MEDICAL DEVICE MANAGEMENT POLICY

Non-Clinical POLICY

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	Yes-no harm		
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1.0 INTRODUCTION

The main objective of this policy is to establish the foundations for a culture of effective medical device management at all levels.

2.0 POLICY STATEMENT

This Policy applies to all areas of the Trust and at all levels.

The Trust aims to ensure that all risks associated with the acquisition, use and disposal of medical devices are effectively managed in line with the Trust's Risk Management Policy and Strategy.

This Policy is informed by guidance from the Medicines and Healthcare Products Regulatory Agency (MHRA) and the Department of Health[1,2]

The Trust will have systems in place to ensure that the following medical device management activities are undertaken in a systematic manner, in line with other Trust policies, thereby ensuring devices are safe and available for the delivery of the Trust's services to the benefit of patients:

- Selection and acquisition
- Acceptance testing and inventory
- Training in Device Usage & Training Compliance Reporting
- Maintenance – User, planned and corrective
- Clinical Governance issues (including incident investigation and Patient Safety alert response)
- Device disposal and condemnation
- Cleaning and Decontamination

The Trust will ensure that a centralised inventory of medical devices is maintained to enable the effective management of such devices. Additionally, Central Sterile Services Department manage a separate inventory for surgical instrumentation and Therapy Services for some passive mobility aids.

This Policy applies wherever medical devices are acquired, procured, provided, prescribed, maintained and used throughout the Trust.

The Policy has been developed by Clinical Engineering Services and in consultation with the Medical Device & Equipment Group.

3.0 DEFINITIONS/ ABBREVIATIONS

A ***"medical device"*** is defined as any instrument, apparatus, appliance, material or health care product, (excluding pharmaceuticals), that can be used in the diagnosis, treatment or monitoring of a patient.

According to the UK MDR 2002 (inc amendment 2024), a medical device is described as any instrument, apparatus, appliance, material or other article used whether used alone or combination, together with any software necessary for its proper application, in humans to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these. It must bear appropriate quality labelling e.g. UKCA and/orCE-markings.

In practice, this includes within its scope all reusable items, those on the inventory held by Clinical Engineering Services incorporating Medical Equipment Management Department (MEMD). These are durable devices that have unlimited reuse cycles specified and as such carry no explicit expiry date, usually requiring periodic technical maintenance and subject to use on an unlimited number of patients over their lifecycle.

In its wider scope it also encompasses reusable accessories and single-use/disposables that may be used in conjunction with the above durable devices or as stand-alone disposables.

The ***"Trust"*** means the Sherwood Forest Hospitals NHS Foundation Trust.

"Staff" means all employees of the Trust including those managed by a third party organisation on behalf of the Trust.

The **Medical Device & Equipment Group (MDEG)**, acts as an interdisciplinary forum to:

- Identify Equipment required to support service delivery, service re-design, cost improvement programmes & delivery of best practice in healthcare.
- Review Governance aspects of acquisition and use of medical devices including user training, incidents and risks, national safety alerts, audits.

FSCA/FSN – Field Service Corrective Action/Field Safety Notices direct from the manufacturer.

MHRA – Medicines and Healthcare products Regulatory Agency who issue guidance and device-related safety alerts that may require the recall/modification of devices or their accessories including instructions for use.

MDSO – Medical Device Safety Officer, Trust-appointed liaison officer for device governance issues.

MDIS – Medical Device Information System, the electronic repository for all device inventory and service history data.

PAQ – a Pre-Acquisition Questionnaire response is required from any supplier on the first occasion of supply of a specific reusable make/model device, to gain assurance on essential key characteristics of its safety, quality, suitability and sustainability.

4.0 ROLES AND RESPONSIBILITIES

The Trust will ensure that this policy is widely publicised.

All staff that use medical devices will be expected to comply with the policy, as will those who procure, prescribe, deliver training, maintain and clean these devices.

It is the responsibility of all Heads of Service to:

- Ensure all staff adhere to this policy for all aspects of device management
- Nominate a key contact from their staff who completes an annual presence/service status check of devices permanently allocated to their area against an inventory listing ("core equipment") generated from the online customer portal, feeding back details to MEMD to determine any remedial/reconciliation actions
- Be aware of other Trust policies that relate to medical devices [3]
- Engage as required with Trust sub-groups & working committees with responsibilities for device management[4]
- Ensure all staff are aware of key principles relating to safe medical devices practices including
    - Only requistioning/approving approved reusable devices in the context of a specific Procurement-issued PAQ number
    - Ensuring that devices delivered direct are quarantined and do not prematurely enter clinical use prior to satisfactory completion of technical acceptance tests by Memd
- For reusable devices issued on loan to patients to use at home
    - Secure patient loan agreement sign-off
    - Retain allocation records of specific device details (such as MEMD or make/model/serial number) to facilitate Trust response in the event of managing risks on receipt of a manufacturer safety recall notice
    - For those devices deemed to carry an otherwise intolerable risk profile (contributory factors listed in 7.4) ensures processes are in place for timely retrieval of devices due essential maintenance.
- Escalate to Divisional MDEG representative device-related usage issues including existing/emerging replacement equipment requirements.

MDEG's remit is reflected in its current Terms of Reference.

The Medical Director is the board member representing device-related governance concerns

CSTO DGM usually chairs MDEG

Head of Clinical Engineering Services leads with the following responsibilities:

- MDEG hair, as required, including reporting and escalation to Risk Committee
- Device Governance agenda including Trust MDSO role
- Standing member of key Trust forums such as Capital Resources Oversight Group, Divisional Clinical Governance, and Estates Governance, Medical Gas Safety Committee, Radiation Safety Group & Trust Decontamination Committee.

Responsibilities of the Principal Engineer (Clinical Engineering Services) include:

- MEMD Quality Manager, with technical governance lead for effective compliance with all MHRA/FSN safety alerts requiring device upgrade/modification
- Lead for support of Trust's Medical Device Information System
- Lead for technical workforce training programmes

Responsibilities of the Maintenance Manager (Clinical Engineering Services) include

- Leading on all technical workshop activities
- Delivering an effective and timely Planned Periodic Maintenance (PPM) programme
- Timely escalation of emerging concerns that impact performance delivery

Responsibilities of the Clinical Engineer (Clinical Engineering Services) include

- Delivery of existing Clinical Equipment Schemes, such as Resuscitation
- Service development support for emerging clinical schemes
- Liaison with the Lead for Training & Clinical Adviser for Medical Equipment

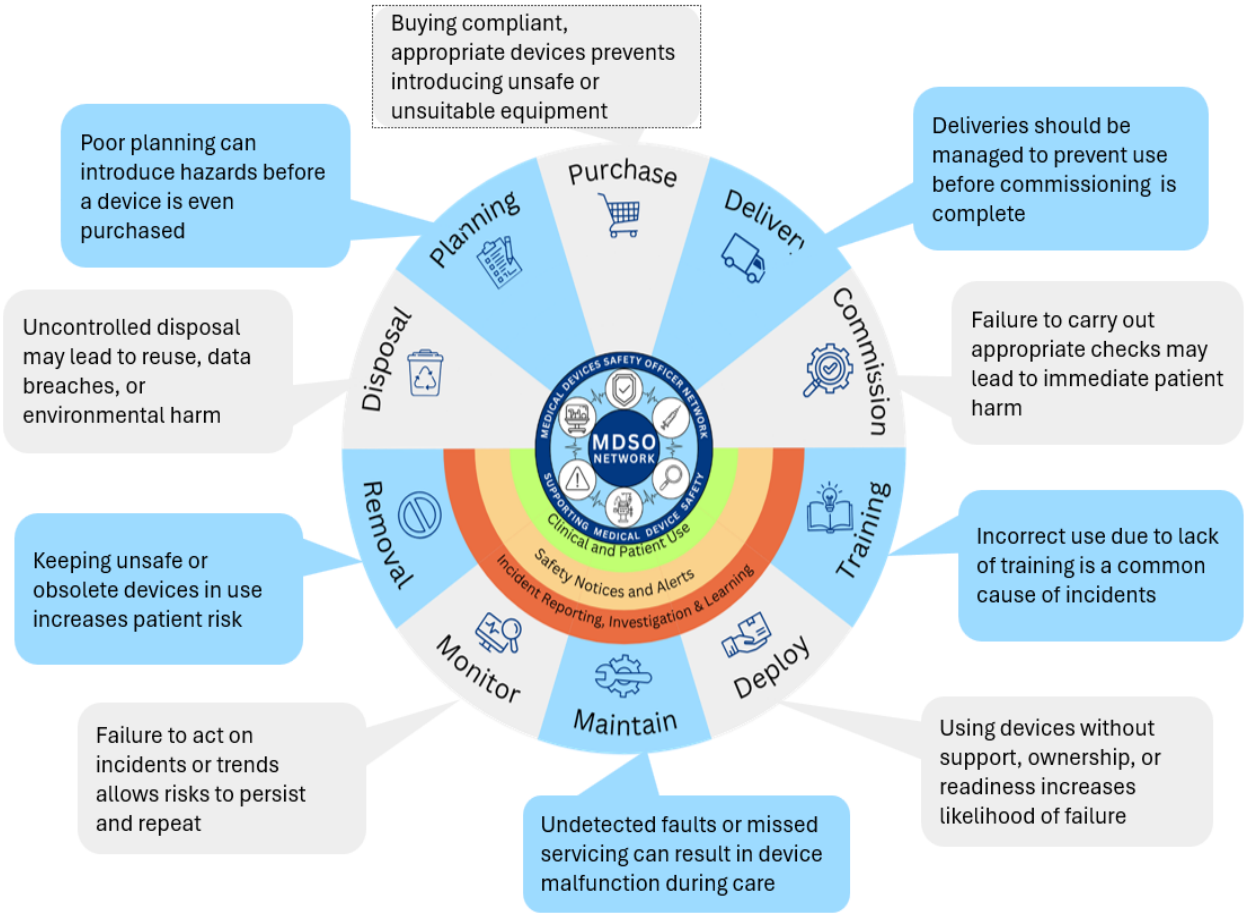
Responsibilities of the Lead for Training & Clinical Adviser for Medical Equipment are detailed in the Medical Equipment User Training Policy.

The above four senior service posts share responsibility for ensuring continual quality improvement via a proactive internal audit programme for all ISO processes.

5.0 APPROVAL

The Medical Device Management Policy was consulted with the Medical Device & Equipment Group and Divisional Management; along with subject matter experts.

6.0 DOCUMENT REQUIREMENTS



6.1 Selection & Acquisition

Medical devices can be acquired by the Trust from many sources, including outright purchase, consignment deals, Managed Equipment Services (MES), donation etc. Irrespective of funding source or provenance, all proposals to acquire new medical device make/model technologies require prior approval from the Medical Device & Equipment Group (MDEG) and (as appropriate) the Capital Resources Oversight Group and, with the exception of straightforward replacements, a case of need will have to be submitted.

Wherever possible the Trust will standardise on the same device make/model, which has several benefits including minimising the risks associated with unwarranted diversity levels (and hence enabling the deliverability of an effective user training programme), maximizing device system interoperability and minimizing life-cycle support costs where a fleet of specific devices are used Trust-wide etc. At the same time it is acknowledged that such risks are balanced against other factors such as managing impact of single supply chain vulnerabilities. Relevant sources of detailed information would be consulted e.g. independent published device evaluation reports (NICE etc.) along with generic human factors interface learning (such as that from Healthcare Safety Investigation Branch HSIB)

A single list of approved devices is centrally maintained by Clinical Engineering in conjunction with Procurement. Subject to funding approval being granted, devices from this list have already been vetted and may be purchased via the Procurement Department. Alternative generically-equivalent devices to those on the list will only be acquired by prior agreement with MEMD

For other items a specification together with evaluation criteria will be established and, depending on the complexity of the device(s) involved, a purchasing strategy will be agreed identifying all key stakeholders. If appropriate a group will be established to commission trials to inform a decision on the preferred supplier having taken into account whole life-cycle costings and the clinical effectiveness/suitability of devices. Other factors will be borne in mind at arriving at an outcome preference, such as environmental waste and carbon footprint impacts

Off-patient demonstration often affords a sufficiently comprehensive opportunity to assess the relative practical benefits and disadvantages of shortlisted options. Otherwise, live trials (involving direct patient care) should only be considered where the benefits of completing such a trial outweigh those new risks introduced as a consequence of proceeding with a trial, with only limited location(s) selected with adequate levels of training achieved coupled with robust company representative supervision. Trials should only ever proceed in the context of a fully-approved PAQ response being in place.

Devices proposed for trial/free loan to the Trust must be prior approved as follows:

- For any reusable devices, Medical Device & Equipment Group
- For disposables, the Sharps & Ward Consumables Groups

Devices on trial/free loan to the Trust must be covered by:

- Evidence of valid indemnity insurance cover from the supplier
- Signed-off delivery note reflecting both parties agreement
- and additionally for reusable devices:-
    - completed satisfactory Pre-Acquisition Questionnaire
    - completed Decontamination Certification
    - copy of the directions for use and cleaning Instructions.

All unlimited-cycle reuse devices must be tested by Clinical Engineering prior to being utilised; this notably includes all mains-utility powered devices. The Sterile Services Department will provide a similar service for loan surgical instrumentation along with reusable surgical devices with limited number of recycle usages.

To inform suitability and facilitate formulation of realistic anticipated effective device life and associated costs, the supplier will complete a satisfactory pre-acquisition questionnaire (PAQ) response and additional questions specific to the Trust requirements

The PAQ will be vetted by a multi-disciplinary team including:-

- Clinical Engineering for evaluating technical support issues
- Lead for Training & Clinical Advisor for Medical Equipment to assess user training factors
- Decontamination Specialists to confirm compliance with Trust local requirements
- In the case of network-connected devices, Information Technology specialists to profiling adequate cybersecurity hygiene assurances

- Along with where appropriate oversight from relevant Trust specialists/Clinical Leads e.g. Resuscitation, Point-of-care-testing, Moving & Handling Co-ordinator, Transfusion, Medicine's Management etc

Where devices are used in conjunction with a proprietary disposable, an assessment of assurances around supply chain resilience will be completed. Due consideration is applied to context of care environment, with a noted increasing prevalence of alternative care settings eg virtual ward remote location usage. Compliance with the PAQ process is required to be universal, irrespective of both the ultimate usage setting (such as ward, clinic, care-home, domiciliary, ambulance etc) or the acquisition route eg is direct with a supplier, through a framework agreement, via supply chain catalogue, on consignment deal, etc

Short-listed devices for demo/trial will be rated by a Trust-owned user feedback template in order to capture relative advantages/shortcomings of competing options eg intuitive design, interoperability, clinical effectiveness etc. Completed forms should be treated as confidential-to-the -Trust and always handed to a senior Trust nominated person, never back to the company representative.

Proposals to change/introduce new devices that impact existing Trust fleets must always gain MDEG approval before being taken forward, as appropriate, to higher Trust forums for further approval.

When new devices have been requistioned, Procurement will arrange for the purchase order to be placed. Whilst a few specialist departments administer their own local purchasing system (such as MEMD, Pharmacy, Orthotics) complete reusable powered devices would be outside their scope. In particular if Pharmacy procure prescribed drug/device hybrid combination, where these are reusable this Policy will apply.

Trust default practice is to purchase brand-new devices with full original manufacturer's warranty, only under exceptional circumstances and with adequate service history detail, would
pre-used equipment be considered for purchase. Full payment against subsequent invoice is usually only cleared once acceptance tests have been successfully completed.

Furthermore, where appropriate, the Trust may hire devices from rental suppliers to meet specialist requirements/peak demand which will only be progressed via Procurement procedures from an agreed shortlist of suppliers, taking consideration of factors such as user training and compatibility with Trust-owned devices.

Risk-factor informed revenue/capital rolling-replacement programmes developed by MDEG address timely replacement of many key device fleets deployed across the Trust. For other more specialist devices, individual services are responsible for identifying funding as required.

Control measures that limit the variety of devices procured include mechanisms to mask inappropriate lines from the national Supplychain Catalogue to minimise inadvertent selection of non-preferred devices that have not achieved local approval. Additionally, input from such as the Ward Consumables Group is taken to rationalise those lines that are approved whilst retaining contingencies for supply disruption.

6.2 Acceptance Testing and Inventorying

Prior to use all medical devices must be acceptance tested according to MHRA guidelines, this is to ensure the order is correct, the device is functioning, accessories are present, a suitable maintenance programme can be established and accurate warranty expiry dates can be established. This also affords the opportunity to ensure any fleets of identical devices are configured to a consistent local profile. In terms of time-setting practices, devices will usually be configured to GMT irrespective of the prevailing daylight-saving season.

Clinical Engineering will be responsible for ensuring all devices transferred to the Trust receive an appropriate acceptance test and are added to the Trust's Medical Device Information System prior to going into Service. In practice this will include all powered reusable devices, along with any associated user-detachable power supplies and capital accessories.

So notable exclusions include single-patient/limited-reuse devices (and implants) and manually-powered non-electrical devices such as pressure bags etc. with the exception of those that make a specified measurement to a defined tolerance e.g. sphygmomanometers.

6.3 Training in Device Usage

All users must be trained prior to using a medical device and a training needs assessment is required prior to a device being used. For further details see the Trust's Medical Device User Training Policy and seek the advice of the Lead for Training & Clinical Adviser for Medical Equipment. Some devices e.g. those emitting ionizing or intense/laser radiation, are additionally subject to use in the context of Local rules and personal protection controls.

6.4 User, Planned & Corrective Maintenance

Clinical Engineering is responsible for establishing routine Planned Periodic Maintenance (PPM) regimes for all appropriate medical devices, in consultation with stakeholders. Servicing intervals and scope will take account of such factors as manufacturer's guidelines, anticipated benefits (such as preventative factor in terms of both replacing parts with a predictable fault characteristic and/or timely capture of faults that might otherwise not be evident to the user) in conjunction with other evidence sources such as past history analysis, ensuring that the appropriate level of planned maintenance is undertaken, incorporating calibration requirements as necessary. Where extended periodicities to the norm/legacy are under consideration, risk factors included in any review would include manufacturer's specifications, clinical criticality, complexity, extent to which powered by external sources, how intensely it is anticipated to be handled, options for remote status interrogation etc.

Clinical Engineering will provide adequate notice of planned maintenance visits so that the ward or department can make every effort to make devices available for inspection. If a device is unavailable for maintenance at the time of a service visit Clinical Engineering will inform the area of items not seen and agree a plan to see the items at an alternative date.

Additionally for devices such as beds and mattresses that are loaned from the central equipment library at Kings Mill Hospital site, wards should make every effort to return devices due/overdue service dates, sourcing a replacement as store capacity permits. Clinical Engineering will regularly review items that have missed maintenance and escalate this to managers as

appropriate. In the case of commissioning sub-contractors for specialist services, such as weigh scale calibrations, it is vital that clinical areas make every effort to afford access to devices as there are limited opportunities for a repeat visit until the next annual cycle is due.

Clinical Engineering will repair faulty devices within their workshops or via external service agents/manufacturers as appropriate. Clinical Engineering will identify on the Trust's Medical Device Information System whether devices are supported in-house or via external service contracts. (Control of Contractors Policy).

Where an external support contract is indicated, clinical stakeholders will advise on the appropriate cover scope/specification with a formal add/delete review completed on renewal to capture any changes to requirements including scope and appropriate support levels. Delivery KPI's will be set and monitored as appropriate, with timely service visit scheduling and follow-up visit reports proactively monitored.

Clinical Engineering will ensure that records of all maintenance and repairs undertaken on medical devices are recorded on the Trust's Medical Device Information System, thus maintaining a traceable service history. Furthermore, only original-equipment manufacturer parts or equivalent specification will be utilised.

Clinical Engineering Services is externally quality-audited by the British Standards Institute as part of its on-going ISO 9001 certification. The registration's scope includes the vast majority of Clinical Engineering's processes including all technical maintenance services.

It is the responsibility of medical device users to know how to:

- Report resuscitation kit (trolley/bags etc) that are used/opened/expired returning to backup point from where a replacement can be sourced
- Complete daily check of resuscitation equipment and log on check sheet
- Report faulty medical devices, i.e. phone Memd on KMH ext. 3216 or for non-urgent items via the online portal.
- Decontaminate and clean devices after clinical use and prior to service, i.e. as laid out in the Trust Policy on decontamination of healthcare equipment prior to inspection, service or repair, which includes the decontamination safety certificate.
- Prior to clinical usage, check that it is safe to proceed based on device
    - Surfaces dry to touch e.g. following decontamination, especially around power components (cord, switch, inlet and casing joins etc.)
    - Has no loose parts, casing/screen cracks, no visual signs/smells of thermal damage, no unusual sounds emanating etc.
    - Passes any of your essential safety checks e.g. with bedframes: brakes, power cord undamaged, cot side, CPR etc.
    - Bears labelling that it's within its service validity date (inc. power cord)
    - Alarm and other settings are appropriate to the current patient, aware that devices returned from technical service may have different settings

  - Noting device time-setting discrepancy on power-up in patient notes (generally fleet devices will be issued set to GMT)
  - Local QA sample validation up-dated e.g. POCT Diagnostic devices.
- Correctly store devices and accessories, housekeeping examples include:
  - Utilising correct mounting to protect from avoidable physical damage
  - Protecting vulnerable mechanisms from transport damage eg parking syringe pump drive mechanism in tucked away “home” position, not protruding beyond main housing
  - Keeping plugged-in on-charge to optimise available battery capacity
  - Ensuring adequate stock of associated consumables.
- Timely report for collection all surplus devices to be returned to the library at KMH.
- Sign for devices delivered back into clinical use upon handover following servicing.

All above reporting activities are in the specific context of the device’s unique inventory number. Specific challenges arise with Trust procurement of devices for named-patient post-discharge usage where risks may be shared with a third party contract provider.

Devices issued for patient loan

There is a need to assess the appropriateness of any proposal to send a patient home with a Trust-owned durable device taking into account such factors as[5]:-

- Appropriateness e.g. marketed as suitable for domiciliary use (powered by battery or class2 mains electrical design), complexity, value etc.
- Associated risks e.g. small-parts choking hazard, coin-cell battery ingestion risk etc
- Level of requisite manufacturer-prescribed technical maintenance
- Anticipated level of on-going clinical supervision
- Arrangements for training including availability of adequate instruction for use
- On-going supply of any associated consumables and replace-on-fail arrangements
- Recall mechanism if it is subject to an essential safety update/due service
- Decontamination arrangements upon return
- Confirmed duration of loan e.g. in context of prescribed maintenance intervals
- Operational impact on capacity/flow in terms of how long it will be unavailable for use on other in-patients.

Services are responsible for retaining records of devices issued for patient loan and as informed by above risk factors, follow established processes for managing follow-up retrieval.

As a guide, the central list of approved devices advises on the limited suitability of devices for use in a non-acute domiciliary setting.

6.5 Clinical Governance Issues

All incidents involving medical devices should be reported via Datix with Clinical Engineering being alerted in the specific context that an associated incident will be logged. This will trigger appropriate due process is followed with independent investigation, preserving evidence to facilitate the identification of root cause(s), from which collective learning can be identified and disseminated. Given potential for repeat harm to be incurred, along with risks of failing to

accurately identify the specific device involved, to realize optimum learning from such issues, it is imperative on users

- to timely quarantine implicated devices
- to retain any consumables used with the device at the time of the incident

Assumptions of device capability to retain deferred error logs/networking should be avoided. Clinical Engineering will take lead responsibility for external reporting of adverse incidents to the MHRA. Devices involved in incidents should be quarantined pending investigation outcome.

When the Trust receives MHRA device safety alerts via the Department of Health's Central Alerting System (or Field Service Corrective Action/Field Safety Notices direct from the manufacturer) staff must take actions assigned to them in order to address the notices, typically one or more of such as install firmware revision/install physical upgrade, update user training, temporarily switch to alternative disposable/consumable etc. The Medical Device Safety Officer (MDSO) will act as the external liaison officer for both progression of local incident investigations and sharing/networking practice-learning matters. Broader learning opportunities afforded on such matters as multiple device interoperability, workflow compliance etc are also considered by taking into account additional sources of information, such as Health Services Safety Investigation Board (HSSIB)

Devices in use should be fully functional. In exceptional circumstances if a service-lead proposal arises to leave a partially-functional device in temporary further use after exhausting all alternative options and subject to the specific nature of the limited functionality, a non-conformance quality concession notice will be raised by Clinical Engineering which will require clinical sign-off at Deputy Ward/Clinic Leader level or higher.

Device usage should be limited to as designated in the manufacturer's instructions. Usage in any other way is considered 'off-label', an example including re-using a device marketed as single use. Such off-label usage is outside Trust Policy, as following an incident potential to seek redress would be compromised. It should only arise in the context of a documented risk assessment and usually against the back drop of a local major incident and/or a national patient safety alert acknowledging a necessity to consider such extreme temporary solutions.

Trust Information Governance principles will be followed when devices with retained patient id-sensitive records are handed over to a third party, whether this is following trial, warranty exchange/repair or when finally condemned.

7.6 Device Disposal

Clinical Engineering will be responsible for determining when medical devices should be removed from service and condemned; in the interim advising appropriately on known obsolescence details as support (contracts) enter best-endeavours status and ultimately withdrawn. Other adverse factors taken into consideration include level of cyber security vulnerability presented. A rolling risk-prioritized approach is adopted to address highest risks at the earliest opportunity. At the end of their life medical devices must be safely disposed of in accordance with MHRA and Trust's Infection Prevention/Control and Information Governance Policy and removed from the Trust's Inventory (and the Capital Asset List as appropriate) as part of the condemnation process.

Devices will be disposed of for a variety of reasons; however, Clinical Engineering will take responsibility for determining the appropriate disposal route, such as trade-in, salvage in compliance with waste stream directives or transfer to an authorised auction house, with Clinical Engineering responsible for physical disposal.

Therefore Clinical Engineering must be consulted prior to disposal so that a strategy can be agreed and records updated and the Trust's Standing Financial Instructions on Asset Disposal be adhered to with any associated contracts curtailed.

A periodic review of devices that have not presented for service over protracted periods will be completed by MEMD, assessing trends and aiming to address reasons why these might have bypassed the condemnation process e.g. inappropriately disposal (such as scrap or direct return to supplier), non-repatriated devices transferred/discharged with patient, miss- appropriated etc.

6.7 Device Cleaning and Decontamination

All medical devices must be appropriately decontaminated and effectively cleaned in order to minimise infection risks. It is equally important to recognise that devices should also be clean to convey a positive assurance of Trust processes from the patient's and relative's perspective.

Devices must be presented in a clean fashion prior to routine maintenance and a decontamination safety certificate (available electronically via the Infection Control section of the Trust intranet site), must be completed prior to faulty devices being sent/collected for repair/library return/reprocessing.

Attention must be paid to ensuring that devices are decontaminated prior to leaving clinical areas and cleaned and stored appropriately when not in use. The highest risks of infection are associated with re-usable surgical instruments (and other invasive devices) and these must be cleaned and transported to the Sterile Services Department where they will be appropriately reprocessed in a controlled, quality assured environment.

6.8 Loaning devices for use by other organisations

In the case that Trust devices are being considered to loan for use by another organisation, key factors to bear in mind include:

- Duration and impact of reduced local availability
- Management of associated Information Governance issues
- Management of on-going issues such as maintenance and/or safety upgrade
- Securing sufficient assurances re-decontamination status upon return

For the above considerations, all loans should be managed as appropriate, namely MEMD-numbered devices via Clinical Engineering and all surgical instruments via CSSD

In the case of non-NHS organisations, further indemnity provisions also follow.

[1] Management of Medical Devices MHRA (2021)
[2] Care Quality Commission, Regulation 15 Premises & Equipment, Department of Health
[3] These include: Medical device user training, Safety alert broadcast/best-practice, Infection Control, Point of Care Test Devices, Risk Management, Control of Contractors, Radiation Safety and Standing Financial Instructions.

[4] The Capital Resource Oversight Group (CROG) has responsibility for reviewing and prioritising capital equipment asset acquisition requests and the Medical Device Equipment Group reviews device safety and promotes best practice.
[5] Devices in Practice-Checklists for using medical devices June 2014, MHRA

7.0 MONITORING COMPLIANCE AND EFFECTIVENESS

Minimum Requirement to be Monitored (WHAT – element of compliance or effectiveness within the document will be monitored)	Responsible Individual (WHO – is going to monitor this element)	Process for Monitoring e.g. Audit (HOW – will this element be monitored (method used))	Frequency of Monitoring (WHEN – will this element be monitored (frequency/ how often))	Responsible Individual or Committee/ Group for Review of Results (WHERE – Which individual/ committee or group will this be reported to, in what format (e.g. verbal, formal report etc.) and by who)
Operational KPI	Quality Manager Clinical Engineering	Statistics	monthly	Divisional service line
Work programme	Head of Service, Clinical Engineering	Report	6 monthly	Risk Committee

8.0 TRAINING AND IMPLEMENTATION

All clinical staff will be made aware of this policy through their induction and professional updates.

This policy forms part of the corporate policies of the Trust, and will be made widely available to staff, via the intranet.

9.0 IMPACT ASSESSMENTS

- This document has been subject to an Equality Impact Assessment, see completed form at Appendix 1
- This document is not subject to an Environmental Impact Assessment

10.0 EVIDENCE BASE (Relevant Legislation/ National Guidance) AND RELATED SFHFT DOCUMENTS

Evidence Base:
The MHRA provides a variety of documents that evidence the need for effective medical device management, which include:

- Management of Medical Devices Bulletin MHRA
- Medical Device Alerts issued via the DoH Central Alert System
- CQC 2017 Reg 15-Premises & Equipment
- Annual adverse incident thematic review summaries
- Ad-hoc MHRA device bulletins

NHS England publications and NICE guidelines that relate to medical devices are also additional evidence to underpin the need for this policy.

Related SFHFT Documents:
- N/A

11.0 KEYWORDS

12.0 APPENDICES

- Appendix 1 - Equality Impact Assessment

APPENDIX 1 - EQUALITY IMPACT ASSESSMENT FORM (EQIA)

Name of service/policy/procedure being reviewed: Medical Device Management Policy			
New or existing service/policy/procedure: Existing			
Date of Assessment: July 2026			
For the service/policy/procedure and its implementation answer the questions a – c below against each characteristic (if relevant consider breaking the policy or implementation down into areas)			
Protected Characteristic	**a) Using data and supporting information, what issues, needs or barriers could the protected characteristic groups' experience? For example, are there any known health inequality or access issues to consider?**	**b) What is already in place in the policy or its implementation to address any inequalities or barriers to access including under representation at clinics, screening?**	**c) Please state any barriers that still need to be addressed and any proposed actions to eliminate inequality**
The area of policy or its implementation being assessed:			
Race and Ethnicity	N/A	N/A	N/A*
Gender	N/A	N/A	N/A
Age	N/A	N/A	N/A
Religion	N/A	N/A	N/A
Disability	N/A	N/A	N/A
Sexuality	N/A	N/A	N/A
Pregnancy and Maternity	N/A	N/A	N/A
Gender Reassignment	N/A	N/A	N/A
Marriage and Civil Partnership	N/A	N/A	N/A

Socio-Economic Factors (i.e. living in a poorer neighbourhood / social deprivation)	N/A	N/A	N/A

What consultation with protected characteristic groups including patient groups have you carried out?

N/A

What data or information did you use in support of this EqIA?

N/A

As far as you are aware are there any Human Rights issues be taken into account such as arising from surveys, questionnaires, comments, concerns, complaints or compliments?

N/A

Level of impact

From the information provided above and following EQIA guidance document Guidance on how to complete an EIA (click here), please indicate the perceived level of impact:

Low Level of Impact
*Potential device bias-any viable opportunities to accelerate the adoption of devices with more evenly balanced/non-biased performance in design across such as race and gender spectrum eg emerging diagnostic oxygen saturation probe algorithm/technologies

Name of Responsible Person undertaking this assessment: Peter Lee, Clinical Engineering

Signature:

Date: July 2026

APPENDIX– ENVIRONMENTAL IMPACT ASSESSMENT

The purpose of an environmental impact assessment is to identify the environmental impact, assess the significance of the consequences and, if required, reduce and mitigate the effect by either, a) amend the policy b) implement mitigating actions.

Area of impact	Environmental Risk/Impacts to consider	Yes/No	Action Taken (where necessary)
Waste and materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	N N N/A	
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released? (e.g. lubricants, liquid chemicals) • Does the policy fail to consider the need to provide adequate containment for these substances? (For example bunded containers, etc.)	N N/A	
Water	• Is the policy likely to result in an increase of water usage? (estimate quantities) • Is the policy likely to result in water being polluted? (e.g. dangerous chemicals being introduced in the water) • Does the policy fail to include a mitigating procedure? (e.g. modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)	N N N/A	
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air? (For example use of a furnaces; combustion of fuels, emission or particles to the atmosphere, etc.) • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	N N/A N/A	
Energy	• Does the policy result in an increase in energy consumption levels in the Trust? (estimate quantities)	N	
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	N	