The Walton Centre
NHS Foundation Trust

Medical Devices Policy

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esponsible Director:	**Director of Nursing & Governance**	
pproved by and date:	**Patient Safety Group - TBC**	**TBC**
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Target Audience:	All clinical employees with involvement in any part medical device process.	
Document Approval, History/Changes	**See Appendix 8.** For further information contact the Governance Department on [redacted]	

Think of the environment…Do you have to print this out this document? **You can always view the most up to date version electronically on the Trust intranet.**

Executive Summary

This policy has been devised to enable The Walton Centre NHS Foundation Trust (WCFT) to discharge its duties under statutory provisions. Patient, staff, and visitor safety is our priority, and we aim to reduce the likelihood of harm from the use of medical devices. This will be achieved by implementing organisational arrangements at every level to reduce identified risks to the lowest possible point as reasonably practicable.

Executive Directors and Senior Managers should be conversant with the contents of this document. Lead managers and staff should refer to Section 4 which provides detailed responsibilities and practice to be implemented.

Contents

1. Introduction

1.1.1 To discharge its duties under relevant statutory provisions, The Walton Centre Foundation NHS Trust (the trust) will provide organisational arrangements to ensure that devices provided are safe for patients, users, and staff. The trust is committed to safeguarding both patients and users from any risk that may occur while using medical equipment. The trust will effectively procure medical devices to reduce variation of similar devices and the impact on training resources and maintenance contracts.

2. Scope

2.1.1 This policy applies to all permanent, locum, agency, bank, and voluntary staff who are involved in the evaluation, selection, purchasing, commissioning, training, storage, maintenance, prescribing and disposal of medical devices either owned or hired by the trust.

3. Definitions

3.1. Medical Device

3.1.1 The term medical device's covers a broad range of products used every day throughout the trust to support the treatment and care of patients. The Medical Devices Directive [10] states any instrument, apparatus, appliance, material, or health care product (excluding drugs), used for a patient or client for the purpose 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
- Equipment where it is intended for alleviation or compensation for a disability is not classed as a medical device i.e., toileting equipment

3.1.2 End user - a patient that uses a medical device whilst unsupervised at home.

3.1.3 Electrical Bio-Medical Engineering (EBME) - EBME is a specialist service for maintenance, repair, and management of medical equipment

3.1.4 Approved Service Contractor - an external company provided with a contract by the trust to maintain and repair specific medical devices within the trust that fall out of the remit of EBME

4. Duties

4.1.1 The Quality Committee is responsible for:

- taking receipt of minutes from the Medical Devices & Facilities Group
- reviewing quarterly risk management report in relation to medical devices activity

4.1.2 The Compliance Group is responsible for:

- monitoring the action plans for evidence of compliance with Care Quality Commission (CQC) outcomes

4.1.3 Medical Devices & Facilities Group is responsible for:

- approval of this policy and underpinning arrangements
- providing assurances (including evidence) for statutory and CQC requirements
- establishing sub-groups to oversee; product evaluation and training requirements in the form of a Training Needs Analysis (TNA)
- assigning clinical risk categories to medical devices
- taking receipt and reviewing relevant medical device alerts and corresponding action plans
- taking receipt of quarterly reports from the Trust Medical Device Lead including:
    - adverse incidents relating to equipment use
    - gaps in CQC evidence
    - non-compliance with Training Needs Analysis (TNA)

4.1.4 Head of Risk is responsible for:

- providing a quarterly update report to the Medical Devices & Facilities Group
- carrying out spot checks that equipment is listed, and removed (when applicable) from the medical devices database
- formulation, standardisation, and provision of medical device competency statements to Medical Device Leads
- compiling and grouping medical devices into defined categories to:
    - Assign risk factors to medical devices using the trusts Risk Management Strategy of Low, Medium & High. The risk factors will use several inputs including, incidents (including near misses), litigation and learning from adverse events
    - Low and Medium risks - inform both the Local Training Needs Analysis (TNA) See Appendix 4
    - for High risks inform the Corporate TNA
- taking receipt of annual competency sign off from Ward/Departmental Managers
- liaising with the EBME Department in relation to medical device incidents
- investigation of medical device related incidents including a Root Cause Analysis (RCA) in line with the Trust incident Reporting Policy
- liaising with the Clinical Equipment User Library provider
- contract management responsibilities for the EBME outsourced contract

4.1.5 The EBME Manager – Currently provided by Liverpool University Hospitals NHS FT (LUHFT) – Is responsible for

- providing a maintenance, testing, calibration, and repair facility (to current legislation and industry standards) to the Trust, for medical devices agreed at purchase, and accepting medical devices into the trust
- if EBME are unable to maintain trust assets, they will provide an approved Service Contractor to facilitate this process
- maintaining a database to track and maintain medical device assets provision of:
    - maintenance schedules
    - compliance reports
    - assurances that the asset register matches products in place
    - the provision of technical support and information as necessary
- That the service is provided on the following conditions:

- Life support and other critical equipment will be given priority
- Equipment is made available for service
- EBME Manager has sufficient staff available to maintain the contract
- maintain accurate records of all calibration, including periodicities required by industry standards/manufacturers guidance within the EBME database
- provide an annual assurance report to the Procurement Manager

4.1.6 The Head of Procurement is responsible for:

- leading tender/quotation exercises and place purchase orders after Medical equipment forms and pre purchase questionnaires have been approved
- providing a comprehensive service specification
- ensuring provision is also made for manufacturer's technical updates to be sent to the EBME department this to be included in the purchase specification
- reviewing contract conditions to ensure the trust has assurances that the service is safe and provides value for money
- provision of any subsequent maintenance of an asset register
- providing Ward/Departmental Managers with dates that equipment is to be made available for maintenance

4.1.7 Ward/Department Managers are responsible for:

- the provision of adequate measures and resources to ensure medical devices are fit for purpose, maintained and available (including loan equipment to other wards See 7.1)
- keeping adequate records of reusable devices and equipment in their area not covered by the EBME department.
- completion and sign off ward/department staff competencies identified within the local TNA
- ensuring new starters complete local induction and on-going assessments regarding identified medical device competencies
- identifying and deficiencies (including existing staff) ensure training is provided and completed
- monitoring compliance with local TNA, including local induction arrangements

4.1.8 Departmental Medical Devices Lead is responsible for:

- providing a point of competence
- representing the clinical area at the Medical Devices & Facilities Group
- collating and maintaining completed competency records
- quarterly monitoring of medical devices, including verifying locations within the hospital
- informing the Contracts Manager/Trust Medical Devices Lead of any medical device that has been condemned or brought into the trust to enable the medical device database to be updated
- ensuring all staff are aware of the Clinical Equipment User Library which can be accessed through the policies and procedures section of the trust intranet
- supporting the Ward Manager in completing a training needs analysis

4.1.9 Clinical staff is responsible for:

- carrying out pre-use checks
- recording daily use checks (for high-risk equipment) see 5.6.3 below

- using medical devices safely and in accordance with manufacturer's instructions
- completion and return medical device competency checklist to manager
- maintaining skills and knowledge to work safely with identified medical device
- informing the line manager of any deficiency in knowledge
- reporting faults/out of date maintenance in accordance with section 5.6.1 and Appendix 1
- informing their line manager of any devices that remain unrepaired (if excessive time elapsed)
- Ensuring that the end user receives training for the prescribed device and is competent in its use prior to release see 5.4 below.

5. Process

5.1. Procurement

5.1.1` For an overview of the trusts lifecycle management of Medical Devices see Appendix 1.

5.1.2 The Trust procurement process is covered within the Trust Purchasing and Tendering Policy.

5.2. Equipment Trials

5.2.1 If an equipment trial is required the supplier must provide adequate indemnity insurance. The EBME contract provides support with ensuring all indemnity information is collected and in place prior to the equipment trial. Once the EBME team are contacted by the service requesting the equipment trial they will liaise with the Trust Medical Devices Lead to ensure the level of cover is sufficient.

5.2.2 Training on the trial equipment must be arranged and completed prior to the commencement of the trial. Where appropriate a competency form may need to be developed.

5.2.3 If the equipment is a physical asset that comes into direct contact with the patient a safety test must be arranged with the EBME team prior to use.

5.3. Acceptance of Medical Devices

5.3.1 On arrival into the trust all relevant medical devices are required to be delivered to the EBME department who will carry out a commissioning check to ensure safety and verify performance. All equipment will need to be checked & tested and require proof of training prior to release to the department.

5.3.2 The following devices will be commissioned internally via the specialist service contractor:

- beds
- fixed installations ceiling track hoists, hoist slings
- large devices e.g., MRI Scanner

5.3.3 A pre use check is required for for daily living equipment e.g., Zimmer frame, commodes etc. and can be provided by the EBME department.

5.3.4 For clarity the EBME department are required to attach labels to loan equipment, this will include a job number and 'do not use after' date.

5.4. Record Keeping

5.4.1 To ensure an effective maintenance and reactive repairs process record keeping is of the upmost importance. Accurate and accessible records will support device management ensuring devices are correctly identified and controlled.

5.4.2 The EBME Department is responsible for maintaining a comprehensive inventory and service history of reusable equipment under their remit. For any devices not under the remit of the EBME contract the service lead must maintain adequate records.

5.4.3 To ensure equipment can be traced, the EBME Department must be informed when equipment leaves or is returned to the Trust prior to or after a loan event.

5.5. Prescribing

5.5.1 Healthcare Professionals that prescribe medical devices must be suitably qualified and experienced to understand the function of the device and its application. Taking into consideration the needs of the user/carer prescribers must provide information about the device to the end user ensuring the following information is provided:

- The devices intended use
- Instructions for safe use of the device
- Any safety issues and/or limitations
- Any maintenance and cleaning requirements.

5.6. Decontamination

5.6.1 All medical devices must be free from contamination and if necessary sterile prior to use. All medical devices must be decontaminated by the user prior to release for maintenance or repair; this includes attaching a Yellow Label (See Appendix 2).

5.6.2 If a device cannot be decontaminated inform EBME. It is illegal to dispatch contaminated items by post.

5.6.3 A medical device must be decontaminated as soon as practicable after use, prior to service and loan to other organisations or end users. Specific guidance on decontamination can be found in the trust's Decontamination Policy.

NB: All clinical equipment should be reviewed prior to purchase to check that the Trust has the appropriate facilities, equipment, or contract to be able to decontaminate the equipment. This process will be overseen by the Trust Decontamination Group.

5.6.4 **No** clinical equipment should come into the trust without the check.

5.7. Inspection, maintenance, and repair

5.7.1. All medical devices require routine maintenance and/or calibration at a frequency recommended by the manufacturer. This may take form of checks by the user, maintenance by EBME or maintenance by a service contractor. See **Appendix 1** for process flowchart.

5.7.2. Maintenance can be provided by EBME or a service contactor. The EBME Manager will oversee the service contracts and if this is required it should be highlighted prior to purchase.

5.7.3. It is the responsibility of everyone to ensure the equipment they use is in a serviceable state prior to clinical use. This is to include the following:

- There is no visible damage to the equipment,
- Equipment passes pre use checks,
- Equipment has not reported as faulty
- The service due date hasn't expired.

5.8. Pre-inspection prior to use (new equipment)

5.8.1. The user must ensure the following checks are undertaken on any new equipment:

- The equipment is assembled correctly, calibrated and information e.g., user manual is available for future reference
- The Portable Appliance Testing or medical grade electrical safety testing is completed
- Any lifting equipment (including slings) has received a LOLER inspection, and this is recorded onto the asset register.
- Ensuring labels/asset number are attached to the device.

5.9. Daily use checks

5.9.1. The user must ensure that equipment receives a daily check prior to use ensuring the following

- There are no obvious faults if fault identified see 5.10 below
- Calibration checks are carried out (where applicable)
- Service maintenance labels are visible and in date
- Check sheets are completed for:
    - Hoists
    - Resuscitation equipment

5.10. Process for breakdown repairs

5.10.1. If a device is found to be faulty or there are any issues with the pre-use and/or the daily checks the user must carry out the following:

- Inform colleagues in the department or who are likely to use the equipment that that the device is faulty
- Take the device out of use and attach a "Yellow sticker" securely with details of fault and confirm decontamination (See Appendix 2 for reference)
- if the device has a visible asset label contact the EBME Team on [redacted] or email [redacted] to report the fault supplying the following information:
    - Location

- Biomed. ID Code e.g., WN0001
- Nature of fault (not working properly is not very helpful)
- Contact name
- When the equipment is available for repair

5.10.2. If the equipment is under maintenance arrangements with an external Service Contractor, EBME will contact and make arrangements for repair. if significant time has elapsed please escalate to the Head of Risk who will be able to support.

5.10.3. Priority for repairs or maintenance will be given to areas of acute care and clinics with waiting patients.

5.10.4. The Radiology and Neurophysiology departments will have specialist equipment where the service leads will contact the service contractor directly.

5.10.5. Bed and mattress issues are to be reported directly to the Trust specialist supplier (Medstrom) via on-line I-Tracker

5.11. Pre-Planned Maintenance (PPM) for Departments/Wards

5.11.1. For any PPM the EMBE Manager will:

- provide the Trust with an annual maintenance schedule
- circulate lists to Ward/Departmental Managers to ensure devices are available for scheduled maintenance/recalibration (where applicable)
- update records/maintenance database

5.11.2. In the event of equipment not being available for maintenance the EBME/Service Contractor will email the ward/departmental manager and arrange for a revised visit date

5.11.3. the Contracts Manager will inform the Ward/Departmental Manager/Departmental Medical Device Lead to prioritise availability and inform the Trust Medical Device Lead via a monthly report, listing equipment not maintained as per schedule

5.11.4. The trust Medical Device Lead will report this to the next available Medical Device Group for monitoring/action

5.12. Equipment returned from EBME

5.12.1. The equipment will be returned to the allocated department with adhesive “Service Tape affixed”. This shows that the equipment has gone through the EBME departments quality assurance system. This process will also notify the user that the equipment has been repaired and that function checks may be required as settings may have been altered.

5.12.2. The member of staff receiving the repaired equipment from EBME can remove the service tape then complete pre-use checks

5.13. Storage

5.13.1. Poor storage conditions can adversely affect medical devices. Ward and departmental managers must operate systems to avoid inappropriate storage of medical devices including dirty or wet storage, inappropriate temperature, physical damage etc.

5.14. Disposal

5.14.1. The reuse, resale and disposal of medical devices are covered by the MHRA guidance published in January 2021 - Managing Medical Devices. For local guidance please refer to the Trust Asset Disposal Policy and Appendix 5 for Disposal Form.

5.15. Replacement of equipment

5.15.1. A device will not be considered serviceable if any of the following apply:

- The equipment is worn or damaged beyond economical repair
- The equipment is unreliable
- The equipment is clinically or technically obsolete
- Spare parts no longer available
- The equipment cannot be cleaned effectively
- The equipment is subject to MHRA Issued Medical Device Alert manufacture recommends removal from use

5.15.2. In the occasion that any of the conditions identified in 5.15.1 are relevant the EBME department will issue a Condemnation Note to the user/department.

5.15.3. The Capital Monitoring Group monitors the life span and replacement date of high value equipment. A business case is required for replacement of high value medical devices and equipment.

5.16. Loan Equipment - Internal Loans

5.16.1. The service that receives borrowed equipment is responsible for the suitability and condition of the medical device/equipment.

5.16.2. The individual who uses the borrowed equipment must be competent in its use.

5.16.3. The Ward/Departmental Manager is responsible for ensuring that the equipment is recalled for routine maintenance/servicing whilst out on loan.

5.16.4. It is the responsibility of the service to ensure that a record is kept of any equipment that is loaned to another service. This ensures both that the location of the equipment is always known and that the responsibility for it is transferred at time of the loan. Managers should review the items out on loan on a regular basis to ensure that equipment that is no longer in use is returned to the original owner, this includes ensuring that the medical device database is updated.

5.17. Loans Equipment - To Carers/End Users

5.17.1. For any equipment that is loaned to patients/carers on discharge from hospital as part of their on-going care needs, or as part of their outpatient treatment: several considerations must be taken into account:

- The general health and mental state of the patient and/or carer
- The sensory capabilities of the user: vision, hearing, touch
- The co-ordination: manual dexterity
- The cognitive ability and memory
- The patient/carer expectations about the device will operate
- The physical environment in which the device will be used and others who might have access to it
- The patient/carer awareness of their responsibility to look after and monitor the equipment issued to them and to return NHS owned devices on completion of their treatment
- That the equipment is returned promptly after use

5.18. Written guidance for end users

5.18.1. Before a medical device is issued to a patient or carer they should receive training in how to use the device. This should be supported by written guidance. The manufacturer's instructions should provide some information, but this should be tailored to the needs of the individual patient or carer. Written guidance should cover the following:

- The name of the device
- The operation and control of the device
- How to check the device while in use
- How to recognise a device failure or fault
- What action is to be taken in the event of a device failure or fault
- What individuals are to be contacted in an emergency

5.18.2. This guidance is provided to the user by the specialist nurse/therapist or the discharging nurse.

5.19. Record Keeping

5.19.1. Accurate records of any loans to outside agencies/ end users/ carers are essential; these dates must include:

- Name and address of the person receiving the medical device
- A Signature certifying receipt of the device and instructions in its use
- Start date of the loan
- End date of the loan

5.20. Single Use Equipment

5.20.1. Some medical devices are designated (see sign below) by the manufacturer as "single use" and are identified with the symbol either on the device or the packaging. Devices with this designation may be either, unsuitable for sterilisation or decontamination due

to their materials or construction or be insufficiently robust to withstand more than one use.

5.20.2. All single use equipment should only be used for one procedure, prior to disposal.

5.20.3. Certain equipment may state “single patient use” e.g., slide sheet, sling, these devices can be used more than once, if it is used on the same patient.

5.21. Adverse Incidents

5.21.1. An adverse incident involving a device should be reported via the Datix incident reporting form, for detailed guidance please see the trust “Incident Reporting Policy”.

5.21.2. The following apply for any devices involved in an incident:

- The device should be quarantined
- The devices settings should not be altered
- Single use items should be retained

5.22. Training

5.22.1. Radiographers employed at WCFT understand the capability, applications and range of technological equipment used in the department and can check that equipment is functioning accurately and within the specifications, and to take appropriate action in the case of faulty functioning and operation. Competency forms are completed on an annual basis. They will complete trust competency forms for equipment such as hoists.

5.22.2. The Trust training process is identified in Appendix 3 and includes training needs analysis for low and medium risk medical devices.

5.22.3. During the Local Induction period the Ward/Departmental Manager will ensure:

- the relevant medical devices competencies are completed, and training provided if required
- Medical device introduction is attended (within the Trust Corporate Induction)
- Local induction checklist is completed and returned to the T&D Department in line with the Trusts Induction & Mandatory Training Policy.
- All medical device competencies can be accessed via the intranet.

5.22.4. All ward/departmental managers or medical devices lead on an annual basis will ensure that all medical device competencies are up to date and to identify and gaps in knowledge of their staff. If any gaps are identified they will be required to arrange training.

5.22.5. During the yearly Personal Development Review (PDR) process, Line Managers should review the training record of each member of staff to verify that their training is up to date on all the Medical Devices they use as part of their role.

6. Monitoring

6.7. Maintenance of Medical Devices and Equipment

Minimum Requirement To Be Monitored	Frequency	Process for monitoring	Responsible individual	Responsible group for review of results	Responsible for development of any action plans	Responsible for monitoring of any action plans and implementation
Maintenance of Medical Devices and Equipment						
Duties	Annually	Review of Policy	Head of Risk	Medical Devices & Facilities Group (MDFG)	MDFG	MDFG
How the organisation includes all items of diagnostic and therapeutic equipment on an inventory	Annually	Audit	As above	MDFG	MDFG	MDFG
How reusable diagnostic and therapeutic equipment is maintained	Annually	Audit	As above	MDFG	MDFG	MDFG
How reusable diagnostic and therapeutic equipment is repaired	Annually	Audit	As above	MDFG	MDFG	MDFG
Medical Device Training						
Duties	Annually	Review of Policy	Head of Risk	MDFG	MDFG	MDFG
How the organisation includes all items of diagnostic and therapeutic equipment on an inventory and records disposal	Annually	Audit	As above	MDFG	MDFG	MDFG
How the organisation identifies which permanent staff are authorised to use the equipment listed on the inventory	Annually	Audit	As above	MDFG	MDFG	MDFG
How the organisation decides the training required	Annually	Audit	As above	MDFG	MDFG	MDFG
How the organisation decides the frequency of updates required	Annually	Audit	As above	MDFG	MDFG	MDFG
How the organisation records that all permanent staff complete training	Annually	Audit	As above	MDFG	MDFG	MDFG
How the organisation follows up those who do not complete training	Annually	Audit	As above	MDFG	MDFG	MDFG
Action to be taken in the event of persistent non-attendance	Annually	Audit	As above	MDFG	MDFG	MDFG

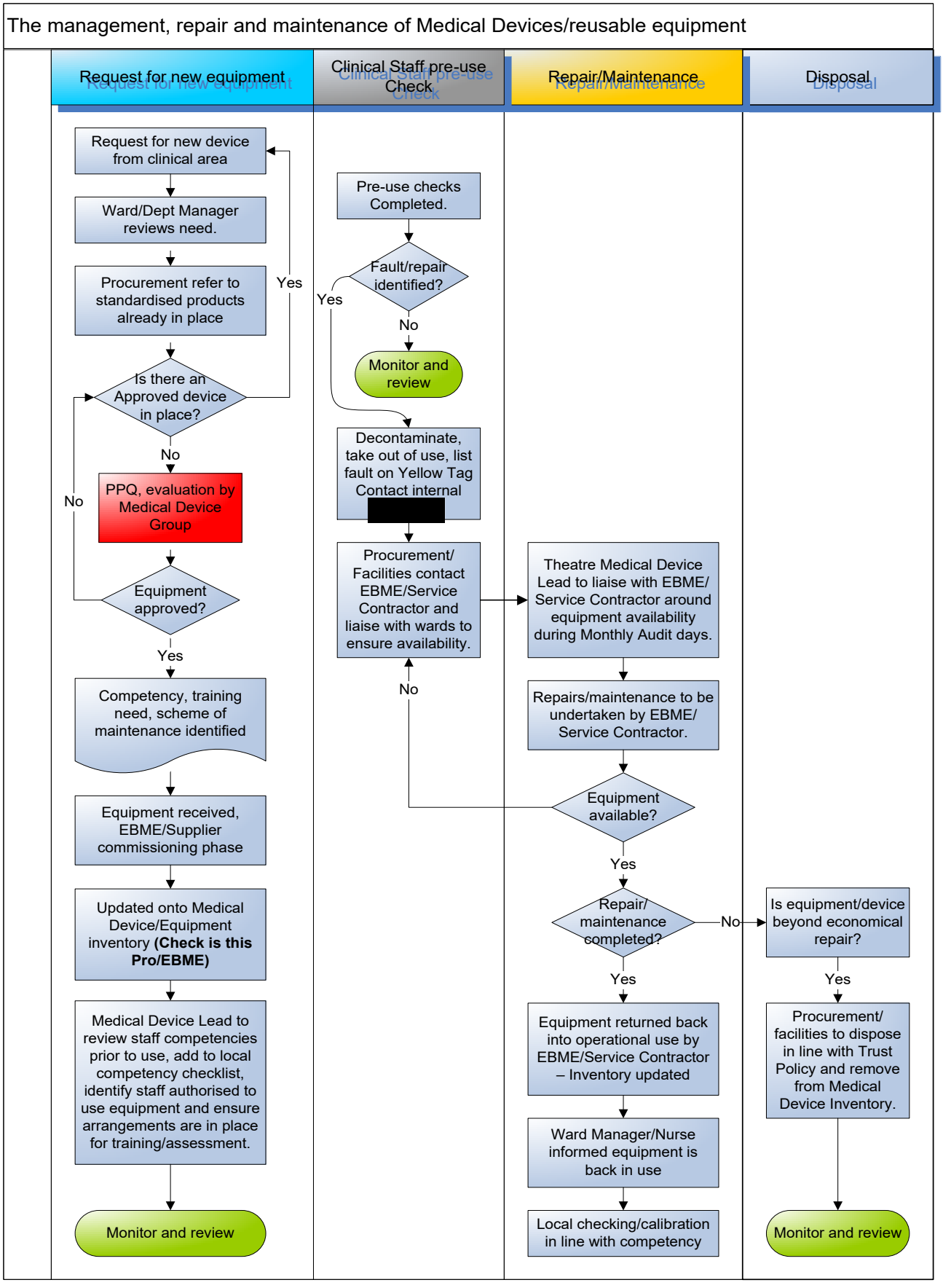
7. References

- Health & Safety at Work Act 1974
- Management of Health & Safety at Work Regulations 1999
- Electricity at Work Act 1989
- Provision and Use of Work Equipment Regulations 1998
- Lifting Operations and Lifting Equipment Regulations 1998
- Control of Substances Hazardous to Health 2002 (as amended)
- Medical Device Regulations 2002
- Waste Electrical and Electronic Equipment (WEEE) Regulations 2006
- Managing Medical Devices – MHRA January 2021
- Service Specification
- CQC Essential Standards - Reg 16 - Outcome 11
- Health & Social Care Act 2008 Regulated activities

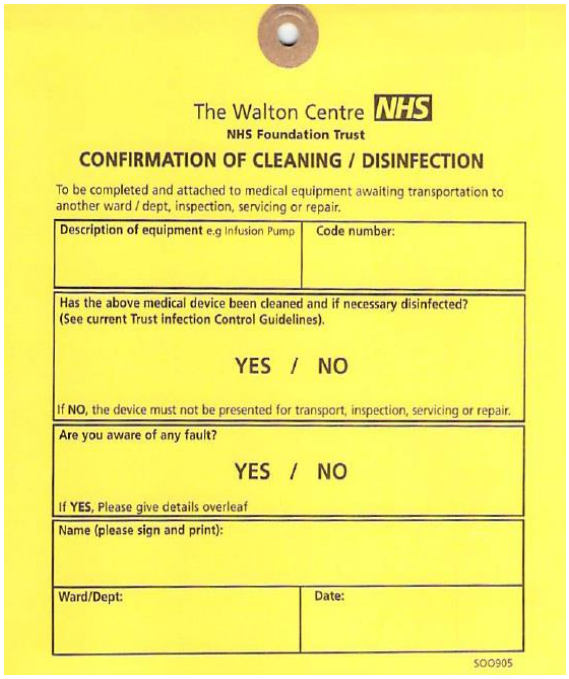
7.7. Supporting policies

- Decontamination Policy.
- Health & Safety Policy
- Incident Reporting Policy

Appendix 1 - Process for lifecycle Management of Medical Devices



Appendix 2 - Fault reporting form (Yellow Tag)



The Walton Centre NHS
NHS Foundation Trust

CONFIRMATION OF CLEANING / DISINFECTION

To be completed and attached to medical equipment awaiting transportation to another ward / dept, inspection, servicing or repair.

Description of equipment e.g Infusion Pump	Code number:

Has the above medical device been cleaned and if necessary disinfected?
(See current Trust infection Control Guidelines).

YES / NO

If **NO**, the device must not be presented for transport, inspection, servicing or repair.

Are you aware of any fault?

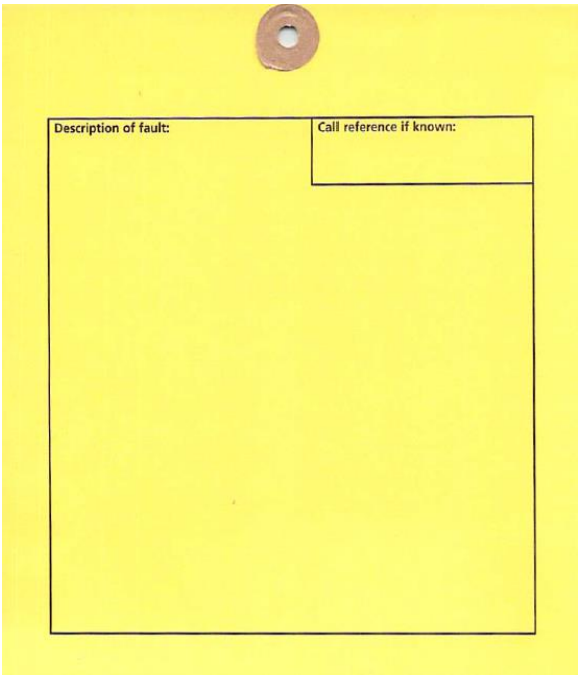
YES / NO

If **YES**, Please give details overleaf

Name (please sign and print):

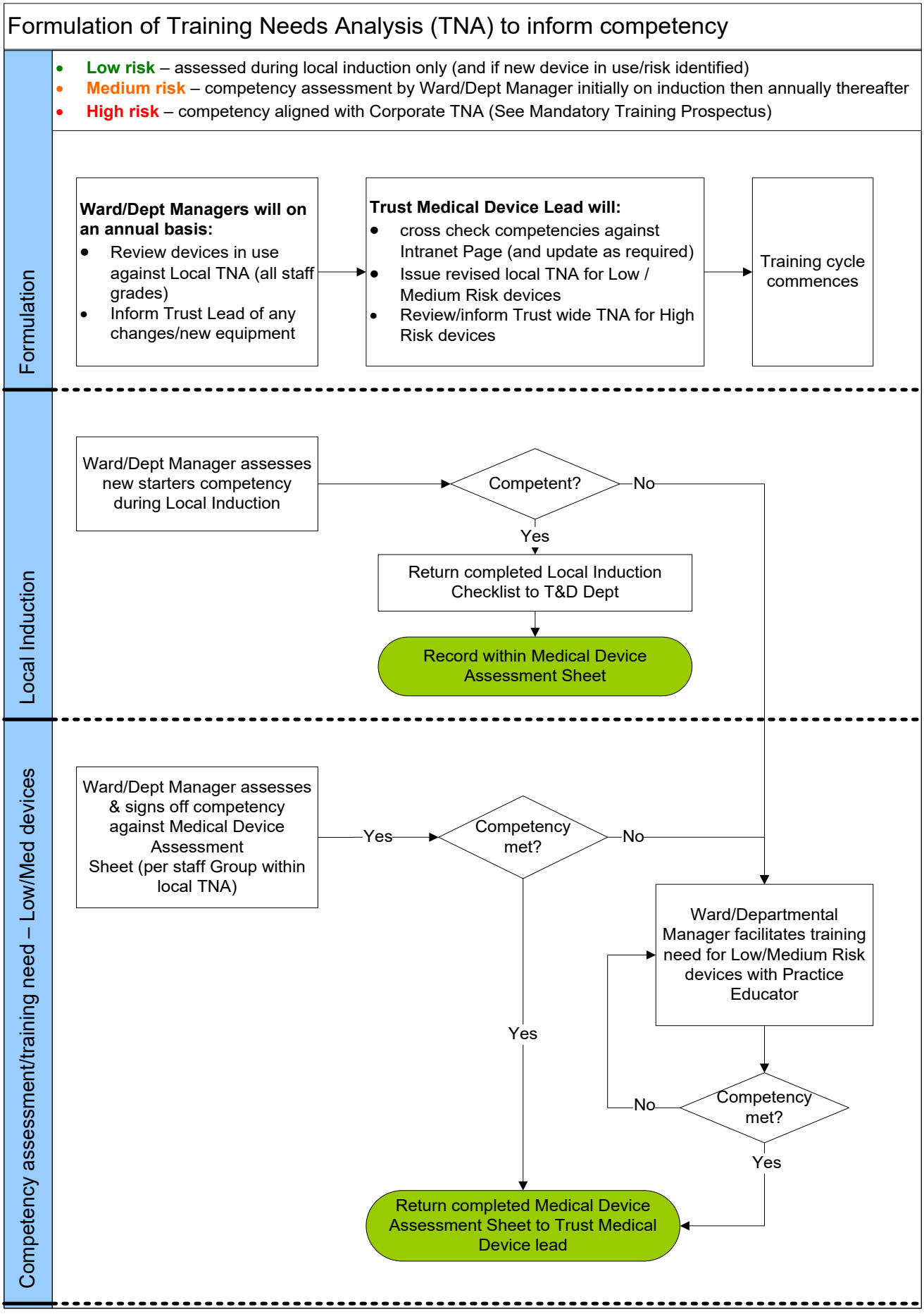
Ward/Dept:	Date:

SOO905



Description of fault:	Call reference if known:

Appendix 3 - Training Needs Analysis Process



Appendix 4 - Medical Device Training Needs Analysis

							Nursing Staff		Medical Staff		Allied Health Care Professionals				Additional Clinical Services				
Device risk factor	**Delivery/assessment method**	**Update**	**Reviewer**	**Training**	**Exec Lead & Operational Lead**	**Driver**	Registered Nurses Matrons/Nurse Specialists	HCA/TAP	Consultants	Medical Staff in Training	Physiotherapists/Assistants	Occupational Therapists/Assistant	Radiographers	Radiographic Aides	Neurophysiology Technicians	Neuropsychology	ODP's	Biomedical Scientists & Lab Assistants	Housekeepers
All devices	Corporate Induction	One off	T&D for attendance only	Presentation on medical devices	Director of Nursing/Dep Director of Governance	Medical Devices Regulations 2002	√	√	*	*	√	√	√	√	√	NA	√	√	NA
Low	Self-assessment at Local Induction	One off	Ward/ Dept Mgr./Clinical Supervisor	NA - unless gap identified in competency. Reviewer to arrange and record training update.			√	√	*	*	√	√	√	√	√	NA	√	√	NA
Medium	Competency assessment against local TNA (Medium risk devices)	Annual	Ward/ Dept Mgr./Clinical Supervisor	NA - unless gap identified in competency. Reviewer to arrange and record training update.			√	√	*	*	√	√	√	√		NA			NA
High	Competency assessment aligned with subjects within Corporate TNA	Annual	Resuscitation, Manual handling Monitoring	Mandatory training			√	√	NA	NA	√	√	√	√		NA			NA
High	Competency assessment aligned with subjects within Corporate TNA	Three yearly	Infusion	Mandatory training (NPSA Study Day)			√	NA	NA	NA	√	√	√	√					

* The Medical Education Group have agreed that these staff are deemed competent via professional training.

Appendix 5 - Condemnation Form

The Walton Centre NHS
NHS Foundation Trust

Transfer / Disposal / Condemnation of Equipment Certificate*
***Please delete accordingly**

Description of Equipment		Finance use only
Model No. Serial No. Asset No.		Asset ID:
Estimated Replacement Cost		
Estimated residual value		
Approx. age of equipment		
Current Location of Equipment Department Room No		
Transferred to Department Room No		
Specific Reason for Condemnation (delete accordingly)	Unsafe to use Beyond economical repair No spares available Other (please specify)	Removed Year & Qtr.
Disposal to be arranged by		

Authorised by (print) Designation:	Signature	Date
Certified by (print) Director / Deputy Director of Finance	Signature	Date

Appendix 6 - Equality Impact Assessment (EIA) Form

The Walton Centre NHS Foundation Trust

This section must be completed at the development stage i.e., before ratification or approval. For further support please refer to the EIA Guidance on the Equality and Diversity section of the Intranet.

Part 1

1. Person(s) Responsible for Assessment: [redacted] 2. Contact Number: See cover sheet

3. Department(s): See cover sheet 4. Date of Assessment: December 2021

5. Name of the policy/procedure being assessed: Medical Devices

6. Is the policy new or existing?

New Existing

7. Who will be affected by the policy (*please tick all that apply*)?

Staff Patients Visitors Public

8. How will these groups/key stakeholders be consulted with? Via Medical Devices and Facilities Group and Heads of Department

9. What is the main purpose of the policy? See section 1

10. What are the benefits of the policy and how will these be measured? See monitoring section.

11. Is the policy associated with any other policies, procedures, guidelines, projects, or services? See section 12.1

12. What is the potential for discrimination or disproportionate treatment of any of the protected characteristics? *Please specify specifically who would be affected (e.g., patients with a hearing impairment or staff aged over 50). Please tick either positive, negative or no impact then explain in reasons and include any mitigation e.g., requiring applicants to apply for jobs online would be negative as there is potential disadvantage to individuals with learning difficulties or older people (detail this in the reason column with evidence) however applicants can ask for an offline application as an alternative (detail this in the mitigation column)*

Protected Characteristic	Positive Impact *(benefit)*	Negative *(disadvantage or potential disadvantage)*	No Impact	Reasons to support your decision and evidence sought	Mitigation/adjustments already put in place
Age			✓	See Next Section	Not applicable
Sex			✓	See Next Section	Not applicable
Race			✓	See Next Section	Not applicable
Religion or Belief			✓	See Next Section	Not applicable
Disability			✓	See Next Section	Not applicable
Sexual Orientation			✓	See Next Section	Not applicable
Pregnancy/maternity			✓	See Next Section	Not applicable
Gender Reassignment			✓	See Next Section	Not applicable
Marriage & Civil Partnership			✓	See Next Section	Not applicable
Other			✓	See Next Section	Not applicable

If you have identified no negative impact for all please explain how you reached that decision and provide reference to any evidence (e.g., reviews undertaken, surveys, feedback, patient data etc.)

This policy is limited to very specific aims relating to Medical Devices. It is not a policy concerned with the allocation or provision of particular services to the public, other than to ensure that this is done in accord with relevant legal responsibilities and guidance etc. So, there are no known grounds to suggest that this policy could have any significant risk of it disproportionately impacting on patients or members of the public who have protected characteristics. This policy covers all staff and does not confer direct benefits or impose particular sanctions on any sections of the workforce, nor does it materially affect their normal terms and conditions of work. So, there are no known grounds to suggest that this policy could have any significant risk of it disproportionately impacting on staff who have protected characteristics.

13. Does the policy raise any issues in relation to Human Rights as set out in the Human Rights Act 1998? No

If you have identified negative impact for any of the above characteristics, and have not been able to identify any mitigation, you MUST complete Part 2, please see the full EIA document on the Equality and Diversity section of the Intranet and speak to [redacted] HR Manager or [redacted] Matron for further support.

Action	Lead	Timescales	Review Date

Declaration

I am satisfied this document/activity has been satisfactorily equality impact assessed and the outcome is:

No major change needed – EIA has not identified any potential for discrimination/adverse impact, or where it has this can be mitigated & All opportunities to promote equality have been taken ☒

Adjust the policy – EIA has identified a need amend the policy in order to remove barriers or to better promote equality ☐
You must ensure the policy has been amended before it can be ratified.

Adverse impact but continue with policy – EIA has identified an adverse impact, but it is felt the policy cannot be amended. ☐
You must complete Part 2 of the EIA before this policy can be ratified.

Stop and remove the policy – EIA has shown actual or potential unlawful discrimination and the policy has been removed ☐

Name: [redacted] Date: June 18

Signed:

Appendix 7 - Policy approval checklist

The Medical Device Policy is presented to the Patient Safety Group for Approval.

In order for this policy to be approved, the reviewing group must confirm in table 1 below that the following criteria is included within the policy. Any policy which does not meet these criterion should not be submitted to an approving group/committee, the policy author must be asked to make the necessary changes prior to resubmission.

Policy review stage

Table 1

The reviewing group should ensure the following has been undertaken:	**Approved?**
The author has consulted relevant people as necessary including relevant service users and stakeholders.	Yes
The objectives and reasons for developing the documents are clearly stated in the minutes and have been considered by the reviewing group.	Yes
Duties and responsibilities are clearly defined and can be fulfilled within the relevant divisions and teams.	Yes
The policy fits within the wider organisational context and does not duplicate other documents.	Yes
An Equality Impact Assessment has been completed and approved by the HR Team.	Yes
A Training Needs Analysis has been undertaken (as applicable) and T&D have been consulted and support the implementation	Yes
The document clearly details how compliance will be monitored, by who and how often.	Yes
The timescale for reviewing the policy has been set and are realistic.	Yes
The reviewing group has signed off that the policy has met the requirements above.	Yes

Reviewing group chairs name: [redacted] (Medical Devices Group)	**Date: TBC**

Policy approval stage

☐ **The approving committee/group approves this policy.**

☐ **The approving committee/group does not approve the policy.**

Actions to be taken by the policy author:

Approving committee/group chairs name: TBC	**Date: TBC**

Appendix 8 - Version Control

Version	Section/Para/ Appendix	Version/description of amendments	Date	Author/Amended by
1.0	Whole document	Re-write/update of policy	March 2013	[redacted]
2.0	Whole document	Review of document to ensure compliance	Oct 2014	
2.0	Section 4	Changes to the responsible committee for the policy	Oct 2014	
2.0	Section 4	Changes of the responsibilities for the medical devices group and the medical devices lead	Oct 2014	
2.0	Section 5.3	Trails section expanded to include more detail on the correct process	Oct 2014	
2.0	Section 5.4	Acceptance of medical devices made into its own section, with rest of the section numbers updated	Oct 2014	
2.0	Section 5.8.4	This section was updated to the new process and database	Oct 2014	
2.0	Section 5.10	This section was updated to direct to correct policies	Oct 2014	
2.0	Section 7	Loan equipment section updated and expanded	Oct 2014	
2.0	Section 10	Section updated and expanded to cover difference in radiology	Oct 2014	
3.0	All	Review at policy expiry date	Apr 18	
		Removal of reference to Medical Devices Group and replace with Medical Device & Facilities Group	Apr 18	
		Update to reflect change from Aintree EBME to the RLBUHT as EBME provider	Apr 18	
3.1	5.7	Inclusion of sentence… all clinical equipment should be reviewed prior to purchase to check that the Trust has the appropriate facilities, equipment, or contract to be able to decontaminate the equipment. This process will be overseen by the Trust Decontamination Group. No clinical equipment should come into the trust without that check.	Aug 18	
3.2	All	Review at policy expiry date. Updated comments from the EBME team, reformatted into the Trust current policy template. Rewrite of clauses for enhanced clarity	Dec 21	

Translation Service

If you require this in any other language or format, please contact the Patient Experience Team on [redacted] or email [redacted] stating the leaflet name, code and format you require.

Arabic
الـمر ضى تـ جارب مـ تابـ عة بـ فريـ ق الاتـ صال فـ يرجى آخر، تـ ذسـ يق أو لـ غة بـ أي الـ ذشرة هذه إلـ ى بـ حاجة كـ نت اذا الـ رقـ م عـ لى
[redacted] إلـ ى إلـ كـ تروذ ي بـ ريـ د إر سال أو ،
[redacted] تـ طـ لـ به الـ ذي والـ شكل والـ رمز، الـ ذشرة، ا سم موضحاً.

Chinese **如果你想索取本**传单的任何其他语言或格式版本，请致电[redacted]联络「病人经历组」，或发电邮至[redacted]，说明所需要的传单名称、代码和格式。

Farsi
شماره بـ ا ماریـب تـ جربـ ه مـیت بـ ا لـ ط فا,یـگ ریـد زبـ ان ای هوف رم بـ ه بـ رو شور نـیا بـ ه ازیـن صورت در [redacted]
ردیـبـ گ رتـ ماسـیـز لـیـمـیا بـ ا ای ۳۰۹۳ای [redacted]
خود ازیـن مورد قـ الـ ب و کـ د ، بـ رو شور نـ ام ذکـ ر بـ ا

French
Si vous avez besoin de ce dépliant dans une autre langue ou un autre format, veuillez contacter Patient Experience Team (équipe de l'expérience des patients) au [redacted], ou envoyez un e-mail à [redacted] en indiquant le nom du dépliant, le code et le format que vous désirez.

Polish Jeśli niniejsza ulotka potrzebna jest w innym języku lub formacie, należy skontaktować się z zespołem ds. opieki nad pacjentem (Patient Experience Team) pod numerem telefonu [redacted], lub wysłać wiadomość e-mail na adres [redacted], podając nazwę ulotki, jej kod i wymagany format.

Punjabi
ਜੇ ਤੁਹਾਨੂੰ ਇਹ ਕਿਤਾਬਚਾ ਕਿਸੇ ਹੋਰ ਭਾਸ਼ਾ ਜਾਂ ਫਾਰਮੈਟ ਵਿੱਚ ਚਾਹੀਦਾ ਹੈ, ਤਾਂ ਕਿਰਪਾ ਕਰਕੇ ਪੇਸ਼ੈਂਟ ਐਕਸਪੀਰਿਅੰਸ ਟੀਮ ਨਾਲ [redacted] 'ਤੇ ਸੰਪਰਕ ਕਰੋ, ਜਾਂ [redacted] 'ਤੇ ਈਮੇਲ ਕਰੋ ਅਤੇ ਪਰਚੇ ਦਾ ਨਾਮ, ਕੋਡ ਅਤੇ ਆਪਣਾ ਲੋੜੀਂਦਾ ਫਾਰਮੈਟ ਦੱਸੋ।

Somali
Haddii aad u baahan tahay buug-yarahan oo luqad kale ku qoran ama isaga oo qaab kale ah, fadlan Kooxda Waayo-arragnimada Bukaanka kala soo xiriir [redacted] ama [redacted] ama email-ka [redacted] oo sheeg magaca iyo summadda buug-yaraha iyo qaabka aad u rabtid.

Urdu
ڈ نسیـریـکـ سپـیـا شـ نـٹـیـپـ کـ رم بـ راہ تـ و، ہـو درکـ ار ہـیـم شـ کـل ای زبـ ان گـ ریـد یـکـ س کـ تابـ چہ ہـی کـ و آپ اگـ ر کـ ا شـ کـل مطـ لوبـ ہـ یـاپـ ن اور کـ وڈ ذ ام، کـ ا کـ تابـ چے ای ں،یـکـ ر رابـ طہ پـ ر [redacted] سے مـیٹ [redacted] ںیـکـ ر لـ یـم یـا پـ ر

Welsh Pe byddech angen y daflen hon mewn unrhyw iaith neu fformat arall, byddwch cystal â chysylltu gyda'r Tîm Profiadau Cleifion ar [redacted], neu ebostiwch [redacted] gan nodi enw'r daflen, y cod a'r fformat sydd ei angen arnoch.