Doncaster and Bassetlaw Teaching Hospitals
NHS Foundation Trust

Medical Devices Management and Training Policy

This procedural document supersedes: CORP/PROC 03 v 5 & CORP/RISK 02 v 6

Did you print this document yourself?
The Trust discourages the retention of hard copies of policies and can only guarantee that the policy on the Trust website is the most up-to-date version. **If, for exceptional reasons, you need to print a policy off, it is only valid for 24 hours.**

Executive Sponsor(s):	Director of Estates and Facilities
Author/reviewer: (this version)	Medical Technical Services Manager/Clinical Education Manager
Date written/revised:	October 2022
Approved by:	Medical Devices Management Group/Patient Safety Committee
Date of approval:	January 2023
Date issued:	April 2023
Next review date:	October 2025
Target audience:	Trust-wide

Amendment Form

Please record brief details of the changes made alongside the next version number. If the procedural document has been reviewed **without change**, this information will still need to be recorded although the version number will remain the same.

Version	Date Issued	Brief Summary of Changes	Author
Version 7	February 2022	• Fully revised policy – incorporating the Medical Equipment Training Policy CORP/RISK 2 v.6 into this policy • Accountability/responsibility structure included	Andrew Ferguson/Nicola Vickers
Version 6	September 2019	• References to care groups changed to divisions • Removal of the Theatre procurement group and Medical equipment management group. • Formation of the Medical Devices Management group • Revised procedures for capital business case submissions • Inclusion of a section on software • Inclusion of the Instrument Review Committee	Andrew Leverton
Version 5	November 2015	• Fully revised policy, incorporating CORP/PROC 1 v.4 - Policy for the Use of Medical Equipment Used 'OnTrial/On-Loan' and CORP/PROC 5 v.2 - Policy and Procedures for the Maintenance and Repair of Medical Devices – these are now procedures • Renamed from 'Procurement of Medical Equipment Policy' to 'Medical Devices Management Policy' • Addition of the Medical Equipment Management Group and Theatre Procurement Group • Inclusion of Software based Medical Devices	Andrew Leverton Allison O'Donnell
Version 4	June 2011	• Title change • Amendment form and contents page added. Foreword – last four paragraphs removed	

		• Flowchart - Procedure for Procurement of Items of Equipment Listed in the 'Best Buy' Guide removed • Flowchart – Procedure for Equipment Procurement for Items Not Listed in the 'Best Buy' Guide removed • Equipment Evaluation Form removed. • Form of Indemnity – A removed • Form of Indemnity – B removed • NHS Delivery Note removed • Guidance Notes for Staff for NHS Forms of Indemnity and NHS Delivery Notes removed • Guidance Procedures for the Procurement of Medical Equipment removed • Item 3 - Equipment Specification – Points f) to l) removed • Item 4 – Sourcing and Pre-Purchase Questionnaires – paragraph 4 removed • Item 5 – Business Case – 1 st paragraph changed • Item 8 – Equality Impact Assessment added. Item 9 – Monitoring of Policy added • Appendix A - Medical Equipment Flowchart - Equipment Costing > £5k added • Appendix A - Medical Equipment Flowchart – Equipment Costing < £5k added • Appendix B – Medical Equipment Purchase Form amended	

Contents

Page No.

1 INTRODUCTION 6
2 PURPOSE 6
SECTION 1 – MANAGEMENT 7
3 DUTIES AND RESPONSIBILITIES 7
4 PROCEDURE 12
4.1 Selection and Acquisition (Medical Devices) 12
4.2 Selection and Acquisition (Non-Medical Devices) 12
4.3 Standardisation of Medical Devices 12
4.4 Acceptance Testing 12
4.5 Servicing 12
4.6 Repair 12
4.7 Decontamination and Cleaning 13
4.8 Condemning and Disposal 13
4.9 Risk Management 13
4.10 Managing Adverse Incidents 13
4.11 Safety Notices and Field Safety Action Notices 13
4.12 Medical Devices on Loan or Trial to the Trust 13
4.13 Medical Devices on Loan from the Trust 13
4.14 Radiological Imaging Equipment 14
5 MEDICAL DEVICES AND SHARED SERVICES 14
SECTION 2 - TRAINING 14
6 INTRODUCTION 14
7 PURPOSE 14
8 GENERAL PRINCIPLES 15
9 DUTIES AND RESPONSIBILITIES 15
10 CATEGORIES OF USE 16
11 TRAINING/SUPPORT 17

11.1 Training 17

11.2 Recording and Monitoring 17

SECTION 3 – COMMON ELEMENTS 18

12 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT 18

13 EQUALITY IMPACT ASSESSMENT 18

14 ASSOCIATED TRUST PROCEDURAL DOCUMENTS 19

15 DATA PROTECTION 19

16 REFERENCES 20

APPENDIX 1 – LEGISLATION 21

APPENDIX 2 – NATIONAL GUIDANCE 22

APPENDIX 3 – USER TRAINING TEMPLATE DOCUMENTS 23

APPENDIX 4 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING 255

1 INTRODUCTION

"A medical device is defined by the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), as:

Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

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

(MHRA) 2021[1].

2 PURPOSE

This policy has been designed to outline a systematic approach to the procurement, deployment, use, maintenance, repair and disposal of medical devices and the training of users of medical devices. It also aims to help the Trust ensure its compliance with legislation, regulation and national guidance as outlined in the Medicines and Healthcare products Regulatory Agency (MHRA) Managing Medical Devices Guidance for Health and Social Care Organisations (2021)[1] and should contribute to the provision of quality healthcare by the Trust, the principles of which are summarised in:

- Outcome 11 of the Care Quality Commission (CQC) standards [1] CQC Regulation 15. (Appendix 2).
- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Regulation 18.

By:

- Ensuring good governance structures are in place.
- The optimisation of cost, risk and performance of medical devices.
- Developing strategies for ownership and use of medical devices.
- Identifying relevant legislation.
- Identifying sources of additional guidance.
- Providing balanced information to help local groups develop policy and procedures.

SECTION 1 – MANAGEMENT

3 DUTIES AND RESPONSIBILITIES

Chief Executive
The board member with overall responsibility for medical devices safety and management and for ensuring all staff are aware of this policy.

Medical Director (Executive Lead)
The Medical Director shall ensure that suitable arrangements are in place for the governance of medical devices that follow the guidance in the document Managing Medical Devices Guidance for Health and Social Care Organisations MHRA, (2021).

Director of Estates and Facilities
The Director of Estates and Facilities shall ensure that suitable arrangements are in place for the governance of maintenance of medical devices with the exception of those devices that come under the management arrangements of the Imaging and Cardio-Respiratory departments.

Head of Procurement
The Head of Procurement shall ensure that suitable arrangements are in place to procure medical devices in line with Trust Standing Financial Instructions (SFI), national guidance and Trust policy.

Medical Devices Safety Officer
The Medical Devices Safety Officer (MDSO) shall ensure suitable arrangements are in place to receive, record, distribute and collate data and record on actions undertaken by the Trust in accordance with Medicines & Healthcare products Regulatory Agency (MHRA) alerts and manufacturer/suppliers Field Safety Action Notices (FSAN) and to report back in appropriate timescales. Provide advice to the Trust and users on the use of medical devices.

Medical Technical Services Manager
The Head of Medical Technical Services (MTS) shall ensure that suitable arrangements are in place to ensure medical devices procured meet appropriate safety standards, are acceptance tested, maintained, condemned and disposed of following national guidance and Trust policy.

Head of Infection, Prevention and Control
The Head of Infection, Prevention and Control (IPC) ensures medical devices meet trusts standards for decontamination and cleaning and compliance to national guidelines.

Head of Radiology

The Head of Radiological Imaging shall ensure that suitable arrangements are in place to meet appropriate safety standards following national guidance and Trust policy. Also in conjunction with MTS shall ensure medical devices are acceptance tested and added to the Trusts database for medical devices asset management.

Decontamination Manager

The Trusts decontamination manager shall ensure that suitable arrangements are in place to meet the operational management and contract arrangements for the cleaning and decontamination of surgical instruments.

Authorising Engineer (Decontamination)

The Trust appointed Authorising Engineer (Decontamination ((AE) D)) shall be required to act in an advisory capacity to the Trust on matters relating to decontamination issues and compliance to national guidelines.

Approved Person (Decontamination)

The Trust appointed Approved Person (Decontamination ((AP) D)) shall be required to act in an operational capacity to the Trust on matters relating to decontamination issues and compliance to national guidelines.

Matrons

Shall ensure that all of their ward/department managers are aware of the policy. To investigate and action any incidents relating to medical equipment and escalate these incidents via the appropriate governance structure.

Heads of service/Ward Managers

- The Ward Managers/ Heads of Service are responsible for ensuring that all staff members adhere to this policy.
- Are responsible for ensuring staff carry out performance checks and routine maintenance on medical devices.
- Are responsible for ensuring medical devices are maintained in accordance with this policy, collaborating MTS to complete the process.
- They are responsible for ensuring any significant risks associated with medical equipment are identified and captured in the local risk assurance framework escalating to the corporate trust risk register as and when appropriate.
- They are responsible for maintaining a ‘medical devices’ folder where records relating to all medical devices in their department may be kept.

All staff using medical equipment

- Ensuring they are competent to use the medical device.
- Use the device in accordance with the manufacturer’s instructions.

- Ensuring that where medical equipment is found to be faulty it is taken out of use, cleaned in accordance with the Trust's Decontamination Policy and reported to Medical Technical Services promptly.
- Reporting adverse incidents involving medical equipment, these should be reported using the Trust's Incident Reporting System. Dependent on the circumstances, consideration should also be given to reporting the incident to the MHRA. Where doubt exists, advice should be sought from the Medical Devices Safety Officer.
- Storing medical equipment safely and kept ready for use. Where equipment is powered by rechargeable batteries these must have suitable charging sockets and be charged in accordance with the manufacturer's instructions.
- Single use devices must not be re-used.
- Single patient use devices may be reused on the same patient but always confirm the instructions for use as there may be a limited number of times a device maybe re-used even on the same patient.

Medical Devices Management Group (MDMG)

The purpose of the committee is to advise the trust on matters relating to the general management of medical devices used within the organisation. The committees work is based upon recommendations in the Medicines & Healthcare products Regulatory Agency (MHRA)

Managing Medical devices Guidance for healthcare and social services organisations (January 2021).

This policy will be monitored and audited on an ad-hoc basis by the MDMG as part of their assurance framework. The policy reporting and accountability arrangements are shown below:

Patient Safety Committee (PSC)

The purpose of the group is to ensure an environment which allows the "Clinical Governance Committee" to be assured that the risks associated with the delivery of clinical care are appropriately managed. The group has the operational responsibility to ensure that the impact of clinical risk is minimised within the organisation and that learning is shared across Divisions.

Medical Equipment Group (MEG)

The group headed by the Trusts Medical Director receives, reviews and approves business cases for the procurement of medical devices by whatever procurement method whose purchase cost is in excess of £5,000 inc. VAT. Membership needs to be broad enough to address all policy areas and needs.

Medical Technical Services (MTS)

Ensure that medical devices are acceptance tested, maintained, condemned and disposed of following national guidance and Trust policy.

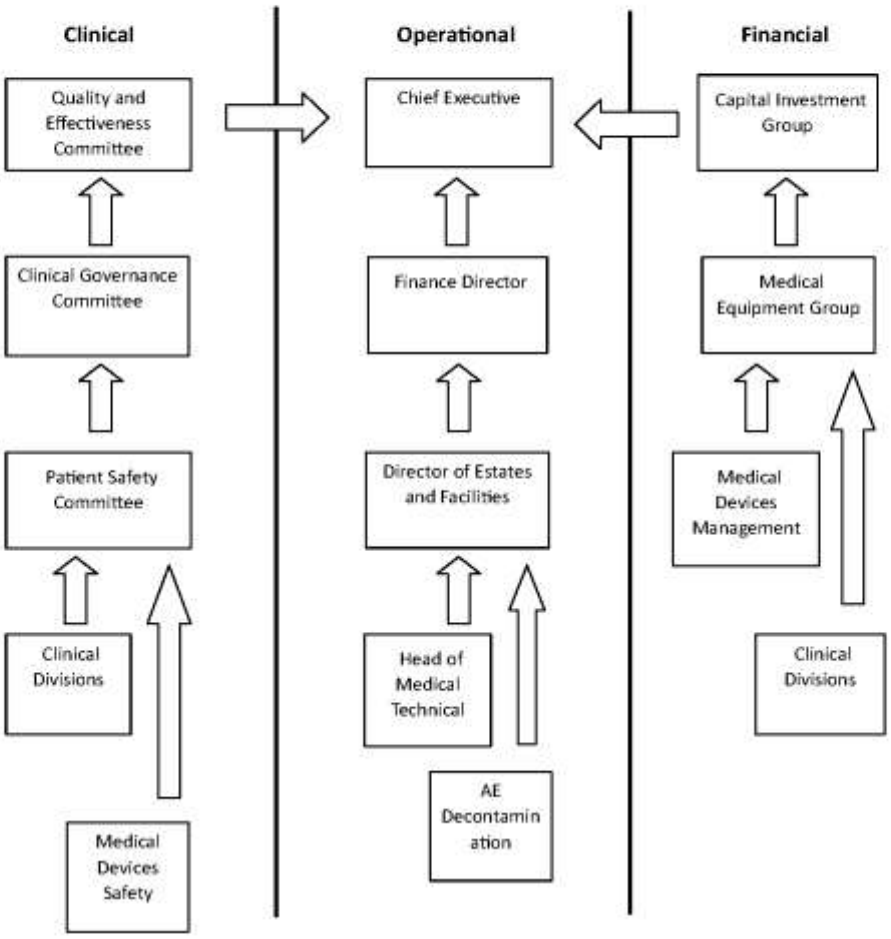
MTS shall follow any legislative requirements for the maintenance of medical devices, e.g. LOLER.

MTS have the authority to withdraw any medical device from service where it is overdue a scheduled maintenance visit and the managing department are unable to confirm that such a visit has been booked.

Digital Transformation Directorate

The Digital Transformation Directorate shall advise the Trust on the establishment of baseline security requirements recommended by the vendor and be subject to testing throughout its lifetime for medical devices. All requests for equipment which has the potential to generate and/or store Patient Identifiable Data (PID) must include the assurance that appropriate arrangements are in place to ensure confidentiality and security of that data.

Flow diagram



4 PROCEDURE

4.1 Selection and Acquisition (Medical Devices)

The procurement of medical devices shall follow the requirements of the Trusts Selection and Procurement of Medical and Surgical Products Policy.

4.2 Selection and Acquisition (Non-Medical Devices)

Staff shall follow the normal procedures for procuring medical devices and the Trust shall NOT under normal circumstances acquire and use non-registered (medical) devices in-patient treatment and care. But if this becomes necessary they shall follow the procedure outlined in the Trusts Procedure for the Procurement of Non-Medical Devices used in Patient Care.

4.3 Standardisation of Medical Devices

The Trust shall have a programme in place to allow for the standardisation of reusable medical devices, this shall follow the procedure outlined in the Trusts Procedure for the Standardisation of Reusable Medical Devices.

4.4 Acceptance Testing

Acceptance testing of new medical devices shall follow the procedure outlined in the Trusts Procedure for the Acceptance Testing of Medical Devices.

4.5 Servicing

The servicing of medical devices shall follow the procedure outlined in the Trusts Procedure for the Planned Preventative Maintenance (PPM) of medical devices.

4.6 Repair

Servicing and repair medical devices shall follow the procedure outlined in the Trusts Procedure for the Repair of Medical Devices.

The Trust shall **NOT** modify medical devices where the modification shall affect the operational performance of the device without the written authority of the manufacturer, supplier or an appropriate national agency.

4.7 Decontamination and Cleaning

The cleaning and decontamination and cleaning medical devices shall follow the procedures outlined in the Trusts Cleaning and Disinfection of ward-based Equipment Procedure and the Infection Prevention and Control Precautions Policy.

4.8 Condemning and Disposal

The condemning and disposal of medical devices shall follow the procedure outlined in the Trusts Procedure for the Condemning and Disposal of Medical Devices and the Waste Management Manual.

4.9 Risk Management

Incidents reported on the Datix system shall be dealt with as outlined in the Trusts Central Alerting System Policy.

4.10 Managing Adverse Incidents

Incidents reported on the Datix system shall be dealt with as outlined in the Trusts Central Alerting System Policy.

4.11 Safety Notices and Field Safety Action Notices

MHRA safety notices and Field Safety Action Notices (FSAN) shall be actioned as outlined in the Trust Procedure for the Management of MHRA Safety Notices and Manufacturers Field Safety Action Notices (FSAN).

4.12 Medical Devices on Loan or Trial to the Trust

The management of medical devices loaned to the Trusts from other organisations shall follow the procedure outlined in the Trusts Procedure for the Loan of Medical Devices to the Trust.

4.13 Medical Devices on Loan from the Trust

The management of medical devices loaned by the Trust shall follow the Procedure for the Loan of Medical Devices from the Trust.

4.14 Radiological Imaging Equipment

The management of radiological imaging equipment shall follow the Employer's Procedures under IR (ME) R 2017.

5 MEDICAL DEVICES AND SHARED SERVICES

Where the trust provides clinical care in partnership with another healthcare provider either on or off our sites, it shall be a requirement that a Service Level Agreement (SLA) be agreed between the parties that includes the outlining of the governance of medical devices used within the service.

SECTION 2 - TRAINING

6 INTRODUCTION

Medical devices and medical equipment play an increasingly important role in the assessment, management and quality care of patients.

Medical equipment training is an element in the fundamental care standards produced by the Care Quality Commission (CQC) (2010 and 2017) and is also a standard produced by the NHS Litigation Authority (NHSLA) (2013). These standards help promote patient care and safety, so it is essential that the training highlighted within this policy is adhered to.

The need for training depends on many factors including the device, and can involve end users, carers, professional users or other staff:

- Will it be required for all anticipated users, carers or staff?
- Will it be required for maintenance, repair and decontamination to enable staff to carry out all their duties?
- Is the same model already in use and registered on a database for medical devices?
- If so, will refresher or update training be needed?
- If not, are new training and records needed?

7 PURPOSE

Doncaster & Bassetlaw Teaching Hospitals NHS Foundation Trust will ensure that all members of staff are provided with adequate information, training and supervision as appropriate; to enable the safe use of medical equipment relevant to their role, this is in accordance with the Health and Safety at Work Act (1974).

The Trust will keep adequate records of such training and ensure that staff are aware that medical equipment **MUST NOT** be used if they are not authorised and competent to do so.

8 GENERAL PRINCIPLES

Healthcare professionals working for the organisation as employees or contractors, have a professional duty to ensure their own skills and training remain up to date. The Trust should ensure that continuous professional development and training activities include the safe use of medical devices during annual staff appraisal.

It is expected that staff shall:

- Not use equipment unless authorised and competent to do so.
- Ensure that any equipment requiring interpretation or analysis that the appropriate skills have been attained.
- Refer to own professional standards regarding accountability and competency.
- Have access to operators manual for all equipment used, be this paper or electronic format.
- Ensure that medical equipment is suitable for use.
- Be aware of any consumables related to medical equipment they use.

ALL STAFF SHOULD BE MADE AWARE AT LOCAL INDUCTION OF THEIR INDIVIDUAL RESPONSIBILITIES RELATING TO MEDICAL EQUIPMENT USAGE.

9 DUTIES AND RESPONSIBILITIES

Chief Executive
Responsible for supporting the implementation of Trust wide training to ensure that all relevant staff are aware of the policy and comply with the standards set out.

Associate Director of Nursing/Midwifery/Therapies
To ensure that divisional matrons are aware of the policy. To be informed of incidents within their division relating to medical equipment.

Clinical Directors
To ensure that all consultant teams are aware of the policy and that medical professionals complete appropriate documentation.

Matrons
To ensure that all of their ward/department managers are aware of the policy. To investigate and action any incidents relating to medical equipment and escalate these incidents to Associate Director of Nursing /Midwifery/Therapies as appropriate.

Ward/Department Managers
Responsible for ensuring that staff within the ward/department are aware of this policy. Provide support to the training co-ordinator with monitoring compliance of staff training along with sourcing training opportunities as required. Training can be arranged by contacting Medical Technical Services.

Equipment Training Link
The designated person on the ward/department who will be responsible for ensuring that the equipment folder is kept up to date.

All staff
Are responsible for only using equipment that they have been trained to use, should staff not have been trained on the equipment they should discuss with their ward manager and arrange for training prior to using the equipment.

Patient Safety Review Group
Responsible for receiving and commenting on an annual report on the status of medical equipment training. Will provide guidance and support where applicable to improve processes.

10 CATEGORIES OF USE

The ward/department manager or training link will complete a matrix of the medical equipment utilised within their area. This will indicate to staff the level of use expected from them regarding each piece of medical equipment along with the risk category assigned to that specific piece of equipment.

The categories for use are:

Level 1
- Collect equipment.
- Report faults with equipment – broken or damaged.
- Clean equipment.
- Store equipment.

Level 2
- Use the equipment.
- Identify alarms/warnings and take actions.
- Set up the equipment and conduct necessary pre checks.
- Identify consumables appropriate to use with the equipment.
- Contraindications/cautions for using the equipment.
- Report faults – as per level 1 along with any operational faults.
- They will also meet all of the criteria outlined for Level 1.

Level 3
- Train other members of staff on the equipment as they will have completed a train the trainer's session with the manufacturer
- They will also meet all of the criteria outlined for Level 2 and Level 1.

11 TRAINING/SUPPORT

11.1 Training

There are different options available for training relating to medical equipment, which staff can utilise should training needs be identified.

Manufacturers are able to attend and provide training on equipment, and there are also in house trainers available for certain pieces of medical equipment. There are some E-Learning packages available and additional packages added as they become available.

For any training needs that are identified please contact your ward/department clinical educator or Medical Technical Services who will be able to advise on the best course of action.

Staff will be expected to review the matrix compiled by their ward/department which will indicate which level of use and risk level has been identified for each piece of medical equipment and therefore what is required from staff.

For professionally registered staff the completion of a self-declaration form on ESR indicating they are competent on all the equipment and to the level specified in their ward/department folder is available. When completing this form these staff are abiding to their regulating bodies professional standards and will be alerted via ESR each time this needs to be renewed.

For non-registered staff this assessment must be completed as part of a discussion with the ward/department manager or designated accessor and once this assessment has been completed, this can be loaded onto ESR so again notifications will be sent.

Training on certain pieces of medical equipment will need to be updated, such as defibrillators and hoists and this training is included in the relevant practical training sessions.

Please note: The training requirements of staff will be identified through a learning needs analysis (LNA). Role specific education will be co-ordinated/ delivered by the topic lead. Alternatively, training may be accessed via an approved e-learning platform where available.

11.2 Recording and Monitoring

There is a medical equipment folder in each ward/department and this will include the following:

- A list of medical equipment utilised in the area.
- A list of manufacturers and contact information.
- A list of staff employed.
- Identification of the training link(s).

- Training matrix.
- Training algorithm.
- Any training records e.g. copies of certificates from e-learning, registers of any training provided etc.

ESR training records should be accessed by ward/department managers via manager self-service to monitor compliance in each area.

For students and agency staff where training is NOT captured on OLM, if they have an equipment passport this should be photocopied and kept in the equipment folder as evidence. The staff should retain the original copy and keep it with them at all times when at work.

See Appendix 5 for user training templates.

SECTION 3 – COMMON ELEMENTS

12 MONITORING COMPLIANCE WITH THE PROCEDURAL DOCUMENT

What is being Monitored	Who will carry out the Monitoring	How often	How Reviewed/ Where Reported to
Training records	Medical Devices Management Group	Annual	Ward/Department managers via Survey Monkey
Compliance with risk assessments, staff training and updates	Ward/department managers	6 months prior to annual review	EOG and divisional Governance Groups
All Medical Technical Services procedures	Medical Equipment Management Group	Every 5 years or after any changes	MEG

13 EQUALITY IMPACT ASSESSMENT

The Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that none are disadvantaged over others. Our objectives and responsibilities relating to equality and diversity are outlined within our equality schemes. When considering the needs and assessing the impact of a procedural document any discriminatory factors must be identified.

An Equality Impact Assessment (EIA) has been conducted on this procedural document in line with the principles of the Equality Analysis Policy (CORP/EMP 27) and the Fair Treatment For All Policy (CORP/EMP 4).

The purpose of the EIA is to minimise and if possible remove any disproportionate impact on employees on the grounds of race, sex, disability, age, sexual orientation or religious belief. No detriment was identified. (See Appendix 4)

14 ASSOCIATED TRUST PROCEDURAL DOCUMENTS

Alert Management System Policy.
Cleaning and Disinfection of ward-based Equipment.
Data Protection Policy.
Employer's Procedures under IR (ME) R 2017
Equality Analysis Policy.
Fair Treatment for All.
Health and Safety Policy.
Medical Gas Systems Policy.
Mobile Communications Policy.
Optical Radiation Policy.
Point of Care Testing Policy and Guidelines.
Procedure for the acceptance testing of medical devices.
Procedure for the condemning and disposal of medical devices.
Procedure for the Inspection Preventative Maintenance (IPM) of medical devices.
Procedure for the loan of medical devices from the Trust.
Procedure for the loan of medical devices to the Trust.
Procedure for the management of MHRA safety notices and Manufacturers Field Safety Action Notices (FSAN).
Procedure for the operation of the Medical Equipment Library (MEL).
Procedure for the Planned Preventative Maintenance (PPM) of medical devices.
Procedure for the procurement of non-medical devices used in patient care.
Procedure for the repair of medical devices.
Procedure for the standardisation of reusable medical devices.
Risk Identification, Assessment and Management Policy.
Selection and Procurement of Medical and Surgical Products Policy.
Standard Infection Prevention and Control Precautions Policy.
Waste Management Policy.
Waste management manual.

15 DATA PROTECTION

Any personal data processing associated with this policy will be carried out under 'Current data protection legislation' as in the Data Protection Act 2018 and the UK General Data Protection Regulation (GDPR) 2021.

For further information on data processing carried out by the trust, please refer to our Privacy Notices and other information which you can find on the trust website: https://www.dbth.nhs.uk/about-us/our-publications/information-governance/

16 REFERENCES

Hegarty, F., Amorre, J., Blackett, P., McCarthy, J., Scott, R. (2017). Healthcare Technology Management - A Systematic Approach. Boca Raton FL: CRC Press.

APPENDIX 1 – LEGISLATION

This is not an exhaustive list.

Consumer Protection Act 1987 (Consumer Safety and Product Liability).

Health and Safety at Work etc. Act (HASAWA) 1974.

Ionising Radiation (Medical Exposures) Regulations 2017 IR(ME)R.

Ionising Radiations Regulations 2017(IRR).

Management of Health and Safety at Work Regulations 1999

Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

Sale and Supply of Goods Act 1994 (Chapter 35).

The Common Law of Negligence: Law Reform (Contributory Negligence) Act 1945.

The Control of Substances Hazardous to Health Regulations 2002.

The Electrical Equipment (Safety) Regulations 1994.

The Electricity at Work Regulations 1989.

The Employers' Liability (Compulsory Insurance) Regulations 1998

The General Product Safety Regulations 2005.

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010. Regulation 16 Safety, availability and suitability of equipment.

The Lifting Operations and Lifting Equipment Regulations (LOLER) 1998.

The Pressure Systems Safety Regulations 2000

The Provision and Use of Work Equipment Regulations (PUWER) 1998.

The Waste Electrical and Electronic Equipment Regulations 2006 and the Waste Electrical and Electronic Equipment (Amendment) Regulations 2007.

Trade Descriptions Act 1968.

Unfair Contract Terms Act 1977.

APPENDIX 2 – NATIONAL GUIDANCE

Care Quality Commission (2017). Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 15. Available from: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-15-premises-equipment

[1]MHRA. (2021). Managing Medical Devices Guidance for Health and Social Care Organisations [Online]. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/982127/Managing_medical_devices.pdf [Accessed 1/5/2021].

APPENDIX 3 – EQUIPMENT TRAINING MATRIX

Site:	**Division:**	**Ward/Department:**
Date Completed:	**Name:**	**Designation:**

Device *(Please amend/add for your specific area)*	**Job Roles** *(Please amend for your specific area)*								
	Ward/Dept Managers	Registered Nurses	Nursing Assistants	Assistant Practitioners	Healthcare Assistants	House Keepers	Allied Health Professionals	Medical Staff	Service Workers
Electric Beds (state model)	Level 2	Level 2	Level 2	Level 2	Level 2	Level 1	Level 2	Level 1	Level 1
Wall Mounted Suction	Level 2	Level 2	Level 2	Level 2	Level 1	Level 1	Level 2	Level 2	Level 1
Wall Mounted Oxygen	Level 2	Level 2	Level 2	Level 2	Level 1	Level 1	Level 2	Level 2	Level 1

(Please store this record in your ward/department equipment training folder)

APPENDIX 3 – HEALTHCARE/THERAPY ASSISTANT EQUIPMENT TRAINING ASSESSMENT

Name: _____ Ward/Department: _____

Job Tile & Band: _____ Date Completed: _____

I have reviewed and understood the medical equipment training matrix for my department and the level of training expected.

Equipment Name	Level Assessed	Staff Member Signature	Assessor Signature

Declaration of assessor

I am a registered professional deemed competent to level 2 use of equipment as indicated above.

Full Name: _____ Designation: _____

(Please store this record in your ward/department equipment training folder)

APPENDIX 4 - EQUALITY IMPACT ASSESSMENT PART 1 INITIAL SCREENING

Service/Function/Policy/Project/ Strategy	Care Group/Executive Directorate and Department	Assessor (s)	New or Existing Service or Policy?	Date of Assessment
Medical Devices Management and Training Policy	Trust wide	Andrew Ferguson/Nicola Vickers	Existing	1/10/2022

1) Who is responsible for this policy? Medical Devices Management Group

2) Describe the purpose of the service / function / policy / project/ strategy? Providing guidance on the management and governance arrangements of medical devices within the Trust

3) Are there any associated objectives? Compliance to CQC and DHSC outcomes.

4) What factors contribute or detract from achieving intended outcomes? – Financial constraints may impact on delivery of intended outcomes

5) Does the policy have an impact in terms of age, race, disability, gender, gender reassignment, sexual orientation, marriage/civil partnership, maternity/pregnancy and religion/belief? Details: [see Equality Impact Assessment Guidance] - No

6) Is there any scope for new measures which would promote equality? [any actions to be taken] – No.

7) Are any of the following groups adversely affected by the policy?

Protected Characteristics	Affected?	Impact
a) Age	No	
b) Disability	No	
c) Gender	No	
d) Gender Reassignment	No	
e) Marriage/Civil Partnership	No	
f) Maternity/Pregnancy	No	
g) Race	No	
h) Religion/Belief	No	
i) Sexual Orientation	No	

8) Provide the Equality Rating of the service / function /policy / project / strategy – tick (✓) outcome box

Outcome 1 √	Outcome 2	Outcome 3	Outcome 4

If you have rated the policy as having an outcome of 2, 3 or 4, it is necessary to carry out a detailed assessment and complete a* **Detailed Equality Analysis form – see CORP/EMP 27

Date for next review: 1/10/2027

Checked by: Acting Director of Estates and Facilities **Date: 1/10/22**