are appropriately disposed of, to avoid the proliferation of clutter and to maximise available storage space?						

Equality Impact Assessment Form

STAGE 1 - INITIAL ASSESSMENT

Appendix 7

For each of the protected characteristics listed answer the questions below using **Y** to indicate Yes and **N** to indicate No	**Sex** (male/female/transgender)	**Age** (18 years+)	**Race/Ethnicity**	**Disability** (hearing/visual/physical / learning disability / mental health)	**Religion/Belief**	**Sexual Orientation** (Gay/Lesbian/	**Gender Re-Assignment**	**Marriage/Civil Partnership**	**Pregnancy & Maternity**	**Carers**	**Other Group**	**List Negative/Positive Impacts Below**
Does the policy have the potential to affect individuals or communities differently in a negative way?	N	N	N	N	N	N	N	N	N	N	N	
Is there potential for the policy to promote equality of opportunity for all/promote good relations with different groups – Have a positive impact on individuals and communities.	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	
In relation to each protected characteristic, are there any areas where you are unsure about the impact and more information is needed?	N	N	N	N	N	N	N	N	N	N	N	**If Yes**: Please state how you are going to gather this information.

Job Title	**Medical Equipment Manager**			**Date**	August 2021

IF 'YES an NEGATIVE IMPACT' IS IDENTIFIED - A Full Equality Impact Assessment STAGE 2 Form must be completed. This can be accessed via http://intranet/Departments/Equality_Diversity/Equality_Impact_Assessment_Guidance.asp

Please note: As a member of Trust staff carrying out a review of an existing or proposal for a new service, policy or function you are required to complete an Equality Impact Assessment. By stating that you have NOT identified a negative impact, you are agreeing that the organisation has NOT discriminated against any of the protected characteristics. Please ensure that you have the evidence to support this decision as the Trust will be liable for any breaches in Equality Legislation.

Appendix 8

POLICY MONITORING AND REVIEW ARRANGEMENTS

Para	Audit/Monitoring requirement	Method of Audit/Monitoring	Responsible person	Frequency of Audit	Monitoring committee	Type of Evidence	Location where evidence is held
15	Carry out a sample audit of the medical equipment maintenance processes on a randomly selected wards and depts. across sites as contained within appendix 5 of this Policy - TW10-051 Medical Equipment	Sample audit of both service and repair process conducted by external service contractors as well as the in-house staff	MEM	12 months	MEMG	Service reports, Work Order reports recorded on the Medical Equipment Database	Medical Equipment Database