MEDICAL DEVICES/EQUIPMENT MANAGEMENT POLICY

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Authors Name:			
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Policy to be followed by (target staff):

To be read in conjunction with the following documents:

Milton Keynes University Hospital NHS Foundation Trust. *Capital Framework Policy.* FAC/GL32. Version 6, Last review 2023.

Milton Keynes University Hospital NHS Foundation Trust. *Decontamination Policy.* FAC/GL/29. Version 4, Last review 2022.

Milton Keynes University Hospital NHS Foundation Trust. *Foundation Trust Standing Financial Instructions Policy.* FIN/GL/1. Version 10.0, 2022.

Milton Keynes University Hospital NHS Foundation Trust. *Incident Reporting Policy and Procedure (including Serious Incident Procedure).* RM/GL/17. Version 9.2, Last review Mar 2021.

Milton Keynes University Hospital NHS Foundation Trust. *Safe Working with Electricity Policy.* FAC/GL/5. Version 4.1, Last review 2020.

Milton Keynes University Hospital NHS Foundation Trust. *Safety Alerts Policy.* ORG/GL/23. Version 4.0, 2022.

Milton Keynes University Hospital NHS Foundation Trust. *Waste Disposal Policy.* FAC/GL/4. Version 6, 2023.

CQC Fundamental standards:
Regulation 15 – Premises and equipment

Commented [AA1]: Jacqueline, pls update the index section and advice on the approval groups. The draft policy went to estates governance group and MDG, is it to go next to H&S committee then TD committee then TEC (management board changed to TEC?, pls advice, thank you.

Commented [JS2R1]: Is there a Trust Medical Devices Group? IS this a new document? Yes, to H&S, No to TDC, Yes to TEC

Commented [AA3R1]: Yes there is a an MDG and I chair it, the meeting covers mainly medical equipment related safety issues hence we have amended the policy name as Medical device/equipment management policy and MDEG for clarification, we are not clinical.

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Policy Statement

Medical Devices/Equipment are increasingly used by healthcare professionals to support care and treatment of patients. The Milton Keynes University Hospital NHS Foundation Trust is committed to ensuring the safety of patients and medical devices/equipment that are managed, by placing robust systems in place to reduce the risks associated with the acquisition and use of medical devices/equipment during their whole life cycle.
This document sets out the policy for managing medical devices/equipment by promoting the requirement for procedures, which introduce a safer more efficient high quality of management of all medical devices/equipment.
This document follows recommendations from the Medicine and Healthcare Product Regulatory Agency's (MHRA) document Managing Medical Devices January 2021.

This policy is written with due regard to the Health & Safety at Work etc. Act 1974 and the Provision and Use of Work Equipment Regulations 1998, which place legal duties on the organisation to ensure equipment is suitable, fit for the intended purpose, inspected and maintained, and used by individuals who have received adequate information, training and instruction.

Purpose and scope

The purpose of this policy is to outline the Trust's approach to managing risks associated with the use of medical devices/equipment. The procedures contained in this document are based on guidance by the Department of Health, The Medicines and Healthcare products Regulatory Agency and designed to comply with the Care Quality Commission's fundamental standards.

In an effort to simplify this policy document it has been subdivided into five associated procedures;

MKUH-PC-01: Medical Equipment Acquisition Procedure (Appendix 1)
MKUH-PC-02: Medical Equipment Training Procedure (Appendix 2)
MKUH-PC-03: Medical Equipment Maintenance Procedure (Appendix 3)
MKUH-PC-04: Medical Equipment Acceptance, Deployment & Disposal Procedure (Appendix 4)
MKUH-PC-05: Medical Equipment Library Procedure (Appendix 5)

This policy applies to all staff working within MKUHFT, whether permanent or temporary who are involved in the use, procurement, maintenance or management of medical equipment.

All items of re-usable Medical equipment acquired through Trust funds, public donations, operating leases, hire, loan, consumable deals, free gifts and equipment directly funded by the Trust capital scheme or from Division's revenue budgets, comes under the guidance of this policy.

Abbreviations used

ADO- Associate Director of Division
AIC- Adverse Incident Centre
BC- Business Case
CAPMAN – CareAware Capacity Management® CareAware Capacity Management solutions include: CareAware Patient Flow: Patient throughput is a combination of clinical workflows, bed management, environmental services and transportation services. Transparency and visibility allow for efficient operations through use of CareAware Patient Flow.
CAS – Central Alert Systems
CBIG – Capital Business Investment Group
CC- Critical Care
CCU – Coronary Care Unit
CE - Clinical Engineering.
CEO – Chief Executive Officer
CFAM – Cerebral Function Monitoring
CPRG – Clinical Procurement Review Group
CQC – Care Quality Commission is the independent regulator of health and social care in England.
CPM – Continuous Passive Motion
CTG – Cardiotocography
DoCC – Department of Critical Care
EBME – Electro-Bio Medical Engineering
ECG – Echocardiogram
EMG – Electromyography
EO – Equipment Officers
EPR – Electronic Patient Record System - comprises a series of software applications which bring together key clinical and administrative data in one place.
EqIA – Equality Impact Assessment
EQ LIB – Equipment Library
FM/FBP – Finance Manager/ Finance Business Partner
HSDU – Hospital Sterilisation and Decontamination Unit
ICT – Information and Communications Technology
IFU – Instructions For Use
IPCT – Infection Prevention and Control Team
KPI – Key Performance Indicator
MDEG – Medical Devices/Equipment Group – risk manages all systems regarding Medical Equipment use within the Trust.
MDA – Medical Devices Alert
MDEG – Medical Devices/Equipment Group- risk manages all systems regarding Medical Equipment use within the Trust.
MEL – Medical Equipment Library
MEM – Medical Equipment Manager
MEO – Medical Equipment Officer
MHRA – Medicines and Healthcare products Regulatory Agency – Enhances and safeguards the health of the public by ensuring medicines and medical devices work and are acceptably safe.
MIA – Master Indemnity Agreement
MRI – Magnetic Resonance Imaging
NHSSC – NHS Supply Chain
NIBP – Non-invasive Blood Pressure
NNU – Neonatal Unit

OEM – Original Equipment Manufacturer
P2P – Purchase to Pay system
PA – Personal Assistant
PAQ – Pre-Acquisition Questionnaire that is provided by the supplier before medical equipment is purchased.
PBP – Procurement Business Partners
PPM – Planned Preventative Maintenance
POCT – Point of Care Testing
RFID – Radio Frequency Identification refers to a wireless system comprised of two components: tags and readers. The reader is a device that has one or more antennas that emit radio waves and receive signals back from the RFID tag. Tags, which use radio waves to communicate their identity and other information to nearby readers, can be passive or active.
SBS – Shared Business Services
SD – Syringe Driver
SFI – Standing Financial Instruction
TOR – Terms of Reference
URN – Unique Reference Number
VAT – Value Added Tax
W&C – Women and Children
WEE – Waste Electrical and Electronic

Definitions

Medical Device – "'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, 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,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"

Source: Article 1.2 of Directive 93/42/EEC as amended by Directive 2007/47/EC.

Examples of medical devices/equipment (not an exhaustive list)

Function	Examples
Diagnosis or treatment of disease	Diagnostic laboratory device, X-ray machines, magnetic resonance imaging (MRI) scanners, vascular catheters, dressings, surgical instruments, syringes, hip replacement implants, standalone software for diagnosis
Monitoring of patients	ECG, pulse oximeter
Critical care	Infant incubators, blood-gas analysers, defibrillators, ventilators, vascular stents
Improve function and independence of people with physical impairments	Hoists, orthotic and prosthetic appliances, pressure care devices, walking aids, wheelchairs
Community-based healthcare	Dressings, domiciliary oxygen therapy systems, urine drainage systems
Emergency services (ambulances)	Stretchers, trolleys, defibrillators

Source: Medicines and Healthcare products Regulatory Agency (MHRA). (2021d) *Managing medical devices: guidance for healthcare and social services organisations.*

Medical Equipment –
Medical equipment are defined as medical devices/equipment requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers'.

All medical equipment are medical devices—but not all devices are considered as equipment. For example, implants and single-use devices are clearly not equipment that needs to be inventoried or repaired occasionally, as they leave the hospital premises with the patient or are discarded after use.

"For the purpose of this report we have defined medical equipment to include all medical devices connected to patients as part of their care in hospital, and medical devices used for diagnostic or laboratory purposes. Medical equipment may also be used to support research and teaching. Medical equipment therefore represents a sub-set of medical devices, which also include items such as hospital beds, replacement joints and surgical appliances."

Source: National Audit Office. (1999) The management of medical equipment in NHS acute trusts in England. (HC 475, 1998-99). [Online]. Available from: https://www.nao.org.uk/wp-content/uploads/1999/06/9899475.pdf [Accessed 10 May 2024]

Asset Management Database - An inventory of medical equipment

Professional users - Also referred to as staff or users are Trust employees using medical equipment as part of their patient care.

End users - Patients, careers, relatives.

1.0 Roles and Responsibilities

1.1 The Chief Executive and the Trust Board

The Trust Chief Executive has overall responsibility for all aspects of health and safety and for policy implementation.
The Chief Executive will nominate a Lead Executive Director for the management of medical devices/equipment: Deputy CEO.

1.2 Associate Director of Estates

The duty holder is responsible for ensuring that systems are in place that allows the Trust's medical equipment assets to be maintained in accordance with MHRA guidelines. The duty holder will also ensure there is a process in place for auditing and monitoring of the training logs for medical equipment and that this is reported to the Medical Devices/Equipment Group and that any short comings are brought to the Trust's attention to allow the appropriate corrective actions to be put into place.

Systems will be in place to ensure that the Trust reports and investigates incidents involving medical equipment, in line with the Trusts Incident Reporting policy.

To provide the appropriate management of the Trusts Medical Equipment Asset Database to allow appropriate advice and guidance to the Trust as to allow the capital prioritisation and replacement of medical equipment.

1.3 Medical Equipment Manager

The duty holder is responsible for ensuring that agreed systems of work are followed to ensure the Trust's medical equipment assets are maintained in accordance with MHRA guidelines. The duty holder will also ensure that processes in place for auditing and monitoring of the training logs are completed in a timely manner for medical equipment and outcomes reported to the Medical Devices/Equipment Group and that any short comings are brought to the Trusts attention to allow the appropriate corrective actions to be put into place.

Systems are followed and in place to ensure that the Trust reports and investigates incidents involving medical equipment, in line with the Trusts Incident Reporting policy.

To provide the appropriate information to ensure the management of the Trusts Medical Equipment Asset Database to allow appropriate advice and guidance to the Trust as to allow the capital prioritisation and replacement of medical equipment.

1.4 Chief Officers

Chief Clinical/Nursing/Medical officers are responsible for ensuring that all staff who are required to use or supervise the use of medical devices/equipment receive appropriate training to comply with legal requirements and good practice and Medical Equipment Training is in accordance with the Medical Equipment Training Procedure. Chief officers will co-ordinate with the Medical Devices/Equipment Group, Specialist Sub-Groups and other managers to identify the appropriate equipment and configuration for use within the directorate.

1.5 ADO divisions and Operational Managers

Operational Managers are responsible for the identification of all medical device/equipment requirements within their areas of responsibility. This includes the necessity of ensuring that items of equipment not on any inventory (e.g. contracted, loaned) are assigned to the relevant Medical Equipment Officer (MEO) so that the equipment can be correctly deployed, regularly monitored and contractor's service provision controlled.

Managers are also responsible for ensuring that members of staff are released to undertake training to the required level.

The ADO divisions /Operational Manager will also be responsible on a day-to-day basis for ensuring that suitable and sufficient equipment is available to meet clinical needs.

1.6 Ward/Department Manager

Managers have the responsibility for keeping accurate records of their own asset inventories and ensuring that all nursing staff identified as using medical devices/equipment attend the training provided, and keep verifiable records, as described in the Medical Equipment Training Procedure. Managers or designated Medical Equipment Officers (MEO's) have primary responsibility for equipment management and are responsible for checking the performance and condition of equipment prior to and after use, routine maintenance (e.g., battery charging), decontamination and the prompt reporting of equipment defects.

Support and advice are available from the Trust's Medical Equipment Manager.

1.7 Senior Nurses/Staff

It is the responsibility of the Senior Nurse within each directorate to ensure that relevant nursing staff within the directorate are identified and nominated for training according to the Medical Equipment Training Procedure.

1.8 All Staff and Contractors

Have an obligation under the Health and Safety at Work Act 1974, as detailed in the Trust Health and Safety Policy, in terms of medical devices/equipment management in practice this means that staff and contractors:

- Only use a medical device/equipment if they have been properly trained in its use.
- Only use a device for its intended purpose.
- Check equipment prior to use for signs of deterioration including any cables, covering, plugs and report damages to the CE department.
- Understand how to report adverse incidents using RADAR - 'Incident Reporting System 'and to implement any proceeding action
- Are not afraid to ask either the Medical Equipment Library or CE staff if they require any advice regarding a medical equipment.

Before using any medical device/equipment staff and contractors should:

- Always check that the testing and maintenance of a device is up to date: each device MUST have a test 'Next Due Date' sticker so that users are aware that equipment is within the maintenance date. For advice contact the CE department. Equipment users must ensure the device is clean, safe and labelled in accordance with the procedure (MKUH-PC-03) for maintenance and calibration'. If not, then the device/equipment must be prepared in accordance with appropriate decontamination procedures and written information provided by the user as to the risks associated with using the device.
- Ensure that all staff use the approved documents where applicable and specific to their area of work.
- Be responsible for ensuring that they manage use and prescribe medical devices/equipment safely and report any incidents or near misses and any concerns regarding shortfalls in safety or other aspects of medical equipment management.
- Ensure they understand the purpose, operation and limitation of equipment together with measures to minimise risks.

Clinical users have a duty of care to their patients and others.

1.9 Home users

Could be patients, their carers or relatives who use medical equipment unsupervised. They should be instructed to use the equipment for its intended purpose with training provided by the community nurses. They should take care of the device/equipment in their use when no longer required and return hospital property.

1.10 Medical Equipment Officer

The ward/department manager will nominate a Medical Equipment Officer (MEO) who will be responsible for ensuring that all procedures relating to the Medical Devices Management Policy are complied with. The ward/department manager has overall responsibility.

The MEO will ensure that:

- Periodic (minimum of annually) inspections of the directorate/ward/department records are completed and take the necessary action to ensure that servicing of all medical equipment is carried out.

- In accordance with the Trust Standing Financial Instructions (SFI), for new

or replacement medical equipment under the value of 5k is to include 'Equipment Request form for Purchasing (E-form)'. Pre-Acquisition Questionnaire (PAQ) with decontamination instructions and a written quote. The PAQ and quote are obtained from the relevant companies (The Medical Equipment Manager or the Medical Equipment Library Manager can assist with this process).

- The maintenance booking for routine servicing of medical equipment via CE and/or the Medical Equipment Library is carried out and maintain a record within the department.

- Arrangements with the Medical Equipment Training Coordinator or the relevant speciality e.g. Resus team, on any training on medical equipment has been made and also for maintaining the register of training on the Staff Training Log. Advice can be obtained from the Medical Equipment Training Coordinator.

- Records are kept of medical equipment loans to patients and others and that these are regularly checked ensuring that any medical equipment that leaves the hospital site Appendix B 'Equipment Leaving the Hospital' (see MKUH-PC-05 Medical Equipment Library Procedure) is completed in full and returned to the Medical Equipment Library.

- The procedure for condemnation and disposal of equipment is followed and will be dealt with in accordance with the Medical Equipment Acceptance, Deployment and Disposal Procedure MKUH-PC-04 and in accordance with the Trust SFI Appendix A: Asset Acquisition/Disposal Notification Form (see Medical Equipment Acceptance, Deployment and Disposal Procedure MKUH-PC-04).

- CE department is informed of all equipment that is permanently moved to other ward/department

- The Master Indemnity Agreement (MIA) provides protection to an NHS trust when it is in receipt of equipment or goods from a supplier. All procedures for loan, testing or trial equipment are followed without exception and ensuring that Appendix B 'MIA Call-Off Agreement' (see Medical Equipment Acceptance, Deployment and Disposal Procedure MKUH-PC-04) is completed in full. It is crucial to note that no equipment may be used on trial until a completed and signed indemnity form has been received by the CE department.

In the event of failure to nominate an (MEO) Equipment Officer the ward/department manager will take on this responsibility. Please see Terms of reference for Medical Equipment Officer Appendix C and Guidelines for MEOs Appendix F (see MKUH-PC-02 Medical Equipment Training Procedure)

1.11 Medical Devices/Equipment Group (MDEG)

The Medical Devices/Equipment Group is responsible for all aspects of Medical Device/Equipment management and in particular for the implementation of Assurance Standards for Medical Device Management and advising the Trust on standardisation, procurement and training process for all medical devices/equipment.
The Medical Devices/Equipment Group contains wide ranging representation from clinical, engineering, purchasing and finance staff. This group is responsible for prioritising purchasing, improving communications, fostering consensus between clinical and technical supervisors in relation to proposed changes. Reducing confusion about who is responsible for device management tasks, training and safe device operation, is also a key objective.
Medical Equipment Safety Committee sits within this group.
The terms of reference for this group can be seen at Appendix A.

1.12 Risk and Workplace Safety Coordinator

Is responsible for the day to day operation of the trust safety alert system for the dissemination of safety alerts produces through the national Central Alerting System. He/she will manage alerts, raise concerns and escalate issues in accordance with national guidance and the Trust Safety Alerts Policy.

1.13 Health & Safety Advisor

Is the Trusts competent person in relation to health and safety as required under the Management of Health & Safety at Work Regulations 1999.

He/she is responsible for oversight of the Trust process for the management and dissemination of safety alerts issued through the Central Alerting System and in line with the Trust Safety Alerts Policy. Accountability for ensuring the procedures are complied lies with the Chief Corporate Services Officer.

Although not directly involved in the management of medical devices/equipment and equipment, he/she will provide advice and support to all staff within the Trust in relation to health and safety legal compliance including the use of work equipment, referring to the Estates Department/Medical Equipment Manager/Equipment Library Manager where subject is out of their expertise.

He/she will arrange for any incident in relation to medical equipment which requires reporting to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrence Regulations 2013.

1.14 Procurement Manager

To ensure compliance with Trust SFI (Standing Financial instruction), legal obligations and European legislation with regard to tendering and contract procedures.

To ensure compliance with guidance, codes of conduct and good practice with regard to the procurement and supply of medical devices/equipment. To place purchase orders once required PAQ have been approved and URNs (Unique Reference Number) have been obtained from NHSSC in accordance with Trust standardisation process.

1.15 Estates Services

To maintain an asset register of all assets within Milton Keynes University Hospital NHS Foundation Trust.

To maintain/advice on Medical Equipment contractual agreements between the Trust and various companies involved.

1.16 Medical Equipment Manager

The Medical Equipment Manager has a responsibility with regards to.

- Capital replacement program for medical equipment.
- Acting in support of the Associate Director of Estates and provide a single point of contact for advice and liaising on matters concerning medical equipment.
- Supporting capital and revenue procurement and future investment planning.
- Advising and supporting clinicians with the delivery of medical equipment user training.
- Supporting the Trust to develop policies and procedures.
- Key Member for Medical Devices/Equipment Group.
- Authorising PAQ approvals.
- Working with the Trusts' key PAQ approvers and clinicians to invest on medical equipment that is required for clinical areas.
- Providing guidance on medical equipment standardisation.
- Liaising with CE to get the best service for the Trust and implementing procedures.
- Liaising officer between the manufacturers/suppliers and the Trust
- Medical Equipment Safety Liaising Officer for the Trust.
- Carrying out RADAR incident investigations on medical equipment
- Ensuring compliance with international and national standards, guidance, codes of conduct and good practice.
- Advising clinicians on maintenance contract levels working with CE
- Managing CE contract
- Advising disposal notices to clinicians

1.17 CE Manager

The CE Manager has a responsibility with regards to;

- Ensure that assets under their remit are maintained as per manufacturers' recommendations and as the contractual agreement between Dräger Medical UK Managed Hospital Services (the 'CE Provider') and Milton Keynes Hospital NHS Foundation Trust.
- Administering and maintaining an Equipment Asset Management system
- Scheduling KPIs for maintenance of reusable medical equipment
- Recording Equipment repairs on the Trust's asset management database
- Taking decisions about the most appropriate strategy for repairs, inspection/planned maintenance, correct disposal of medical equipment including donations of equipment to registered charities and equipment management as described in the Medical Equipment Acceptance, Deployment and Disposal Procedure (MKUH-PC-04)
- Liaising between Risk Management and the Trust in investigating incidences that involves medical equipment

1.18 Medical Equipment Library Manager

The Medical Equipment Library Manager has a responsibility with regards to.

- Managing the medical equipment library.
- Liaising with suppliers for consumables and accessories.
- RFID Asset Tracking Database.
- Co-ordinating RADAR incidents and safety alerts.
- Carrying out a monthly audit of medical equipment maintenance throughout the Trust.
- Updating e-Quip as per the disposal notices
- Managing assets for therapeutic equipment

1.19 Medical Equipment Training Coordinator

The Medical Equipment Training Coordinator has a responsibility with regards to:

- To determine appropriate arrangements for refresher training and ensure that this is delivered to the plan.
- To ensure that managers are informed about training delivered to staff in their areas, communicating at all levels.
- To liaise with the Trusts training department.
- To be responsible for the introduction and design of Equipment Folders for use in clinical areas ensuring that these are updated appropriately and that all staff have access to user instructions.
- To liaise with the manager responsible for the collating of records of clinical incidents for possible training issues taking appropriate action where necessary.
- To develop links with medical devices training coordinators in other trusts and participate actively in benchmarking.
- To deliver training schedules where occasional prolonged concentration will be required.
- To be the medical equipment training representative at Medical Devices Group.

1.20 Head of IT

The Head of IT has a responsibility with regards to.

- Lead and develop the IT team, maintaining a collaborative and constructive working environment within the department
- Responsibility for the network infrastructure, it's maintenance, development and ongoing availability.
- Ensuring data is stored securely and is accessible at all times (e.g. business continuity, disaster recovery and system back up).
- The effective management and development of the Trust's telephony and mobile communications.
- Hardware and Server infrastructure is maintained and developed in line with an agreed ICT strategy.

1.21 eCARE Team

Responsible in collaboration with IT department, for delivery of the eCARE Programme. Liaising with all areas of the Trust, clinical and non-clinical, as well as the

supplier- Oracle to deliver the programme and complete build and configuration work. Included in scope of the project is the configuration of associated devices/equipment that will be used with the eCARE system, therefore also liaising with Medical Equipment Management Team and 3rd party suppliers.

1.22 Trust Lead for Point of Care (POCT) Testing

Is responsible for.

- Ensuring that all procedures relating to POCT devices/equipment and equipment are complaint with the Trust's Point of Care Testing Policy.
- The technical governance for all point testing devices/equipment used or proposed to be used within the Trust and provides the liaison between clinical areas and the pathology dept. to ensure that all devices/equipment used are safe within the Trust.
- Making sure that all devices/equipment have adequate quality control and assurance regimes in place to be able to demonstrate that the quality of the results being produced is similar to those from the laboratory.
- Providing advice prior to the introduction of any new device to make sure that wards and departments followed the standardisation process.

1.23 Hospital Sterilisation Disinfection Unit

All new surgical instrumentation and medical devices reprocessed through HSDU are assessed prior to reprocessing using the IFUs. As part of the Medical Equipment manager's remit the IFUs are sent to the Decontamination Lead for review during the PAQ/business case stage to ensure that the equipment can be processed. Any items found not to be compatible will need to be individually risk assessed.

1.24 Infection prevention team

The infection Prevention and Control team (IPCT) have responsibility for assessing the risks and requirements for the cleaning and decontamination medical devices/equipment and have responsibility for assessing the documents for the cleaning and decontamination of medical equipment.

1.25 Central Alerting System Monitoring Group (Estates)

To identify and act on Safety Alerts which are within the remit of medical equipment management received from various agencies. The group will meet every Tuesday morning to discuss and agree on a plan of action on safety alerts that Milton Keynes University NHS Foundation Trust receives from various agencies (Appendix B). A database will be kept to record alert dissemination, acknowledgements and responses, and alert 'closures'.

2.0 Implementation and dissemination of document

This policy will be published on the Trust Intranet and will be sent to local managers for dissemination and implementation. The Medical Equipment Manager will provide guidance through the procedures and also compile pertinent suggestions from across the Trust. These suggestions will then be reported to the MDEG on quarterly basis for further discussions and eventually incorporated into later versions of this policy as appropriate.

3.0 Processes and procedures

3.1 Managing the Risks Associated with Medical Equipment

To effectively manage the risks associated with re-usable medical equipment. The Trust will ensure that medical equipment is managed;

- **Adequately budgeted for to meet clinical needs**: Both through capital planning and revenue allocation, Operational Managers in agreement with Finance Directorate are responsible for setting their priorities for new acquisitions as well as for replacement of unsafe or obsolete equipment to make sure equipment levels are adequate to meet service demand in a safe manner.

- **Acquired with safety as a driver, and in a cost-effective manner**: patient safety considerations are the main focus of any acquisition project, which starts by assessing the risks to form the basis for the rationale behind the acquisition. Clinical users will be fully involved in the process of defining the need, selection and evaluation to ensure that only equipment that suit their need and are fit for their intended purpose are acquired (see Medical Equipment Acquisition Procedure MKUH-PC-01).

- **Standardised**: the Trust recognises the risks associated with the use of various types and models of equipment for the same purpose; to minimise these risks a strategy of standardisation will be adopted on most commonly used equipment. This strategy will ensure an increase in equipment availability; contribute to lowering costs of acquisition and maintenance and minimising risks associated with training.
  To support the standardisation approach and to make a better use of its assets, the Trust adopted a Medical Equipment Library loan service, (see MKUH-PC-05 Medical Equipment Library Procedure).

- **Properly understood by the users**: The Trust expects all its staff at all levels to adhere to the following principles before using any Medical Equipment:
  Staff will:

    - not use an equipment for which they have not received adequate training and which they do not feel competent to use safely.
    - ensure manufacturers' instructions are available when needed. These or a reference to them should be found in the Local Medical Equipment Log Spreadsheet,.
    - visually check equipment for damage, perform user maintenance if required and check settings before use.
    - ensure disposables and/or accessories are available and that they are of the correct type.
    - Always use original manufacturer disposables and accessories. If this cannot be achieved for any reason, a full risk assessment should be completed.
    - Under no circumstances will any equipment be modified in any way unless explicitly asked for or authorised by the manufacturer in writing.
      (see Medical Equipment Training Procedure MKUH-PC-02)

- **Appropriately maintained**: to ensure its patients and staff are protected against electrical hazards or equipment malfunctions, the Trust uses both in-house maintenance services and external contractors to ensure its equipment are appropriately tested, maintained and calibrated. The maintenance regime in place uses an equipment asset management system to record the history of all maintenance intervention; the maintenance regime follows a priority based on equipment risk assessment scoring. (see Medical Equipment Maintenance and Calibration Procedure MKUH-PC-03)

- **Stored in clean, safe and adequate conditions**: when equipment is not in use it should be safely and securely stored following its manufacturers' storage recommendations. Unsuitable storage could contribute to equipment related incidents.
  Ward / department managers will regularly review their storage arrangement and continuously asses the risks that could rise from unsafe storage; support is available from the Trust's Medical Equipment Manager.

- **Decontaminated following manufacturers specific guidelines**: before any equipment is used on a patient, locally stored or moved to the Medical Equipment Library or to the CE Department it will be properly decontaminated according to its manufacturer's instructions and in line with the Trust's Decontamination Policy.

- **Disposed of in a safe and legal manner**: the Trust follows the Waste of Electronics and Electrical Equipment directive in dealing with its equipment disposal. When equipment is no longer required and in need of disposal, all Trust users should follow the Disposal Procedure, (see Medical Equipment Acceptance, Deployment & Disposal Procedure MKUH-PC-04).

- **Systematically recorded**: The Trust operates a Medical Equipment Asset Management System to record its re-usable diagnostic and therapeutic medical equipment related data such as owner department, location, ownership type, cost of acquisition, maintenance schedules, breakdown-repair history and maintenance contract details.

- **Reported**: Incidents and near misses will be dealt with by following the Trust's incident reporting process in line with the Trust's Incidents Reporting Policy; and should be reported to the MHRA.
  Incidents will be investigated within the clinical area where they occur. There will be corporate level monitoring of equipment related incidents.

  This process is overseen by the Trust's Risk Management Department supported by the Medical Devices/Equipment Group, with reporting through the Trust's governance arrangements to the Patient Safety Board.

  Training – Please see section MKUH-PC-02: MEDICAL EQUIPMENT TRAINING PROCEDURE.

  Incident reporting – All staff are responsible for reporting incidents, accident and near misses in relation to medical equipment onto the RADAR incident reporting system. Investigations will be undertaken in line with the Trust Incident reporting policy. It is the Risk & Workplace Safety Coordinator's responsibility to report defects / faults to the MHRA.

Plans for emergencies/ – what happens if a piece of equipment breaks down, is this included in another procedure which should be identified here.

Disciplinary procedure for non-compliance with policy – All staff must comply with the requirements of this policy. Failure to do so could lead to disciplinary action being taken against the individual in line with the Trust Disciplinary Policy and Procedure.

3.2 Data Security of Network-Connected Medical Devices/Equipment

- **Device Security**
  All medical devices connected to the network must comply with the latest security standards. This includes, but is not limited to, encryption of data at rest and in transit, strong user authentication mechanisms, and regular security updates and patches.
- **Network Security**
  Networks to which medical devices are connected must be secured and regularly monitored for any potential threats or breaches. This includes implementing firewalls, intrusion detection systems, and secure network architectures (e.g.network segmentation).
- **Incident Response**
  In the event of a security incident, a predefined incident response plan must be followed. This plan should include steps for identifying, containing, eradicating, and recovering from the incident, as well as post-incident analysis to prevent future occurrences.

3.2.1 Security Patching

- **Regular Patching**
  All network-connected medical devices must be regularly updated with the latest security patches. This is crucial to protect against known vulnerabilities that could be exploited by malicious actors.

- **Patch Management Process**
  A structured patch management process must be in place to ensure patches are applied in a timely and effective manner. This includes evaluating the patches, testing them for compatibility issues, and then deploying them across the devices.

- **Vendor Communication**
  Regular communication with device vendors is essential to stay informed about the availability of patches and any known issues or vulnerabilities. Vendors should provide timely notifications about patches, which should then be applied as per the patch management process.

3.3 Emerging Medical Device Technology

- **Technology Evaluation**
  Emerging technologies for medical devices must be thoroughly evaluated for safety, effectiveness, and security before they are adopted. This includes

reviewing scientific literature, conducting independent testing, and consulting with experts in the field.

- **Training and Education**
  Staff must be provided with appropriate training and education on new technologies. This includes understanding the capabilities and limitations of the technology, as well as any potential risks or challenges.

- **Continuous Monitoring**
  Once adopted, emerging technologies must be continuously monitored for any issues or advancements. This includes regular reviews of device performance, patient outcomes, and any new scientific research or technological developments.

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Associated Documents

MKUH-PC-01: Medical Equipment Acquisition Procedure (Appendix 1)
MKUH-PC-02: Medical Equipment Training Procedure (Appendix 2)
MKUH-PC- 03: Medical Equipment Maintenance Procedure (Appendix 3)
MKUH-PC-04: Medical Equipment Acceptance, Deployment & Disposal Procedure (Appendix 4)
MKUH-PC-05: Medical Equipment Library Procedure (Appendix 5)

5.0 Governance

5.1 Document review history

Version number	Review date	Reviewed by	Changes made
2.1			Equipment Request form for Purchasing (E-form)
2.2	**05/07/19**		Equipment Request form for Purchasing (E-form)
2.3	**Feb24**		Policy name for clarity, medical equipment definition, added auction process with a flow chart, new user training refresher form, amended purchasing flowcharts, changes to Job titles, new process for Library - Capman use

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
H&S Advisor	H&S and incident reporting	Feb2024	Feb 2024	Updated section 1.12 and H&S advisor role	Yes
CE Manager	Medical Equipment Maintenance	Feb2024	Feb2024	Auction flowchart agreed	Yes
Medical Equipment Library Manager	Equipment Library	Feb2024	Feb2024	Library section updated with using Capman and safety alert process flow chart	Yes
Risk & Workplace Safety Coordinator	Safety alerts	Feb2024	Feb 2024	The role is added	Yes
Head of Risk & Clinical Governance	Risk & Clinical Governance	Feb2024	Feb 2024	Changes to executive titles	Yes
Deputy Imaging Service Lead	Imaging	Feb2024	March 2024	none	Yes

Medical Equipment Manager	Estates	Feb2024	March 2024	Updated the policy	Yes
Procurement Manager and team	Purchasing	Feb2024	Feb 2024	Procurement process update in line with current legislation	Yes
Estates Governance Group	Estates	Feb2024	Feb 2024	Information manager role update- removal from the policy	Yes
Finance Manager for BCs	Finance	Feb2024	March 2024	none	Yes
Medical Devices/Equipment Group	Medical Devices/equipment Management	Feb2024	Agreed changes	Agreed	Yes
Associate Director of IT	IT systems	Feb2024	none	agreed	Yes
Operational Managers	Operational Support	March 2024	none	agreed	Yes
ADOs Divisions	Divisional Support	March 2024	none	agreed	Yes
Decontamination Lead	HSDU	Feb2024	Feb 2024	Updated titles and wording under the HSDU section	Yes
Chief Executive	Trust Management		none	Not required to go to TDC	Yes

5.3 Audit and monitoring

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
Inventory Asset Management	Trust's Asset management database	Estates	Annually	MDEG
Planned maintenance/ calibration Monthly PPM outcome	KPI schedules Monthly Medical Equipment Audit Report	Estates Estates	Annually Monthly	MDEG MDEG
Breakdown repair	Trust's Asset management database (Fmfirst)	Estates	Annually	MDEG
User training	Training folders within each department and training spreadsheet	Estates	Quarterly	MDEG

5.4 Equality Impact Assessment

As part of its development, this policy and its impact on equality has been reviewed. The purpose of the assessment is to minimise and if possible remove any disproportionate impact on the grounds of race, gender, disability, age, sexual orientation, religion or belief, pregnancy and maternity, gender reassignment or marriage and civil partnership. No detriment was identified.

Equality Impact Assessment			
Division	**Estates**	**Department**	**Equipment Management**
Person completing the EqIA	**Author of policy**	**Contact No.**	
Others involved:		**Date of assessment:**	**Time of policy review**
Existing policy/service		**New policy/service**	

Will patients, carers, the public or staff be affected by the policy/service?	Staff
If staff, how many/which groups will be effected?	All staff

Protected characteristic	**Any impact?**	**Comments**
Age	NO	
Disability	NO	
Gender reassignment	NO	
Marriage and civil partnership	NO	
Pregnancy and maternity	NO	
Race	NO	
Religion or belief	NO	
Sex	NO	
Sexual orientation	NO	

What consultation method(s) have you carried out?	
How are the changes/amendments to the policies/services communicated?	

Appendix A: Medical Devices/Equipment Group Terms of Reference

Constitution
The Medical Devices/Equipment Group is a sub-group of the **Capital Business Investment, the Capital Control Group** and Patient Safety Board and has no powers other than those specifically delegated in these terms of reference.

Authority
The MDEG is responsible for all aspects of Medical Device/Equipment management and in particular for the implementation of Assurance Standards for Medical Device/Equipment Management, compliant with CQC regulations and advising the Trust on standardisation, procurement and training process for all medical devices/equipment.

Accountability
The MDEG is accountable to (executive) the Chief Operating Officer

PURPOSE
To support the achievement of the Trust key objectives and to provide assurance to the Management Board. The remit of the Group will be responsible for overseeing the work of any sub-groups established to work on related projects.

The MDG will consider issues relating to the following:

- Medical Device/Equipment selection policies
- Medical Device/Equipment standardisation
- Standardisation of administration systems for medical devices/equipment
- Medical Device/Equipment Acceptance Procedures
- Medical, Nursing & Therapies training relating to the use of Medical Device/Equipment
- Maintenance and Repair Policies
- Medical Device/Equipment Asset list
- Disposal Policies
- Decontamination issues relating to Medical Devices/Equipment
- Financial control of Medical Devices/Equipment purchasing
- Replacement Policies
- Safety and Hazard Notices and MDA Incident Reports
- Recommendation of Capital bids for replacement medical equipment linked to the rolling replacement program
- Relevant risks in relation to Medical Devices/Equipment
- Review Risk register in relation to risks associate with Medical Devices/Equipment
- IT network and EPR connectivity

MEMBERSHIP, ATTENDANCE AND QUORUM
Membership
The Membership of the Medical Devices Group shall be as follows:
Core Members:

- Head of Estates – (invite only)
- Assistant Director of Infection Prevention Control
- Medical Equipment Manager (Chair)
- Clinical leads– 1 representative per division
  Surgery - W&C - Medicine – Core Clinical

- Endoscopy Manager
- Head of Decontamination Services – (invite only)
- Imaging Services Lead
- Estates Services Manager - (invite only)
- Medical Equipment Library Manager
- Clinical Engineering Manager
- Procurement Business Partner
- Finance Manager- BCs
- Risk & Workplace Safety Coordinator
- IT Representative
- Pathology Services Manager (invite only)
- Pharmacy Representative - (invite only)
- Point of care Services Lead - (invite only)

Committee Secretaria:

- PA to Estates Managers

All members should ensure that a deputy attends on their behalf when they are unavailable to attend.
When an individual is no longer identified as a committee member, they are to notify the Group secretariat of the change and handover the responsibility for membership within their area of responsibility.

The Group may co-opt any additional members that it deems necessary.

Attendance
Members of the MDEG are expected to attend all meetings of the Group.

Quorum
A quorum of the MDEG shall be **6** members minimum.

If the meeting is found to not be quorate at the identified date/time, then it will be cancelled, rearranged and recorded.

MEETINGS & CONDUCT OF BUSINESS
Frequency
The MDEG will meet monthly to discuss medical devices/equipment capital procurement and safety related management of medical devices/equipment issues.

Agenda/Papers for the meeting
The Agenda for meetings will be circulated to all members of the Group.
The Group will at least annually:
review these Terms of Reference
consider the key performance indicators that it wishes to consider at each meeting.

The following standing items will appear on each agenda:
Apologies for absence
Minutes of Last Meeting
Matters arising Action Log
Significant Risk Register & CAS (Central Alert Systems) and Incident Reports

Safety issues relating to Medical equipment
CE update – KPI report
Medical Equipment Training Update
Any other Business

The following reports will be required before each meeting and saved on the MDG teams folder.

a. IT/ e-CARE update – IT project lead
b. Capital Plan and BCs update – FBP for BCs
c. Procurement update – All PBPs
d. Medical Equipment Audit – MEL Manager
e. Radar report - to be presented
f. KPI Report- to be presented
g. Training update spreadsheet – to be presented

Process for monitoring the effectiveness of the above arrangements:
The process for monitoring the effectiveness of the MDEG is via an annual review of the Terms of Reference; that includes quoracy, frequency of meeting, delivery of its annual work plan (this includes assessment of regular items of reporting e.g., Medical Equipment Audit, CE KPIs etc.) and identification and dissemination of lessons learnt and improvements made.

DUTIES OF THE MEDICAL DEVICES GROUP

1. The Group will ensure that all items of medical device/equipment, regardless of the source of funding, including Trust Funds, or supply meets with its approval and any standardisation or policies that it puts in place.

2. The role of Medical Equipment Manager and CE Manager will review the Trust's stock of medical equipment from the Asset Management database and present an analysis of the age and needs for replacement to the group before each new financial year.

3. The Group will propose/advise to the **Associate Director (ADO) for each division and the Deputy Finance Manager** an annual **replacement** program for medical device/equipment purchase:
   - The group will develop a policy for ensuring that replacement devices/equipment and new developments are equitably treated.
   - The Group will develop a standard process for all bids for new medical devices/equipment individually costing £1000 or more for suitability. All future bids must be made through this system, regardless of the source of funding.
   - No bid for new devices/equipment will be considered unless it has been communicated to the relevant Medical Director and ADO.
   - All bids for medical devices/equipment must consider the whole life costs including running costs, disposable items, maintenance and EPR compatibility.
   - The Group will liaise with the **Deputy** Finance Director and the ADOs on the replacement of Medical Equipment recommendations as per the MDEG meeting discussion on the safety aspects of medical devices/equipment. - The MDEG members will also review BCs outside of the meeting to support the business case planning and capital planning process.
   - The Group will support a disposal policy to ensure that items that have been replaced are safely removed from the Trust's premises and from the inventory.
   - The group will discuss and agree auction possibilities on condemned equipment.

4. The Group will ensure that all new purchases are suitably accepted into the Trust. This will include entering the data onto the Trust's inventory, ensuring that all staff are trained in its use and that any procedures related to the use of the equipment are in place.

5. For Loan or Trial equipment please refer to the **Medical Devices/Equipment Management** Policy on the Trust's Intranet Site

6. The Group will monitor, & report to the Patient Safety Board that any Safety or Hazard Notices are rapidly investigated and the relevant equipment identified and any necessary action implemented.

7. The Group will ensure that any incidents involving medical devices/equipment are reported to the MDA AIC (Adverse Incident Centre) and the implications for the Trust are evaluated.

8. Improving reporting of and learning from Medical Device/Equipment incidents in the Trust.

9. To ensure the identification, prioritisation and mitigation of Medical device/equipment risks to minimise harm to patients.

10. Identifying, developing and promoting best practice for medical device/equipment safety

11. Coordinating education and training support to improve the quality of medical device/equipment error incident reports and safe medical device/equipment practices.

12. BCs will be monitored via the MDEG group members and any outstanding actions will be reported to the FBP for BCs. The PAQ approval process for each medical device/equipment will be monitored by the Group, covering the following areas;
    Procurement, Infection prevention, IT, Clinical Engineering, Medical Equipment Library, Training and consumables, accessories and ongoing costs.

Agreement of Policies and guidelines

The Group will agree policies and procedures for the selection and standardisation of ranges of medical devices/equipment and once such a policy is in place all purchases of this type of equipment must comply with the policy. Policies will require approval at the Trust Documentation Committee before final publication. The Group will take an overview on the selection, purchase and use of all types of medical device/equipment as defined in the Medical Device Regulations.

1. The Group will ensure that policies relating to single use and decontamination of medical devices/equipment are developed and implemented via HSDU.

Assurance on risks

Management of risks within the Trust is undertaken via a hierarchy (a multi-level escalation model) that is documented in the Risk Management Strategy. Risks scoring 12 and above are identified from the Divisional/Clinical Service Unit and Departmental Risk Registers and these are used to inform the Trust-wide Risk Register. Risks scoring 15 and above that are identified from these are reviewed for inclusion in the Board assurance Framework. Movement on the Trust BAF is tracked via a summary sheet.
The Medical Devices/Equipment Group will maintain an awareness and understanding of the risks contained within the Trust-wide Risk Register.

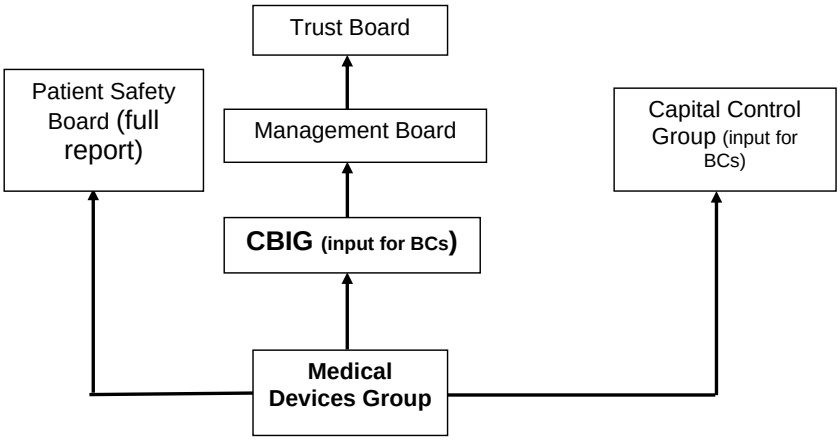
Patient Experience

Review and disseminate Patient Experience information from within the MDEG and other sources, highlighting aspects of learning to enable minimisation of complaints, claims and recurrences and dissemination of good practice. Also highlighting patient experience focused outcomes e.g., Radar, complaints, compliments and reaction levels that are monitored by the Patient Experience Team and Trust based patient surveys and information.

Version control

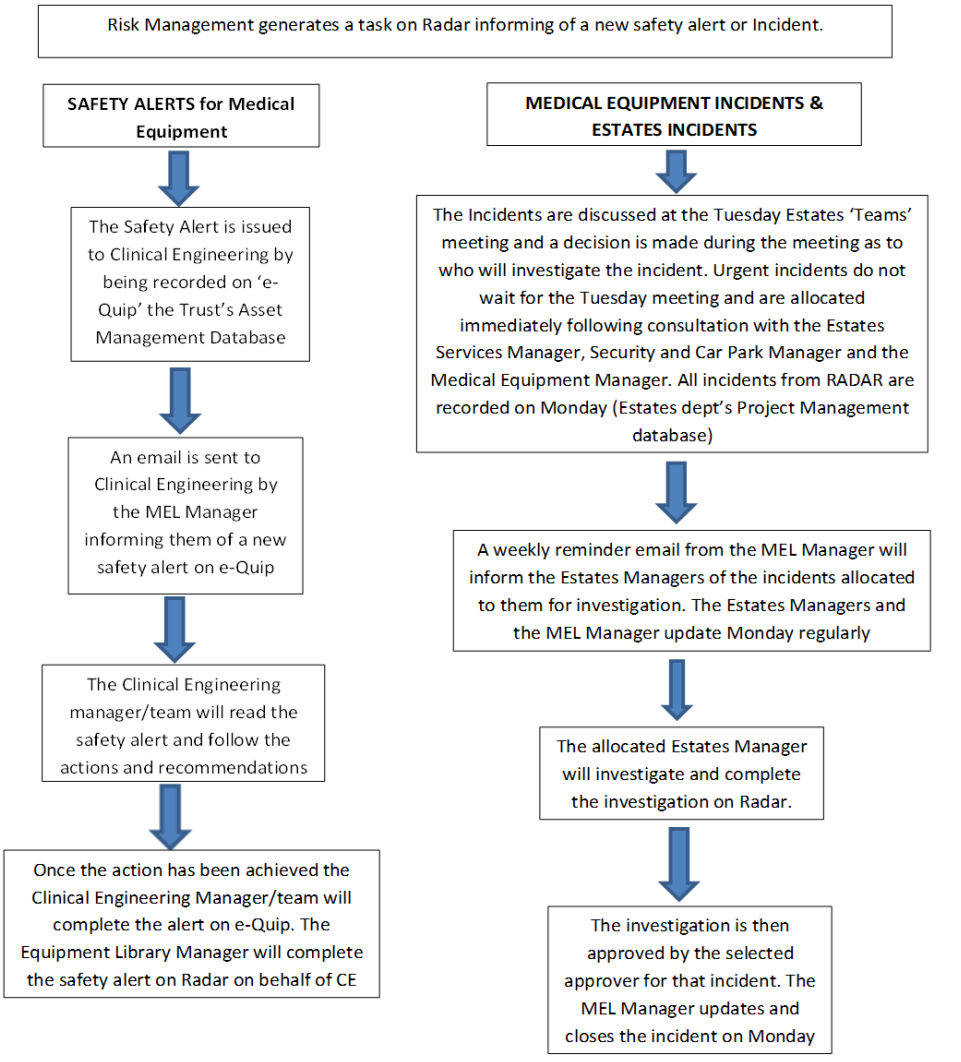
Version	Date	Author	Comments	Status
1.0	2012		Implementation of the Medical Devices Group	Approved
2.0	January 2014			Approved
3.0	May 2016		Minor changes to Appendix 1 and membership	Approved
4.0	Jan2018		Changes applied to Membership, Agenda and reporting route	Approved
5.0	Sept20		Changes applied to Membership, Agenda and reporting route	Approved
6.0	March 23		Changes applied to the Agenda and the TOR	

Sub-groups of the Medical Devices/Equipment Group



Appendix B: Estates central alerting system monitoring group Safety Alerts Response Protocol and Estates Incidents

The Estates department receives a number of safety alerts from various agencies along with incidents recorded on Radar (Database for recording CAS alerts and incidents); this overview is to assist you in ensuring that the deadlines are met within the stated time span.



Any outstanding safety alerts are discussed at the monthly MDEG and Incidents on RADAR are discussed at the weekly Tuesday Estates 'Teams' meeting and updates recorded where necessary.

MKUH-PC-01: MEDICAL EQUIPMENT ACQUISITION PROCEDURE (Appendix 1)

1.0 Purpose

The purpose of this procedure is to clarify the process of medical equipment acquisition including equipment funded through capital, revenue, charitable funds, rentals, loans and donations.

2.0 General requirements for all Medical Equipment Purchases

The Medical Devices/Equipment Group (MDEG) within the Medical Device Management Policy plays a major role in medical equipment selection that will adhere to the principles of standardisation . Finance Programme Manager and Procurement Business Partner shall liaise with the Medical Equipment Manager in any multiple purchases of medical equipment to ensure that the principles of standardisation are met. This includes 'akin to' equipment bought periodically e.g. Blood pressure machines, patient monitoring equipment, syringe drivers, infusion pumps etc.

All new equipment purchases will form part of the Business Case Planning process for the respective year. The selected equipment should match similar equipment already within the Trust to enable standardisation, which will keep some costs to minimum. This enables utilisation of existing maintenance and/or consumables agreements.

Equipment must be fit for the purpose for which it is intended. This should not be based solely on manufacturer or supplier claims. Visits to other NHS establishments already using proposed equipment can be arranged where this would assist in the selection process. Medical Equipment should offer value for money and have a reasonable working life. For advice, contact Medical Equipment Manager and /or the CE Department.

Prior to purchase all medical equipment must be assessed for suitable and appropriate methods of decontamination and the PAQ with the quote must be obtained from the company/supplier. The advice is sought from the Medical Equipment Manager who will liaise with the PAQ approvers (Procurement Business Partner, CE Manager, Decontamination Lead and Infection Prevention Team) before purchasing any medical equipment. The PAQ forms relate to quality assurance, electrical safety and the availability of maintenance, servicing and spares, decontamination procedure. The approval of purchase will be agreed on the shared drive that all approvers can access. Please follow Appendix C capital and revenue routes for purchasing).

The submission to purchase must consider true revenue consequences, to include purchase of necessary training, service manuals, servicing, maintenance, consumable items and running costs, to enable funding to be sought to support the purchase. Revenue consequences to the Directorate should also be identified. Consultation should take place with the Medical Equipment Manager and CE manager to check whether there is a process in force regarding the type of equipment and if necessary, whether there is already a service agreement in place with a particular manufacturer.

All equipment purchases, whether bought through Capital, Revenue, donated equipment, charitable funds or Trust Funds, is subject to those rules laid down in Trust Standing Financial Instructions.. Should the total purchase price be above the limit set for the year by the EU, then the EU tender regulations must be met. Purchasers should be aware that this is a lengthy process.

Equipment bought through Charitable Funds may be liable for VAT exemption or reclamation of VAT. This does not apply to all purchases. Advice may be sought from the Procurement Department. Procurement department is responsible for filling in VAT exemption forms submitted through the purchase order process.

Staff should be aware of their responsibility and accountability under the STANDING FINANCIAL INSTRUCTIONS policy.

'English Law prohibits staff from soliciting or receiving any gift, hospitality or consideration of any kind from contractors or their agents, or from any organisation, firm or individual as an inducement or reward for doing or refraining from doing anything in their official capacity, or showing favour or disfavour to any person in their official capacity'.
This applies in particular when Representatives visit Wards and Departments and offer inducement to purchase, irrespective of what that inducement may be. Perishables and/or accessories that come as an integral part of the unit are not seen as an inducement.

Ward and Department staff do not and should not negotiate prices with Representatives. It is possible that two orders for the same or similar equipment are being made from the Company at the same time and better discounts may be obtained. This should be done by Procurement Department who will liaise with the Medical Equipment Manager and/or the CE department.

All equipment should carry the CE mark, which shows that the equipment meets with statutory controls described in the EU Directives.

The Trust may accept non-CE marked medical device as per guidelines from MHRA below for research purposes.
'If the device is non-CE marked and it is intended to be used on human subjects, then the legal manufacturer would have had to apply to MHRA for a letter of 'no objection' before beginning their trial. If this is the case, we suggest you request the manufacturer to provide a copy of their letter of 'no objection' or justification for not applying for one'.

2.1 Special Requirements for certain types of equipment

Capital Equipment

To ensure that we direct limited capital resources to those schemes that will provide the greatest benefit to our patients and staff; all bids for investment over £5,000 should now make use of the Trust Business Case templates (Appendix D). Bids will have to be submitted on a relevant business case document to the appropriate board as laid out by Trust, Business Case Process Guidance and Standing Financial Instructions (SFIs), both of which can be found on the Trust Intranet.

It is important to note that all bids for equipment that is included in the Capital programme is subject to business case approval. Further scrutiny may hold the bid or delay it within the programme should greater priorities or events intervene.

Business Plan

The capital replacement programme for medical equipment is managed by estates and CE. The prioritised bid list is sent to finance for consideration within the next financial year. Forward planning puts the Trust in a better position to manage medical equipment safely and efficiently. Any medical equipment that is for service development and additional the divisions take the responsibility to put a bid in every year.
Once the bids are agreed to receive capital funding, the relevant business case (See appendix D) must be submitted to the Finance Programme Manager and approved by the appropriate group or Board (see Capital process flow chart Appendix C).

Selection of Equipment

All equipment shall be selected for the purpose and use as stated in the business case, and not over specified. A generic specification is required. It shall serve the function of the department. This process will be overseen by the MDEG, which will adhere to the principles of standardisation.

All equipment shall be purchased in accordance with the standing financial instructions. Where the performance of the equipment needs to be verified, the user department shall trial the equipment to ascertain that the equipment will conform to the specification laid down for its use. The trials results will be reported to the MDEG and used in the tender evaluation to determine the final selection.

Single tender action will only be permitted if proof can be submitted, that no other item of equipment can meet the specification for the service needed, and supported by the Clinical Director of the directorate concerned.

The Medical Equipment Management team will complete the Medical Device Evaluation form (Appendix E) to ascertain on going costs and technical information where applicable. This form can be used to request additional information from the supplier.

Tendering

Shall be carried out by the Head of Procurement who will include other agencies or departments as needed to meet Standing Financial Instructions and the Procurement Act 2023. On return of tenders the selection shall be made following the criteria set out in tender documents, evaluated by the Head of Procurement / Deputy Head of Procurement, following this the quality scores will be moderated by the panel, with procurement chairing the moderation appropriately. The panel will consist of subject matter experts (internal) and the Medical Equipment Manager with the user. The conclusion and ranked submissions would then be submitted to the MDEG for their recommendation to CBIG to purchase.

Costing of Equipment

All business case plans submitted for approval shall include all ancillaries and pre-installation costs i.e. delivery, installation, building and engineering services etc.. The estimated costs for pre-installation building and engineering services, shall be obtained from the Head of Estates. The requirements for manuals both user and technical manuals, must to be identified and included in the cost.

The ongoing revenue implications; the cost of maintenance/technical training and user training, the cost of 'upgrading' the equipment. Licensing' must be identified in the business case.

Delivery of Equipment

All equipment shall be delivered through the Main Stores, who will notify the user department of its arrival liaising with the Medical Equipment Library and the CE department.
Where equipment is delivered and installed by the company or the Trust, a programme of delivery and installation will be agreed between the user department, the company and the CE department (or delegated officers). The equipment will be installed and tested before being put into use and certificates of compliance produced. CE department must commission all medical equipment prior to use.

Loan / Trial / Demo Equipment

The Company Representatives must be adhered to Trust's current process for visits to the Trust at all times and all suppliers must be MIA (Medical Industry Accredited) registered and have a valid MIA (Master Indemnity Overarching Agreement) with NHSSC. For advice, contact The Procurement department and/or Medical Equipment Library.

Prior to loan/trial/demo all medical equipment must be assessed for suitable and appropriate methods of decontamination and the PAQ with the quote must be obtained from the company/supplier. The advice is sought from the Medical Equipment Manager who will liaise with the PAQ approvers (Procurement Business Partner, CE Manager, Decontamination Lead and Infection Prevention Team) before purchasing any medical equipment.

Once the approval is given the company representative MUST have the medical equipment acceptance tested and fill out a call off agreement form with the CE department before the equipment should be used. Any equipment that is used without adhering to this procedure will become the responsibility of the user.

3.0 Duties & Responsibilities

General/Operational Managers and Ward Department Managers are responsible for:
Categorise local and specific needs based on risk assessment
Identify equipment intended purpose and expected output specifications
Completing an Equipment Request form for Purchasing (E-form) (Appendix A) and forwarding to the Procurement department
Ensuring a wide contribution from their staff in the evaluation and selection process
Ensuring that Medical Equipment Evaluation Forms (see appendix B) are completed, if necessary or required, by all staff involved in the evaluation exercise and returned to the Medical Equipment Manager or the Procurement department.
Ensuring that equipment levels are adequate to deliver services safely
Ensuring that maintenance funding requirement is taking into account and budgeted for
Adhering to the Trust's standardisation approach.
Identifying authorised users and completing 'Categorisation of Staff Risk Level' (see Medical Equipment Training Procedure MKUH-PC-002)
Identifying funds for the purchase of revenue equipment and attend the MDEG meeting to discuss requests for capital funding

Medical Equipment Manager is responsible for:
Evaluating ward / department requests including a review of existing and similar technology within the Trust and compliance with Trust standardisation approach
Reviewing equipment specifications in line with user identified intended purpose and output specifications
Identifying suitable potential suppliers of required equipment in consultation with the CE Manager and Procurement Business Partner
Advising users regarding maintenance regime and costs via CE department
Authorising PAQs (Pre-Acquisition Questionnaires) and liaising with Procurement Business Partner
Assisting and supporting the ward/department managers in staff training arrangements

Procurement Business Partner/Deputy Head of Procurement is responsible for:
Advising on more effective procurement route and the most cost effective options
Assessing and advising on life costing liaising with the Medical Equipment Manager
Ensuring that Trust Standard Financial Instructions are followed throughout the procurement stage of acquisition
Initiating and managing quotations and tendering process

4.0 Acquisition Process

Medical equipment acquisitions are a response to an identified clinical need. A generic specification is required to identify what functionalities or parameters the required equipment should perform if the need is to be met.
To support the Trust in prioritising equipment demand, all requests will be added to the Trust's risk register if the required equipment is not acquired.
Pre-acquisition Questionnaire (PAQ), The PAQ and quote are obtained from the relevant companies.
The compliant route will be to purchase medical equipment via the NHSSC framework. Any medical equipment request without a distributor in UK will require a PAQ document completed by the supplier/manufacturer and the T&Cs for that purchase prior to approval for purchase.
Personally owned medical equipment is not to be used on patients at hospital site.
The DPIA (Data Protection Impact Assessment) Proforma also require to be completed by the project lead/business case author for every equipment that hold patient identifiable date. This document will require to be completed at the time of the PAQ approval process.
(The Medical Equipment Manager can assist with this process) and also may be available from the Trust's procurement department, must be obtained for all equipment new to the Trust. Completed PAQs will be authorised by the Medical Equipment PAQ approvers (see PAQ approval flowchart Appendix C). This document identifies the relevant safety standards to which the equipment conforms, together with information regarding operation and maintenance documentation, service needs and costs and also decontamination process.
Capital ordering form will be completed for >5k and forwarded to the capital ordering co-ordinator for capital purchases and the e-form will be attached to each requisition on SBS for revenue purchases <5k.
The Medical Equipment Manager will assess the request by reviewing existing or required equipment in other areas, assess how the new request fits with Trust's standardisation approach, review data in relation to equipment reliability, maintenance issues and previous alerts.
The Medical Equipment Manager will then forward the request to the Procurement Business Partner to carry out further assessments in relation to cost of purchase, alternative agreements to acquisition and appropriate route to procure, taking into account Trust's Standing Financial Instructions and other relevant legal obligations.

Acquisition involving revenue equipment (costing <£5K) should be requested in requisition with the purchasing form (E-form) attached against codes of specific budget lines dedicated to medical equipment replacement on the SBS (Shared Business services) purchase to pay system.(P2P)
For capital medical equipment, advice is sought from the Medical Equipment Manager who will advise and liaise with the suppliers. The PAQ approval process is mandatory. The relevant information for the draft BC would be shared with the BC author including relevant MDG members for their input. Please see Appendix C for flow chart describing full approval process.
The draft business case is submitted to the Finance Manager for business cases for review. All BCs relating to medical equipment should be highlighted to the MEM for medical equipment purchase review by the FM/FBP.
Once capital allocation agreed, the General/Operational Manager of the requesting department sends all relevant paperwork to Capital ordering coordinator in estates to raise a purchase requisition on the SBS P2P system.
Pre-Acquisition Questionnaires (PAQs) are requested as appropriate with the user manuals which states the decontamination process for the medical equipment when quote is requested.
Please follow the evaluation process for medical device (consumables) - Appendix F.

5.0 Standardisation

A standardisation process will be adopted when purchasing new medical equipment. This will ensure that unless there are valid clinical and/or technical reasons, the agreed standard equipment will be acquired within the Trust. The standardised approach will enable the Trust to reduce the risk of newly purchased equipment not being compatible with existing medical devices/equipment, reduce the risk of user error due to unfamiliarity with the make/model of devices/equipment (particularly when working on a different ward/department), improving and enhancing in-house knowledge and use of expertise and will also enable to Trust to reduce purchase and maintenance costs. Ensuring compatibility with Trust's infection control and decontamination requirements and the Trust's cleaning agents.

In order to maximise the above benefits of standardisation the Trust needs to ensure that initial procurement tendering is based upon an intention to standardise on a particular supplier product to reduce risk.

6.0 Other Considerations

Donations: Donated equipment will follow the same acquisition process
Hospital Charity: Equipment acquired through charitable funding must be above and beyond normal Trust requirements. There must be clear justification of how the required equipment will ultimately benefit patients and why it should be funded using charitable funds rather than from Trust's budget. Charitable funds will not be used to pay for service agreements, consumables or other ongoing maintenance costs.

Appendices

Appendix A Equipment Request Form (E-form)
Appendix B Medical Equipment Evaluation Form
Appendix C PAQ Approval Chart
Appendix D-Business Case Template
Appendix E- Medical Device Evaluation Form (Medical Equipment Management)
Appendix F-Evaluation process for Medical Device (consumables)

Appendix A- Equipment Request form for Purchasing (E-form)

Milton Keynes University Hospital NHS
NHS Foundation Trust

Equipment Request form for Purchasing (E-form)

How is this purchase to be funded?

Charitable fund ☐ *Revenue ☐* *Friends of MK ☐*

Reason for application: *Additional ☐* *Replacement ☐* *New ☐*

If replacement what is the condition of the existing equipment? Provide below asset ID of equipment to be condemned

Good working order ☐ *Unreliable ☐* *Lost ☐* *Condemned ☐* *Obsolete ☐*

ASSET ID:

Details of Equipment requested:

Supplier:

Lead time for delivery:

Will staff require training for this equip? *Yes ☐ No ☐* If yes; for medical equipment, please inform the Medical Devices Manager (external company user training costs may be applicable).

Costs *excl VAT*

Purchase:	
Servicing / Maintenance (annual):	

Directorate/Ward/Department:	
Name:	
Title:	
Date:	
Extension No:	

FOR PURCHASES <5k please attach the quote, PAQ (Pre-acquisition Questionnaire) and this form to the requisition on SBS.

Contact Medical Equipment Library or Procurement dept. for advice.

Appendix B- Medical Equipment Evaluation Form

Milton Keynes University Hospital NHS
NHS Foundation Trust

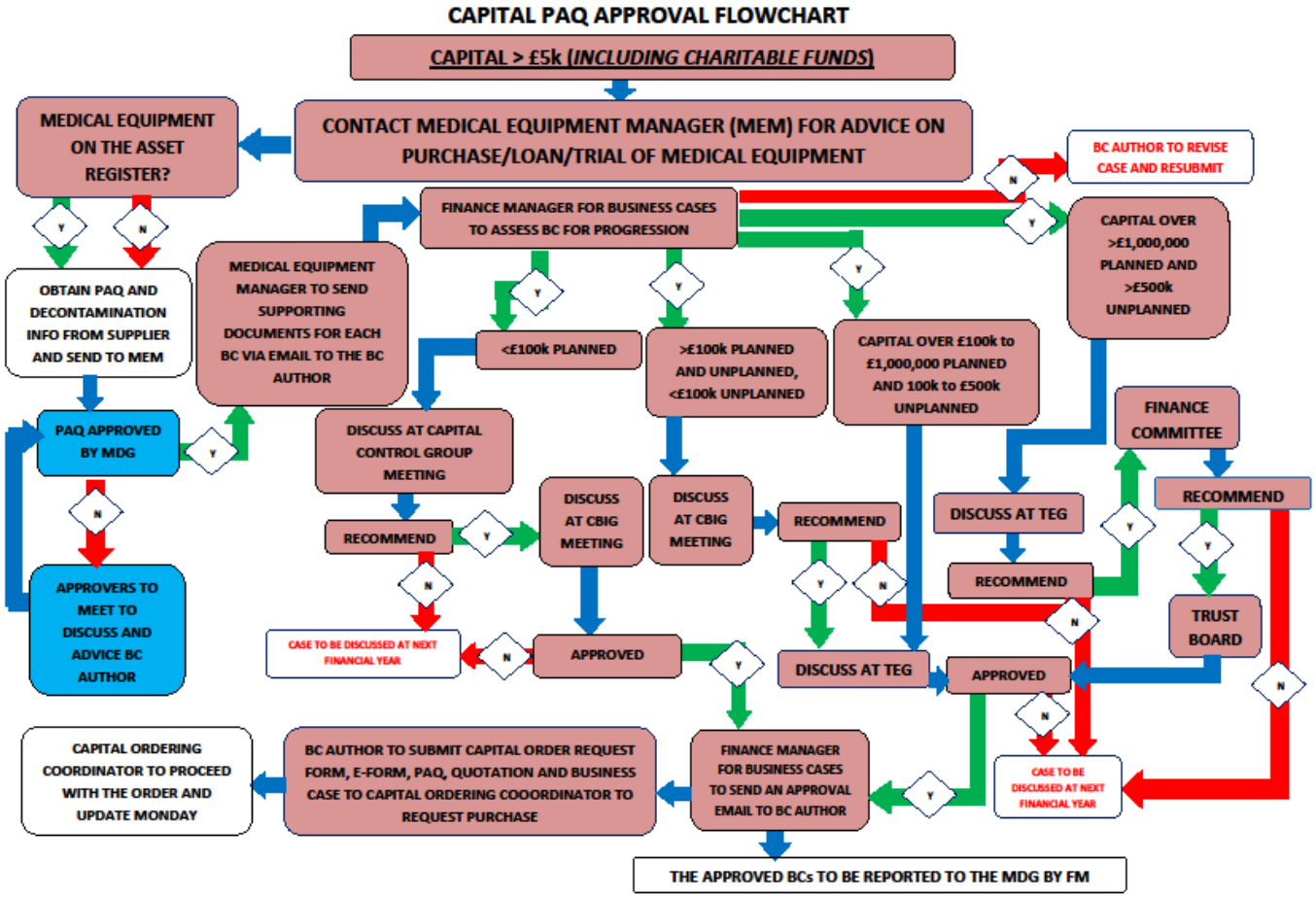
Medical Equipment Evaluation Form

1=POOR 2=UNSATISFACTORY 3=SATISFACTORY 4=GOOD 5=EXCELLENT

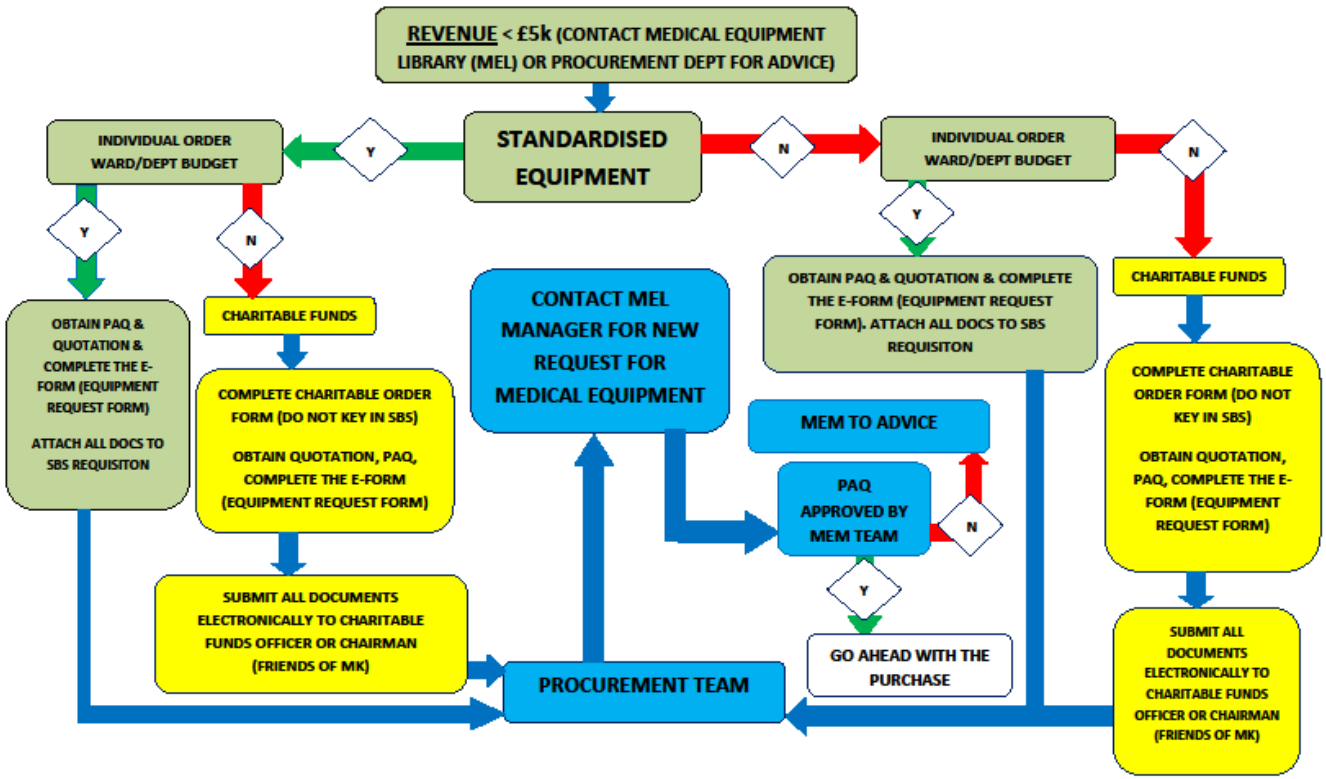
Company				
Device Name / Model				
Ease of Use (Clinical)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Support for Training (Clinical)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Support for Training (M.E.M.)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Ease of Cleaning (Clinical)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Ease of Maintenance (M.E.M.)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Confidence in Supplier (Clinical)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Confidence in Supplier (M.E.M.)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Confidence in Supplier (Purchasing)	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
Overall COST	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5	1 2 3 4 5
General Comments: Wi-Fi compatibility Patient Identifiable				
Total Score				
Preferred Product;				

Agreed by: -

Appendix C- PAQ Approval Flowchart



REVENUE PAQ APPROVAL FLOWCHART



Appendix D- Business Case Templates


Shortform Business Case Template (up to


Standard Business Case Template - Nov


Template Request for Emergency Appro

Appendix E- Medical Equipment Evaluation

DATE:

MEDICAL EQUIPMENT EVALUATION (Medical Equipment Management)

DEVICE TYPE	MODEL

SUPPLIER	MANUFACTURER	SUPPLIER CONTACT NUMBER
SUPPLIER USER SUPPORT	SUPPLIER TECHNICAL SUPPORT	LENGTH OF TIME ON THE MARKET
ANY REPORTED PROBLEMS	RECOMMENDED LIFE OF EQUIPMENT	PARTS LIST/SERVICE MANUAL
USER GUIDE	CE CLASSIFICATION	WARRANTY PERIOD
SUITABLE FOR INTENDED USE	IEC 601 CLASSIFICATION	HOW LONG ARE SPARE PARTS AVAILABLE AFTER LAST MANUFACTURE DATE
EPR CERNER MILLENNIUM CONNECTIVITY Y/N		

IS TRAINING PROVIDED (GIVE DETAILS).....
IS LOAN EQUIPMENT PROVIDED.....
DELIVERY LEAD TIME.....

		COMMENTS
UNIT (LIST PRICE)	£	
DISCOUNT	£	
SERVICE MANUAL	£	
ANNUAL MAINTENANCE COST	£	
CONSUMABLE COSTS	£	
USER TRAINING COST	£	
TECHNICAL TRAINING COST	£	
ACCESSORIES	£	
INSTALLATION COST	£	

PURCHASE PRICE	£	
LIFE COST OF MAINTENANCE	£	
TRADE IN VALUE	£	
ACCESSORIES	£	
LIFE COST OF CONSUMABLES	£	
MISCELLANEOUS/DISPOSAL COST	£	
TOTAL LIFE COST	£	

RECOMMENDATIONS – 1=POOR 2=UNSATISFACTORY 3=SATISFACTORY 4=GOOD 5=EXCELLENT

TRAINING (Clinical&Technical) (M.E.M)					EASE OF MAINTENANCE (M.E.M.)					CONFIDENCE IN SUPPLIER (M.E.M.)				
1	2	3	4	5	1	2	3	4	5	1	2	3	4	5

CONFIDENCE IN SUPPLIER (Purchasing)				
1	2	3	4	5

MEDICAL EQUIPMENT MANAGER Signature .....

CE MANAGER *Signature* .....

PURCHASING MANAGER Signature .....

Medical Equipment Management

Appendix F- Evaluation process for medical device (consumables)

Evaluation process:

1. Identify the product you wish to evaluate
2. Identify a source of funding for the product – is this a new item or replacing an existing item?
3. To develop a business case, please contact **Seet Tyler, Finance Manager- Business Cases who will provide support.**
4. Contact **Procurement Business Partner and Clinical Procurement Nurse** to instigate the evaluation process from their perspective. (If the item is a medical device, then you will also need to contact the **Medical Equipment Manager**)
5. Arrange a meeting with the company representative attended by **Procurement Business Partner and Clinical Procurement Nurse**
6. Obtain completed **Pre-Acquisition Questionnaire and Company Indemnity documentation** from the supplier for Procurement.
7. (If this is a piece of medical equipment you will also need to obtain the cleaning instructions from the company.)
8. Complete **Clinical Procurement Review Group** form with rationale for product use including improvement in patient outcomes, improved patient experience, improved health and safety issues and financial benefits, whether direct or indirect.
9. Work with **Clinical Procurement Nurse Specialist and Procurement Business Partner** to identify estimated usage and potential costs
10. Provide any clinical research evidence and third-party recommendations for the product to support use.
11. If the item is a medical device, then you will need to attend the **Medical Devices Group** and present the product
12. Attend **Clinical Procurement Review Group (CPRG)** meeting to present product for approval for evaluation prior to use.
13. Liaise with Theatre Sister/Charge Nurse and Theatre manager to arrange for education and training support from the provider company during the evaluation
14. Complete evaluation with **SMART** objectives recorded in agreed format
15. Present outcome of evaluation to **CPRG** meeting for final approval to use the product going forward.

Key Contacts and document for the evaluation process:

Procurement Business Partner Surgery – Vacant - TBA

Procurement Business Partner Medicine/Women & Children - Emmanuel Chundula emmanuel.chundula@mkuh.nhs.uk

Procurement Business Partner Core Clinical – Robin Morgan – robin.morgan@mkuh.nhs.uk

Clinical Procurement Nurse Specialist – Susie Birchall ext 86721 - Suzanne.birchall@mkuh.nhs.uk

Medical Equipment Manager – Ayca Ahmed ext 86695 - Ayca.ahmed@mkuh.nhs.uk

Business case contact – Seet Tyler, Finance Manager - Seet.tyler@mkuh.nhs.uk

Pre-Acquisition questionnaire – available from Ayca Ahmed

CPRG form – available from Susie Birchall

To present at the CPRG contact Susie Birchall

To present at the Medical Devices Group contact Ayca Ahmed

Business case template – available on intranet

Susie Birchall, Clinical Procurement Nurse Specialist, Version 2 - 20/5/24

MKUH-PC-02: MEDICAL EQUIPMENT TRAINING PROCEDURE (Appendix 2)

Milton Keynes University Hospital NHS Trust recognises the potential risks associated with the use of diagnostic and therapeutic medical equipment both to patient and staff. In order to manage these risks effectively this operational procedure is devised to describe the process.

1.0 Purpose

All staff that use medical equipment, either directly or indirectly in the diagnosis or treatment of patients, must have sufficient understanding of its use in order to operate in a safe and effective manner. This will increase confidence and efficiency of staff and reduce risk and delay of treatment. All staff that use or intend to use medical equipment must undergo training on the equipment they are authorised to use.

Many episodes of patient treatment or diagnosis depend upon the correct use of such equipment. The proper training of all staff in the use of this equipment is a requirement under the Health & Safety at Work Act (1974) and under the Provision and Use of Work Equipment Regulations (PUWER) 1998.

The Medicine and Healthcare Product Regulatory Agency's (MHRA) document Managing Medical Devices Jan 2021 reinforce this requirement. In particular, they suggest that Trusts have a robust scheme for training all professionals in the use of any medical equipment that requires specialist training, and that records of training are easily accessible. Having such a scheme will also abide by CQC Regulation 15: 'Premises and Equipment' The Trust is committed to meeting these requirements.

There is strong evidence, at a national level, that the misuse of medical equipment due to a lack of training results in many clinical incidents and several deaths each year. The MHRA publishes detailed account of these incidences. To view these incidences, visit the MHRA homepage via www.gov.uk. Therefore, to ensure that patients being treated by this Trust are assured of the safest and most professional use of equipment, all employees must ensure that they are trained in the correct operation of the specific item of equipment, before using it on/with patients.

The aim of this operational procedure is to describe how the Trust is intending to:
Identify all permanent staff required to use a particular medical equipment
Identify Trust's medical equipment inventory by ward/department
Ensure staff training needs are assessed
Ensure appropriate training is provided and recorded

2.0 Roles & Responsibilities

2.1 Directorate Governance Facilitators:

Are responsible for supporting the implementation and monitoring of this procedure, including reporting on staff training compliance; and acting as a point of contact between Directorates, the Medical Equipment Manager and other training providers.

2.2 Ward and Department Managers:

Are responsible for:
Taking ownership for their asset inventory lists, and informing the Medical Equipment Training Coordinator of any changes affecting their inventories to reflect on the training log spreadsheet
Supporting staff in carrying out their individual training needs analysis, encourage individuals to take responsibility to seek training, and ensure that the training log spreadsheet is updated on a regular basis and stored on the shared drive
Ensuring individual training needs analysis are discussed with their staff as part of their annual appraisal
Ensuring local key trainers cascade training to their colleagues assess and sign off their competencies
Ensuring all new staff are attending their local induction for medical equipment training.
Support is available from the Trust's Practice Development team and Medical Equipment Training Coordinator
Taking responsibility for specialised equipment used within their specialties, to ensure all staff are trained and competent to use them safely
Ensuring bank and agency staff training and competencies are checked before they start using Trust's equipment

2.3 All Staff Using Medical Devices/Equipment:

Medical equipment should only be operated by staff who are competent, confident and trained in the use of the equipment. The Trust expects all staff to adhere to the following principles before using any Medical Equipment:
Staff must never use a device/equipment for which they have not received adequate training and for which they do not feel competent to use safely (follow training process flowchart Appendix A).
Staff must inform MEO of any training attended/delivered so they can update Training log spreadsheet and they need to discuss their training needs with their line manager.
Staff will only use equipment on which they have been signed of as competent in using it by a company facilitator or cascade trainer.
User manuals are available from the Medical Equipment Management team.
Visually check equipment for damage, carry out pre-user checks as appropriate and check settings before use.
If the equipment requires disposables/accessories, ensure they are available and are of the correct type.
Under no circumstances should any medical equipment be modified in any way or used with incompatible consumables or accessories.

2.4 Medical Equipment Training Coordinator

Is responsible for supporting medical equipment users to:
Agree and implement training process
Organise, access and facilitate training for core medical equipment type training
Keeps Trust staff training records on the private shared Teams folder which are completed by Medical Equipment Officers and report on agreed key performance indicators
Report level of compliance to be monitored and reviewed through the governance framework

3.0 Medical equipment training

To support Managers in effectively managing their staff medical equipment training, the following documents have been devised and will be made available on the ward managers/medical equipment officers:
Medical Equipment Risk assessment Tool (Appendix B)
Categorisation of Staff Risk Level (Appendix H)
Medical equipment Training Matrix (Appendix K (a,b,c))

3.1 Types of Training

Milton Keynes Hospital NHS Foundation Trust recognises that it has a role to play in ensuring that all staff that use medical equipment are trained to use such equipment in a 'safe' and competent manner. To facilitate this, four types of training will be available to 'end users'. The training will be developed which is prioritised according to the level of risk associated with the equipment.

1. Basic training (low/medium risk equipment).

- Equipment such as blood pressure machines, nebulisers, tympanic thermometers, blood glucose monitors (non-invasive).

2. Specialised training (high/medium risk equipment).

- This applies to specialised areas, such as DoCC, theatres, NNU, CCU, obstetrics, and all other areas where 'specialised' equipment is used.

3. Competency training (high/medium risk equipment).

- Mandatory training on equipment such as volumetric infusion pumps, syringe drivers, defibrillators..

4. Self-certifying/competency (Appendix F (a)) (medium/low risk equipment)- for refresher training for low/medium/high risk equipment – Qualified staff only - Appendix F (c) and (d) apply.

- Self certification is not permitted for High risk medical equipment unless there are no changes to

- the model of the equipment
- the clinical software
- the use/operation with changes to consumables/accessories
- modification by OEM
- mandatory training requirement e.g. defibrillators

However, should there be a requirement for individuals to set up a medical equipment prior to clinical use where the restrictions applied in full use then non-registered staff members can be signed off by their manager for competency within their remit (see Appendix F (b))

Self-certification for low and medium risk medical devices/equipment lasts for 5 years. For high risk medical devices/equipment, it is 3 years, unless it is equipment that requires mandatory training.

Training is mandatory on all high risk medical equipment for all 'clinical' staff however staff may sign themselves off as competent for refresher training on high risk medical equipment as per the section 3.1 after being agreed with the cascade trainer and the ward/dept manager. If training is not required the staff member may be assessed by a 'cascade trainer' before the equipment is used, a breach of this may lead to disciplinary action.

The Medicine and Healthcare Product Regulatory Agency's (MHRA) document Managing Medical Devices/equipment January 2021 states that training is a key element in medical device safety. A training policy should be developed by the medical devices/equipment management group. In essence they highlight the following points:

- Generic equipment management skills.
- Specific training for particular equipment.
- Induction of new staff.
- Inclusion of agency and locum staff and contractors.
- Periodic review / retraining as required.
- Continuing professional development.
- Planned training before a new medical equipment is introduced to the organisation/clinical area.
- Training for those involved in maintenance and repair services.

It continues to state that 'Healthcare professionals working for the organisation, as employees or contractors, have a professional duty to ensure their own skills and training are appropriate and remain up to date'.

When choosing to self-certify the member of staff must fully understand the criteria within the Medical Device User Self-Certification/Competency Statement (Appendix F (a)) BEFORE self-certifying/competency. Nursing staff are bound by the Nursing and Midwifery Council Code of Conduct and the Medical staff are bound by the General Medical Council Code of Conduct, all other staffs are bound by their Code of Conduct guidelines to ensure that they are competent, and must NOT put colleagues, themselves and/or patients at risk.

Staff working within the ward/department will only be allowed to use the equipment once they are adequately trained to do so. This training requirement applies to all grades of clinical/medical/nursing staff that are expected to operate medical equipment. Operational Managers or their deputy will have overall responsibility to ensure that the staff working on the ward/departments is trained appropriately.

When prioritising the training program it is advisable to have 'competency based' training on the highest risk equipment first. A 'risk classification level' has been produced for all medical equipment to aid staff to classify equipment risk level (Appendix B). This takes into account the likelihood and consequence of errors or failures with regards to the use of medical equipment. The risk levels of medical equipment (see Appendix L) have been agreed for general wards whereas specialist areas are going to risk categorise their medical equipment.

3.2 Training Implementation Medical Equipment

The ward/department manager will identify which staff are authorised to use what equipment. If the unqualified staff require to set up high risk equipment then the appropriate competency paperwork must be signed by their manager and the staff member. It will be the manager that will determine which staff are authorised users, unless this conflicts with Trust guidelines.
The MEO is to list and categorise the staff level of all members of clinical staff that use medical equipment (Appendix H)

- Staff level 3: Staff indicated as trained as competent and authorised to use low, medium and high risk medical equipment(s)
- Staff level 2: Staff indicated as trained as competent and authorised to use low and medium risk medical equipment(s)
- Staff level 1: Staff indicated as trained as competent and authorised to use low risk medical equipment(s) only

This is to be updated to include all new clinical staff that are new to the ward/department. Please refer to the Auditable criteria Appendix I.
The ward/department MEO's, Managers and Matron have access to all training records for staff via the Training log spreadsheet which is available via Teams. The training log can be amended to adapt wards/depts. requirement.-ALL new staff must have their training requirements addressed during their induction period, or soon after.
MEO's will use the Training log spreadsheet to ensure staff training records are complete and that training requirements have been met, and that staff are deemed competent in the use of that equipment.

3.3 Medical Equipment Competency Certificate

If a member of staff undergoes 'competency based' training on medical equipment they will be required to sign the 'Medical Equipment Competency Certificate' form (Appendix E). This must also be signed by the assessor. This form can then be kept by the staff member for their personal portfolio and their teams training folder.

Once training is completed, staff should ensure to have the training details updated on the training log spreadsheet (Appendix D).

3.3 Medical Equipment Risk Classification

All medical equipment will be classified into three risk groups; High, Medium and Low Risk. Please see Appendix B.
The risk levels of medical equipment have been agreed for general wards whereas specialist areas are going to risk categorise their medical equipment. To determine the risk level, follow the guidelines on the Medical Equipment Risk Assessment Tool (Appendix B - Equipment Risk and Appendix G- Staff Risk level). The ultimate decision lies with the ward/department/clinical manager. It has been argued that certain equipment may be re-classified depending on the patient it is used on. For example, a tympanic thermometer may be classed as low risk when used on an 'adult' ward; however, when used on a 'neonatal', it may be classed as either medium or high risk.

The likelihood of the event occurring is scored against the consequence of the event occurring, these then give an indication of the risk. Whereas the risk level assessment is not only determined by the type of equipment that is used, but also on the patient.

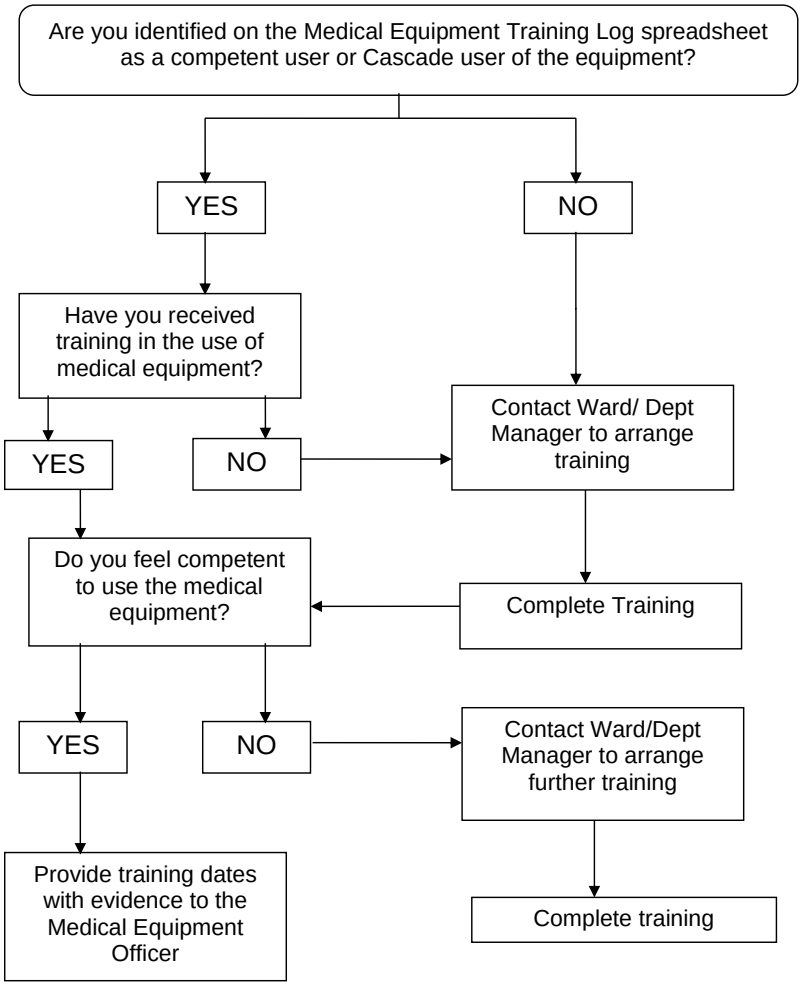
It is undoubtedly the clinicians' decision that determines the risk level on each piece of equipment depending on the type of patient.

Clinicians have a 'duty of care' to ensure that they are fully competent in the use of medical equipment, and to be able to assess the risk associated with such equipment.

3.4 Staff Training Matrix

To highlight the training needs of all staff that use medical equipment within the Trust. This matrix is a guide to qualified nurses and 'other' registered personnel, non-qualified (non-registered) nurses and other auxiliary staff and all grades of medical staff.
Appendix K (a) will identify objectives, strategies, risk classification and types of training for qualified nurses and other registered personnel. Appendix K (b) will identify objectives, strategies, risk classification and types of training for non-qualified (non-registered) nurses and other auxiliary personnel. Appendix K (c) will identify objectives, strategies, risk classification and types of training for all grades of medical staff.

Appendix A- Training Process Flowchart



Appendix B- The risk matrix

This matrix should be used to assess the risk category of a medical device/equipment. It assumes:-

- The device/equipment is safe to use at commencement of treatment, diagnosis etc
- The practitioner possesses the required competency to use the medical device/equipment safely and effectively

	Consequence				
Likelihood	**1 Negligible** No obvious harm injury	**2 Minor** Non-permanent harm	**3 Moderate serious** Significant semi-permanent harm	**4 Major** Permanent harm	**5 Catastrophic** Single or multiple deaths
	1	2	3	4	5
	2	4	6	8	10
	3	6	9	12	15
	4	8	12	16	20
	5	10	15	20	25

Risk

1-6 Low risk

8-12 Moderate risk

15-25 High risk

The following categories demonstrate the possible outcomes

HIGH RISK DEVICE-Score 15-25		Any device/equipment which if misused or fails during use could cause direct harm to the patient and/or user which could potentially result in death.
MODERATE RISK DEVICE-Score 8-12		Devices/equipment whose failure or incorrect use would have a significant impact upon patient care or temporary adverse health consequences but would be unlikely to cause direct serious injury.
LOW RISK- Score 6-4	LOW RISK DEVICE	Devices/equipment whose failure or misuse is unlikely to result in serious consequences. For the purposes of medical devices/equipment 'low risk' and 'very low risk' are to be regarded in the same way i.e. a score of 1-6 covers any device that if used incorrectly or fails during use would be unlikely to have a serious consequence.

Appendix C- Medical Equipment Officers (MEOs) Terms of Reference

Milton Keynes University Hospital NHS
NHS Foundation Trust

Medical Equipment Officers (MEOs)
Terms of Reference

MEO is responsible for making sure medical equipment are used correctly by staff in their clinical area. Therefore they must:-

a) **Report changes** affecting medical equipment in the clinical area to appropriate Clinical, Patient Safety/Supplies/Estate/CE Departments.

b) **Co-ordination** for the procurement/acquisition of medical equipment and their installation, whether permanent, temporary, loaned or gifted devices.

c) **Liaise** with Estates/CE also other appropriate medical equipment maintenance provider regarding medical equipment maintenance services and consequent decontamination requirements.

d) **Identify** individuals who will use medical equipment and are also in need of training on medical equipment appropriate to their role/status working with their manager.

e) **Maintain local records** of individuals for their medical equipment training, recording the levels of competency that indicates that they use the medical equipment correctly.

f) **Promote** the safe use of medical equipment that are used correctly within their clinical area of work.

g) **Facilitate local training** to an individual who uses medical equipment within the ward/department.

h) **Liaise with the Medical Equipment Training Coordinator** to ensure all staff medical equipment training is recorded centrally.

i) **Categorise through risk assessment** medical equipment and individuals into risk categories as follows; high, medium and low ratings. Also to facilitate when identification labels are to be used to highlight the risk level of the device.

j) **Promote independence and comfort** of the device to the End User (e.g. patient).

I have read and understood the terms above. I have been trained in how to maintain and guide staff members in updating the Training Folder relating to Medical Devices Management.

The Clinical Area/s I am responsible for as MEO
Name
Signature
Date
Name of Trainer: - MEDICAL EQUIPMENT TRAINING COORDINATOR

Signature
Date……..

WeCARE

As a teaching hospital, we conduct education and research to improve healthcare for our patients. During your visit students may be involved in your care, or you may be asked to participate in a clinical trial. Please speak to your doctor or nurse if you have any concerns.

Chief Executive: Joe Harrison
Chairman: Baroness Wall of New Barnet

Appendix D: Medical Equipment staff Training Record

DEPARTMENT/WARD:							
The MEO **(Medical Equipment Officer)** is to list and categorise the staff level of all members of clinical staff that use medical equipment, in the department							
Staff level 3: Staff indicated as trained as competent and authorised to use **low, medium and high risk** medical equipment							
Staff level 2: Staff indicated as trained as competent and authorised to use **low, medium risk** medical equipment							
Staff level 1: Staff indicated as trained as competent and authorised to use **low risk** medical equipment only							
NAME	TITLE	STAFF LEVEL	COMMENTS	Defibrillator	Biometer Monitor	Kerato Refractometer	Tonometer Tono Pen XL

Appendix E: Medical Equipment Competency Certificate

TheMKWay
CARE. COMMUNICATE. COLLABORATE. CONTRIBUTE.

Milton Keynes University Hospital NHS Foundation Trust

MEDICAL EQUIPMENT COMPETENCY CERTIFICATE

Part A

Staff Member .....

Band .....

Ward / Department .....

Type of Equipment .....

Model .....

Assessment Criteria:

1. Demonstrates the safe operation of the equipment.
2. Uses appropriate cleaning materials for equipment decontamination.
3. Demonstrates the ability to troubleshoot problems.
4. Can explain the correct procedure for reporting faulty equipment.

Part B - Certification by assessment only

This is to certify that ..... has received competency-based training on the equipment as above.

Assessor's name: .....

Signature: .....

I.....am able to understand and operate the specified equipment above and adopt a safe working practise in this regard.

Staff member (signature): .....

Date: .....

Appendix F (a): Medical Equipment User (Registered staff) Self-Certification/Competency Statement

Medical Equipment User Self Certificatior

Medical Equipment User Self-Certification/Competency Statement

Only for Low and Medium Risk Medical Equipment

Name: **Ward/Dept:**

Job Title: **Manager:**

Date: **Tel & Ext:**

Self – verification of competence is undertaken by assessment against the following statements:

ONLY 'qualified' practitioners are able to self-certify on the use of medical equipment, however, self-certification is **only** intended for medium and low risk medical equipment. The following criteria must be fully understood by the professional user prior to equipment selection (prescription) and application to the patient. If the following criteria cannot be completed further training must be sought. This training must be carried out in accordance to the agreed Trust Standards. This Competency statement has been developed to meet the requirements of the Managing Medical Devices Guidance for healthcare and social services organisations April 2015.

These questions are designed to help you carry out a self-assessment of your competency. You must be able to answer yes to all the questions if applicable to you before considering yourself to be competent. If you are in any doubt or feel that you are not competent, please inform *your manager* to arrange training.

Responsibility for safe use remains with you, so if you are in any doubt regarding your competence to use the medical equipment, you should seek guidance.

Equipment Competency Questions	YES	NO
Am I authorised to use this equipment? ○ **Is it within my remit to use this equipment?**		
Do I have access to the manufacturers' operational manual for this equipment? ○ **Do you know where the user manuals are kept?** ○ **Have you the correct manuals for the equipment in use?** ○ **Do you understand the unit's complexities?**		
Do I understand the purpose and function of this equipment? ○ **Do you know what this equipment does and what it is used for?**		
I am able to change the user setup of this equipment if required. ○ **Do I have all accessories and consumables required?**		
Do I understand the automatic "switch on test procedure" of this device? ○ **Do you know the purpose of the self-test?** ○ **Has the equipment passed the self-test?**		

Appendix F (b): Medical Equipment (Non-registered Staff) Competency Statement

Medical Equipment (Non-registered Staff

Medical Equipment (Non-registered Staff) Competency Statement

Name: Ward/Dept:

Job Title: Manager:

Date: Tel & Ext:

This competency statement has been developed to meet the requirements of the Managing Medical Devices Guidance for healthcare and social services organisations April 2015.

The self-certification assessment form has been developed to give guidance to all ward/department managers in assessing their non-registered staff with regard to medical equipment training.

These questions are designed to help you carry out a self-assessment of your staff's competency. You must be able to answer yes to all the questions if applicable to your staff before considering them to be competent.
Responsibility for safe use remains with all staff members however, you as managers are accountable for their actions, so if you are in any doubt regarding their competence to use the medical equipment as per the ward/department asset list, you should make arrangements for further training.

Equipment Competency Questions	YES	NO
Am I authorised to use any of the equipment on the Asset list? If yes, please list the equipment below.		

Appendix F (c)

Medical Equipment User Self-Certification/Competency Statement
Refresher Training ONLY

Name: **Ward/Dept:**

Job Title: **Manager:**

Date: **Tel & Ext**

Self-Certification of competence is undertaken by assessment against the following statements:
ONLY 'qualified' practitioners are able to self-certify on the use of medical equipment. The following criteria must be fully understood by the professional user prior to equipment selection (prescription) and application to the patient. If the following criteria cannot be completed further training must be sought. This training must be carried out in accordance to the agreed Trust Standards. This Competency statement has been developed to meet the requirements of the Managing Medical Devices Guidance for healthcare and social services organisations January 2021.
These questions are designed to help you carry out a self-assessment of your competency. You must be able to answer yes to all the questions if applicable to you before considering yourself to be competent. If you are in any doubt or feel that you are not competent, please inform *your manager* to arrange training.
Responsibility for safe use remains with you, so if you are in any doubt regarding your competence to use the medical equipment, you should seek guidance.

Equipment Competency Questions	YES	NO
Am I authorised to use this equipment? o **Is it within my remit to use this equipment?**		
Do I have access to the manufacturers' operational manual for this equipment? o **Do you know where the user manuals are kept?** o **Have you the correct manuals for the equipment in use?** o **Do you understand the unit's complexities?**		
Do I understand the purpose and function of this equipment? o **Do you know what this equipment does and what it is used for?**		
I am able to change the user setup of this equipment if required. o **Do I have all accessories and consumables required?**		
Do I understand the automatic "switch on test procedure" of this device? o **Do you know the purpose of the self-test?** o **Has the equipment passed the self-test?**		

Appendix F(d)

Medical Equipment User Competency Statement

REFRESHER TRAINING ONLY

Please see below the list of high, medium and low risk medical equipment which is in your department. Read the **Medical Equipment User Self-Certification/Competency Statement** and select whether you require more training or can self-certify yourselves in the appropriate use of the equipment. You should be able to meet the following criteria –

1) Able to demonstrate the safe operation of the medical equipment.
2) Able to use appropriate cleaning materials for medical equipment decontamination.
3) Able to demonstrate the ability to troubleshoot problems.
4) Able to explain the correct procedure for reporting faulty medical devices.

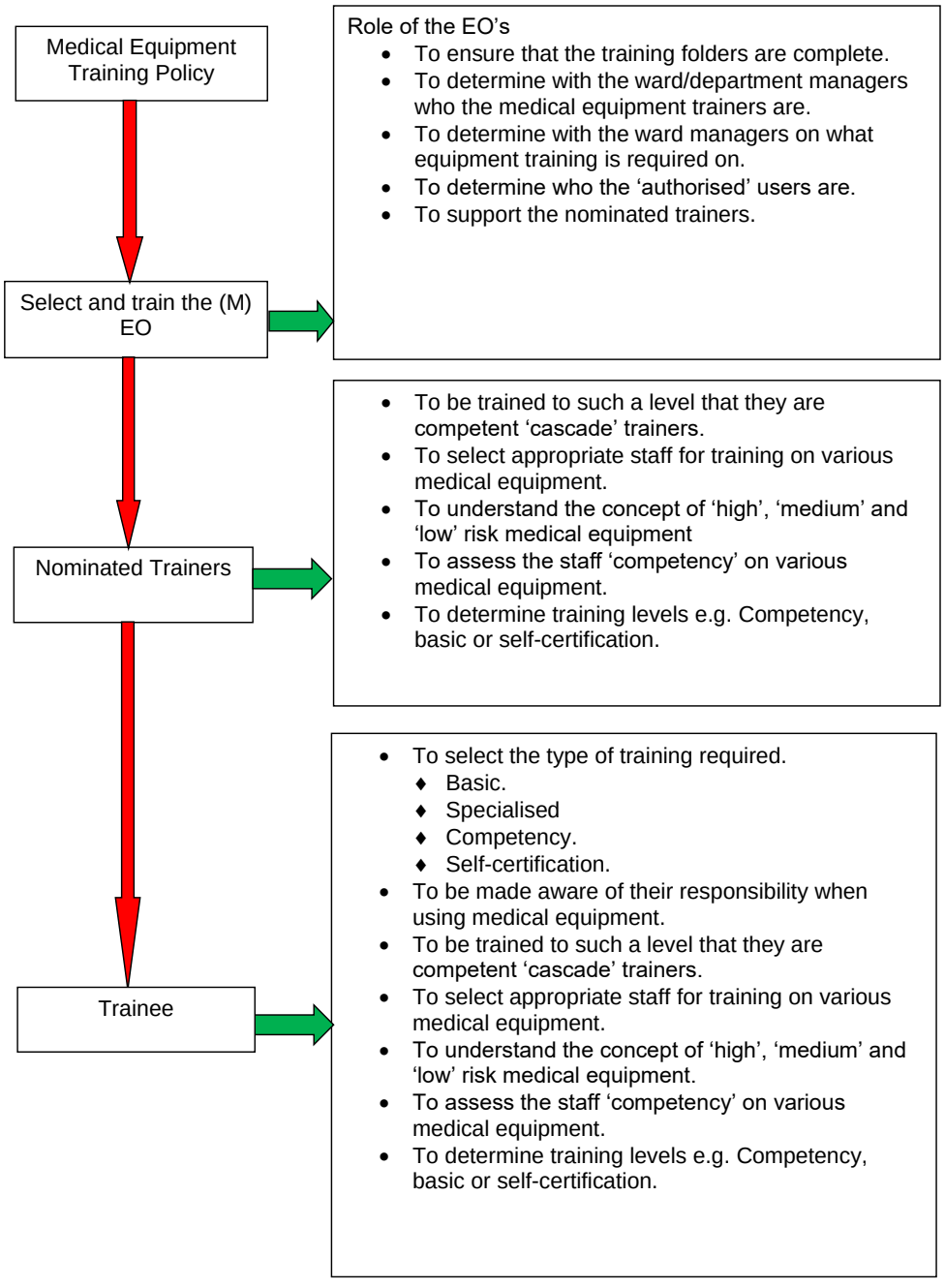
Equipment Type	Model	Self-Certification	Require More Training

Name:

Signature:

Date:

Appendix G: (M) Equipment Officers (MEO's) Training Format Guidelines



The MEO's and the nominated trainers will work closely together to ensure that the staff on their ward/department are fully competent in the use of medical equipment. A record of training on each ward/department by the MEO's, so that evidence can be provided on those who are competent in the use of medical equipment.
The desirable outcomes of medical equipment user training are adapted from Medical Devices/Equipment Management.

- Professional users should be trained in the safe use of medical equipment.
- To be aware of differences between models of a given unit.
- To be able to assemble the device.
- To be able to 'set' the unit to the needs of the individual patient.
- To be able to 'link' the device to the patient.
- To be able to recognise malfunctions.
- To be able to decontaminate the unit
- To be able work with Ecare if applicable.

Appendix H: Categorisation of Staff Risk Level

DEPARTMENT/WARD:	

The M**EO (Medical Equipment Officer)** is to list and categorise the staff level of all members of clinical staff that use medical equipment, in the department

Staff level 3: Staff indicated as trained as competent and authorised to use **low, medium and high risk** medical equipment
Staff level 2: Staff indicated as trained as competent and authorised to use **low, medium risk** medical equipment
Staff level 1: Staff indicated as trained as competent and authorised to use **low risk** medical equipment only

NAME	TITLE	STAFF LEVEL

Appendix I- AUDITABLE CRITERIA- LEVEL 1 TO LEVEL 8

Milton Keynes University Hospital NHS
NHS Foundation Trust

CLINICAL STAFF ARE NOT TO USE MEDICAL EQUIPMENT UNLESS THEY HAVE BEEN TRAINED AS COMPETENT TO USE THE EQUIPMENT.

AUDITABLE CRITERIA- LEVEL 1 TO LEVEL 8

LEVEL 1: Identify MEO & Train the MEO

LEVEL 2: The MEO to confirm medical equipment asset/inventory list

LEVEL 3: The MEO to confirm the identified risk levels of all medical equipment with their manager

LEVEL 4: The MEO is to categorise staff levels

LEVEL 5: The MEO is to update staff members' training records using the 'Teams' Training Folder liaising with staff members

LEVEL 6: Ward/dept. managers to identify training requirements in each area with the assistance of the MEO

LEVEL 7: The MEO and ward/dept. manager to liaise with the Medical Equipment Training Coordinator for advice on training requirements (internal or external)

LEVEL 8: The MEO is to update staff members' training records using the Teams Training Folder liaising with staff members

GUIDANCE ON HOW TO ACHIEVE THE LEVELS 1-8

LEVEL 1: Identify MEO & Train the MEO

Ward/department Managers are to identify suitably qualified MEOs who are able to carry out the functions identified on the MEO Terms of Reference. MEOs are to print & sign this document and save a copy online on their dept teams folder. Nominated MEOs (Band 6 minimum) are to attend a Management of Medical Equipment Training log session

LEVEL 2: The MEO to access medical equipment asset/inventory list

Medical Equipment Training Coordinator prepares the asset list on the training log spreadsheet which then requires confirmation by the MEO. The asset list is to be updated to include all new medical equipment that are new to the ward/department

LEVEL 3: Working with their manager, the MEO will confirm the identified risk levels of all medical equipment.

Medical Equipment Training Coordinator prepares the asset list with the risk levels as per the medical equipment risk levels guidance document and confirms with the MEO.

LEVEL 4: The MEO is to categorise staff levels

The MEO is to list and categorise the staff level of all members of clinical staff that use medical equipment

Appendix K(a): Matrix Registered Nurses

MEDICAL EQUIPMENT TRAINING MATRIX				
Objective	**Strategies**	**Training Strategy**	**Risk Classification**	**Types Of Training**
NURSING QUALIFIED				
To ensure that all qualified nurses and other 'registered' personnel are deemed competent in the safe use of medical equipment	To Identify 'authorised' users	To identify medical equipment into HIGH, MEDIUM or LOW risk equipment	**High Risk Device (RED)** Items that have the potential to cause serious adverse consequences or death should they be misused or fail	Competency Training
			Medium Risk Device (ORANGE) Items that would have a significant impact on patient care or cause temporary adverse health consequences should they be misused or fail	Self-certification User training
			Low Risk Device (GREEN) Items that would be unlikely to cause any serious consequences should they be misused or fail	Self-certification Basic training

Appendix K(b): Matrix Registered Nurses

MEDICAL EQUIPMENT TRAINING MATRIX				
Objective	**Strategies**	**Training Strategy**	**Risk Classification**	**Types Of Training**
NURSING Support Staff (HCAs)				
To ensure that all nursing support staff deemed competent in the safe use of medical equipment	To Identify 'authorised' users	To identify medical equipment into HIGH, MEDIUM or LOW risk equipment	**High Risk Device (RED)** Items that have the potential to cause serious adverse consequences or death should they be misused or fail	Unauthorised Do not use
			Medium Risk Device (ORANGE) Items that would have a significant impact on patient care or cause temporary adverse health consequences should they be misused or fail	User training
			Low Risk Device (GREEN) Items that would be unlikely to cause any serious consequences should they be misused or fail	Basic Training

Appendix K(c): Medical Staff

MEDICAL EQUIPMENT TRAINING MATRIX				
Objective	**Strategies**	**Training Strategy**	**Risk Classification**	**Types Of Training**
MEDICAL				
To ensure that all grades of doctors are deemed competent in the safe use of medical equipment	To Identify 'authorised' users	To identify medical equipment into HIGH, MEDIUM or LOW risk equipment	**High Risk Device (RED)** Items that have the potential to cause serious adverse consequences or death should they be misused or fail	Competency Training
			Medium Risk Device (ORANGE) Items that would have a significant impact on patient care or cause temporary adverse health consequences should they be misused or fail	Specialist Equipment Self-certification
			Low Risk Device (GREEN) Items that would be unlikely to cause any serious consequences should they be misused or fail	Basic Training Self-certification

Appendix L: Risk Levels

Device	Includes	Risk
Critical care - Defibrillators		High
Critical care - Life Support Ventilator		High
General - Infusion Device- General	Infusion Pump, Syringe Pump	High
Theatre - Anaesthetic Equipment	Anaesthetic Machines, Vaporisers, Anaesthetic Ventilator	High
Theatre - Electrosurgery	Surgical Diathermy, Rf Generators, Ultrasonic Surgical Aspirator	High
Theatre - Surgical Tool	Lasers, Cryo Units	High
Patient Monitoring - Nitric Oxide		High
Critical Care - Pacemaker	External Pacemaker	High
General - Infusion Device - Nutrition		High
Obs & Gynae - Fetal Monitor	Fetal Heart Detector, CTG	High
Ophthalmology - Laser		High
Ophthalmology - Surgery		High
Patient Monitoring- Anaesthetic Agent		High
Patient Monitoring - Catheter Laboratory		High
Patient Monitoring - CO2	Combined O2/CO2	High
Patient Monitoring - ECG	Telemetry, ECG Writer, Event Recorder	High
Patient Monitoring - Multiple Parameters	Central Monitoring	High
Patient Monitoring - Respiration		High
Patient Monitoring - Temperature		High
POCT - Medical Laboratory Equipment	Blood Gas Anaysers, Blood Glucose Meters	High
Theatre - Diagnostic Endoscope		High
General - Suction Units	Electrical Vacuum	High
Patient Monitoring - Apnoea		High
Critical Care - Resuscitaire		High
Critical Care - Tourniquet		High
Critical Care - Baby Incubator		High
Diagnostic - Ultrasound		High
Audiology - General Equipment	Audiometer, Analyser	Low
General - Airway Therapy	O2 delivery, O2 Flowmeters	Low
General - Exercise Device		Low
General - Patient Warming/Cooling	Blood Warmer, Warming Blanket	Low
Occupational Therapy - General Equipment		Low
Ophthalmology - Ophthalmic Device	Ophthalmoscope, Sight Tester, Visual Field, Optometry	Low
Patient Monitoring - EEG	EMG, CFAM	Low
Patient Monitoring - SPO2		Low
Theatre - Endoscopy Ancillaries	Light Sources, Accessories, Displays	Low
Theatre - Illumination	Light Sourcse, Video Systems, Displays	Low
Theatre - Surgical Irrigation System		Low
Clinic - Examination Couch		Low
Dental - General Equipment		Low
General - Patient Support	Beds, Trolleys	Low
General - Patient Support - Pressure Relief Bed		Low
Patient Monitoring - Spirometer		Low
Speech Therapy - General Equipment	Laryngograph, Communication Aid	Low
Theatre - Operating Microscope		Low
General - Patient Measurement	Weighing Scales	Low
Pain Relief - Nerve Stimulator		Low
Critical Care - Infusion Device - Pressure Infuser		Moderate
General - Airways Therapy	Humidifier, Nebuliser	Moderate
Patient Monitoring - Cardiac output		Moderate
Physiotherapy - Exercise	CPM, Exercise Bike, Treadmill, Ergometer	Moderate
Physiotherapy - Therapy	Wax Therapy, Hot Pack, Cold Pack, Flowtron Boot	Moderate
Physiotherapy - Treatment Lamp	Ultraviolet, Infrared, Phototherpy	Moderate
Ophthalmology - Ultrasound		Moderate
Patient Monitoring - NIBP		Moderate
Physiotherapy- Stimulator		Moderate
Physiotherapy - Treatment Unit	Shortwave Diathermy, Pulsed RF Microwave, Interferential	Moderate
Physiotherapy - Ultrasound Treatment		Moderate
Patient Monitoring - Pressure		Moderate
Theatre - Insufflator		Moderate

MKUH-PC-03: MEDICAL EQUIPMENT MAINTENANCE AND CALIBRATION PROCEDURE (Appendix 3)

1.0 Purpose

The purpose of this procedure is to outline the Trust process for managing medical equipment maintenance. It covers both planned preventative maintenance (ppm) as well as reactive maintenance due to breakdown repairs. This procedure also covers all Trust's equipment whether serviced in-house or externally contracted to third parties, and falling within the remit of the Medical Equipment Manager.

2.0 Duties & Responsibilities

2.1 Directorate Manager

Will ensure that all medical equipment used within their directorate are maintained in line with their manufacturer recommendations & appropriate funding is made available for the maintenance of medical devices. The cost of maintenance for equipment under the in-house regime will be charged at 10% of asset value for all newly acquired equipment, excluding accidental damage. All other equipment not on in-house maintenance should be sub contracted to third party service suppliers.

2.2 Ward / department Managers

Will ensure that faulty equipment is decontaminated as per the Trust's decontamination policy and staff fill in a decontamination status label before they take any equipment to the CE department.

2.4 CE Manager

Will ensure that inventory under CE remit is repaired, maintained and calibrated according to manufacturers' recommendations, taking into account risk assessment to include criticality and complexity of equipment and area of usage. Schedule planned preventative maintenance and/or calibration on the medical equipment asset management system and report levels achieved to the Medical Devices/Equipment Group on bimonthly basis. It is the responsibility of the CE Manager to ensure that the information recorded on the Trust inventory is valid, accurate and up to date.

2.5 Medical Equipment Manager

Responsible for managing the CE service provider and maintenance agreement for medical equipment and will advise and support clinical users in maintenance agreement via CE department.

3.0 Asset Management Database

Details of diagnostics and therapeutic medical equipment owned by the Trust are recorded on a central database by the CE Department This is a computerised system, which allows storage of such information as location, ownership, age, purchasing details, maintenance schedules, modifications, breakdown-repair history and maintenance contract details and much more.

3.1 Medical Equipment Maintenance and Calibration

The Medical Equipment Manager in consultation with CE Manager and user department's managers will decide on the most appropriate and cost-effective level and regime of maintenance (In-house versus third party suppliers).
External maintenance contracts relating to medical equipment will be centrally managed by the CE Manager.
Monthly KPI reports for maintenance will be discussed at the Medical Devices/Equipment Group.

3.2 Planned Preventative Maintenance and Calibration

The CE Manager has the responsibility of ensuring the Trust that all medical equipment under his/her remit are routinely and appropriately maintained in accordance with the manufacturers' recommendations wherever practicable.
Monthly audits for PPMs are carried out by the Equipment Library Manager and reported at the Estates Governance meeting and the MDEG meeting..
External PPM maintenance contracts will be managed by the CE Manager who will ensure service providers carry out servicing and calibration in accordance with agreed contract specifications, and that maintenance information is recorded on the Trust's Asset Management Database. Copies of service report for equipment that comes under CE remit will be held centrally with the CE department.
(Refer to Appendix B for maintenance process flowchart). Reporting on level of maintenance will form part of a monthly report to the Medical Devices/Equipment Group using agreed KPIs.

3.3 Breakdown-Repairs

All requests for repair must be reported directly to the CE department. This includes equipment maintained in-house and externally contracted.
It is the responsibility of the user to report any equipment malfunctions and breakdowns as soon as reasonably practical. When reporting an equipment malfunction the end user will provide essential information such as equipment asset number, type, location, name of person reporting fault, and finally a meaningful description of the fault.
The reporter will be issued a job number via the CE department in order to facilitate job status tracking. The job number should be recorded by the requester.
Equipment presented for servicing must be clean and free of any contamination; a completed "Certificate of Decontamination Status" form (Appendix A) must be completed and attached in accordance with the Trust's Decontamination Policy.
The users are responsible to ensure that any equipment presented for service is free of blood, body fluids and any other pathological specimens; engineering personnel have the right to refuse to handle visibly soiled equipment.
CE will advise the users on repairs however there are exceptional circumstances where the equipment is conditionally operational or not fit for safe use, CE will raise a concession note (Appendix C) and request the users to sign to agree that they take full responsibility for the partially faulty equipment to be returned without repair.

3.4 Investigation of Incidents involving Medical Equipment and Devices

Medical equipment and accessories which are involved in an incident must be removed from use immediately and safely. The users must return the equipment to the CE department for investigation with decontamination paperwork.

Any larger or fixed equipment which cannot be moved must have a 'Do not use' note and reported to the CE department for investigation.
The users hold the responsibility of reporting the incident on the RADAR system for CE to investigate.
All consumables involved in an incident must be retained to be reported to the MHRA. The investigation will be carried out by the appropriate department.

3.5 Spare Parts

All medical equipment will be maintained in strict accordance with manufacturers' instructions using genuine original equipment manufacturers' parts (OEM). If non-OEM parts are to be used, a rational behind the decision will be documented and full risk assessment will be carried out.

3.6 Test Equipment

Any test equipment used to diagnose and calibrate medical equipment will undergo regular calibration according to its manufacturers' instructions.
Only appropriate and adequate test equipment recommended by equipment manufacturers are used. Test certificates are held within the CE Department.

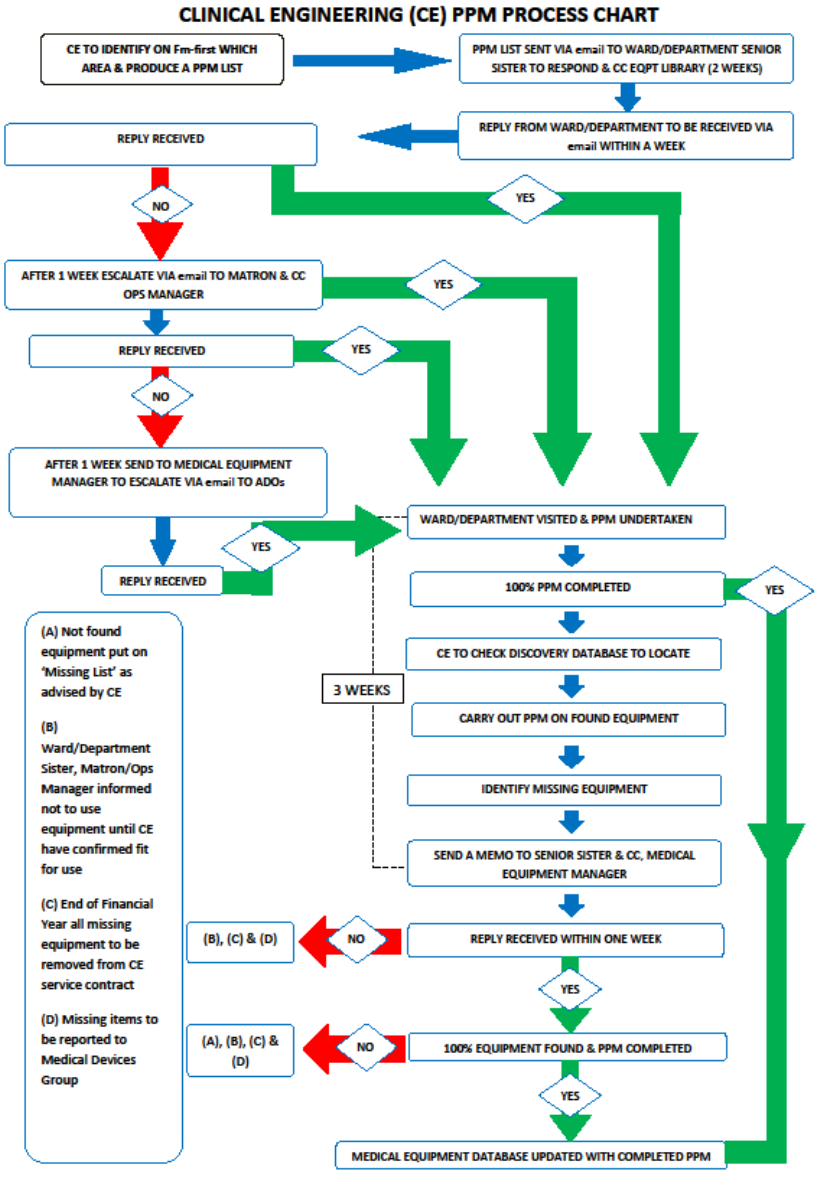
3.7 Modification of Medical Equipment

Modification of medical equipment is limited to upgrades or safety related modifications identified and authorised by the manufacturer of the device/equipment. Under no circumstances will a medical device/equipment be modified with the intention of using such a device in a medical environment without first receiving written approval and authorisation from the manufacturer of that device with explicit agreement regarding the acceptance of liability for the modification.

Appendix A- Certificate of Decontamination Status Form

Certificate of Decontamination Status
Complete the form in BLOCK letters
This form must accompany equipment as evidence of cleanliness/decontamination
Date:
Ward/Dept.:
Staff Name:
Signature:
Asset/Inventory No:
Description of equipment:
Accessories:
Decontaminated/cleaned (as per the Trust's Decontamination policy) **YES/NO** If selected NO please contact the EBME department and the Equipment Library prior to returning the equipment
All equipment MUST be cleaned before they are returned to the EBME department or the Equipment Library
Fault description (please clearly state i.e. error codes

Appendix B- CE PPM Process Chart



Appendix C- Concession Note

Milton Keynes University Hospital NHS
NHS Foundation Trust

CONCESSION REQUEST

DATE:	
CONCESSION Note No:	

Details of Deviation for which Concession is Required

EBME engineer's name:

Concession Identified by: Yes ☐ No ☐

Signed _____ **CE MANAGER**

Concession Approved and Agreed by: Yes ☐ No ☐

Signed _____ Date: _____

Title _____

Any Further Instructions

MKUH-PC-04: MEDICAL EQUIPMENT ACCEPTANCE, DEPLOYMENT AND DISPOSAL PROCEDURE (Appendix 4)

1.0 Introduction

All new medical equipment will undergo an acceptance procedure prior to use. The equipment is checked as per CE acceptance procedure and recorded on the Trust's Asset Management Database before it gets deployed to the ward/department where the responsibility is owned to make sure:
Their staff are trained on the safe use their equipment
Their equipment is appropriately serviced and maintained
Their equipment is cleaned and stored in a safe and usable condition
Single use items are not reused
Action is taken on Central Alerting System alerts
Incidents and near misses are reported

2.0 Acceptance of New Equipment

All medical equipment delivered to the Main Stores Department (including equipment placed on loan or evaluation) will be delivered to the CE Department to undergo a formal acceptance procedure unless it is large and/or specialist equipment which may be delivered directly to the ward/department to be commissioned by the manufacturers/suppliers and supported by the CE engineers. All acceptance procedures will be recorded in the Trust's Approved Test Card and records are kept within the CE Department and recorded on the Asset Management database. An RFID tag will be applied for traceability. Any equipment that will store patient identifiable information will be identified on the Trust's Medical Equipment Asset Management Database.
The purpose of the acceptance procedure is to:
Confirm the goods are received as per the order and that all documentation is correct
Confirm goods are received undamaged and all accessories and technical/user documentations are present and correct

- Carry out performance verification procedure as laid down in the MHRA documentation. '*Managing medical devices: guidance for healthcare and social services organisations (Medicines and Healthcare products Regulatory Agency, 2021d)'*.

Once the equipment has been accepted it will be allocated a unique inventory/asset number and recorded on the Trust Equipment Management Database.
Any configuration requirement for the equipment will be discussed and agreed with the clinicians. CE will be the point of contact for any changes to be made on the configuration for a specific reason (clinical requirement) agreed with the Director of Nursing.
The Medical Equipment Training Coordinator in liaison with the ward/department managers will communicate with the external companies to arrange training.

2.1 Procedure for Loans into the Trust

The Company Representatives Policy must be adhered to at all times and all suppliers must be MIA (Medical Industry Accredited) registered and have a valid MIA (Master Indemnity Overarching Agreement) with Department of Health. For advice, contact The Procurement department and/or Medical Equipment Library.
All medical equipment on loan to the Trust, whether on trial or for a specific purpose should first of all be notified to the CE department, who are responsible for keeping the master indemnity call off agreement register on behalf of the Trust. For loan/trial equipment, the similar procedure must be followed as per the general requirements section on MKUH-PC-01: MEDICAL EQUIPMENT ACQUISITION PROCEDURE); user manual and PAQ must be obtained from the company/supplier to be vetted by the PAQ approvers. All medical equipment must have an electrical safety test by CE before it is used within the clinical areas or evidence of an electrical safety has been carried out by a 3rd party.
A form of Indemnity must be completed by the supplier of such equipment, to protect the Trust from any liability arising in respect of personal injury to or the death of any person, whether patient, visitor or staff, loss of or expense in consequence arising from the installation, presence, use or removal of the equipment, both on or off the Trusts premises, except by negligence of the Trusts staff. (See Appendix B)). No 'loan' equipment shall be used until an Indemnity form has been completed, ALL 'accepting practitioners', of such equipment, must have conformation from the CE department to ensure that the indemnity form has been signed and 'accepted' on behalf of the hospital. It is the responsibility of the accepting practitioner to ensure that the equipment has been safety tested by CE BEFORE the equipment is used for trial/ demonstration. CE will tag the equipment for traceability unless the loan period is less than one month. Any extension on the loan equipment CE must be notified immediately.

When equipment is brought into the Trust via Courier the Indemnity form will be faxed to the relevant company for signature and received back to the Trust BEFORE the equipment can be used.

Staff who default on this indemnity may find they are personally liable at law should any accident or incident arises without such indemnity.

It is the responsibility of the accepting practitioner to ensure that any equipment that contains information on either staff or patient Personal Identifiable data (PID) details on hard disk drives MUST be deleted before it is released in line with Trusts' Information Governance Policy. The supplying company, if possible, must give advice and assurances that all such personal information can be deleted and not retrievable.

3.0 User Maintenance and Pre-Use Checks

The ward/department managers are responsible for equipment maintenance and pre-use checks to ensure that equipment is safe to be used; including cleaning and decontamination are performed in accordance with manufacturers' instructions. Such user interventions are part of equipment user training programs. Users are responsible for recording the results or outcomes of these checks as appropriate.

4.0 Medical Devices/Equipment Related Incidents

In addition to the Trust's Risk Management arrangements and incident reporting procedures the Trust follows the guidance laid down by NHS England and Medicines and Healthcare products Regulatory Agency (2014) *Patient Safety Alert. Stage Three: directive. Improving medical device incident reporting and learning.* 20 March 2014. NHS/PSA/D/2014/006.
All Trust's incidents are recorded by the risk management team. The lead MDSO compiles reports regularly to be submitted to all Trust's directorate governance management teams. Incidents are discussed in these governance meetings, decisions are taken and actions are communicated to all within the directorate to ensure learning from past incidents.

4.1 Key Considerations

All incidents and potentially harmful products are reported, even if on suspicion only to the MHRA. This is the duty of every health care employee.
The MHRA should be informed of incidents involving medical devices/equipment even if they appear to be caused by human error as it may be partly (or wholly) due to defects in the design of the device or instructions for use.
The has been identified as the Trust's lead responsible for reporting Medical Device defects and incidents to the MHRA and other involved agencies. The Medical Equipment Manager who provides advice and technical input as appropriate.
Managers have a responsibility to ensure that all staff, including contractors, at all levels are aware of their responsibilities and of the procedures to be followed with regard to the reporting of incidents and the isolation and retention of defective items.
Local action is taken as necessary to ensure safety of patients, users and others.
Devices/equipment involved in an incident are kept in isolation/quarantine and clearly labelled "Defective Do Not Use". The state of the device at the time of the incident will be recorded to inform subsequent investigations. These records will include controls and settings, switches and dials, alarms and any output readings as appropriate.
If the incident involves single use devices, the packaging, product codes, serial numbers and batch numbers will be kept, if the device is a stock item, Procurement and Supplies Department will also be informed.

5.0 Medical Devices/Equipment Alerts (MDA's)

In order to ensure MDAs actions and recommendations are implemented within MHRA's time frames, and to ensure these actions are completed within deadlines, The Risk Management team compiles reports on MDA progress and submit them regularly to both the Medical Devices/Equipment Group and to the Health & Safety, the Patient Safety Board.

The MHRA Central Alerting System issues medical equipment related alerts to all NHS Trusts. These MDA's are then distributed to all equipment users by the Trust MHRA MDSO within the Risk Management Team. Users are responsible for performing required actions. Refer to Trust's "Safety Alerts Policy". The Medical Equipment Manager provides technical help and support to the Risk Management Team in dealing with MHRA alerts.

6.0 Single Use Medical Devices/equipment

This section of MKUH policy on single use medical devices has been developed to ensure awareness of best practice in the use of single use, single patient use and limited use medical

devices, to assist staff to maintain a high standard of infection control and cost effective use of equipment. The guidance contained within this Policy document reflects the relevant advice issued by the MHRA which is primarily contained within *the* Medicines and Healthcare products Regulatory Agency 2018 document - *Single-use medical devices: implications and consequences of reuse.*
Single use medical devices MUST NOT be reprocessed for re-use.

6.1 Responsibilities

Directors and Managers: Directors and clinical managers will ensure that all staff are aware that, in accordance with the manufacturer's instructions, single-use medical devices will not be re-used and that single patient use devices will only be used on the same patient. Directors and Managers must ensure that:
Staff, and where relevant patients, are given copies of and understand the manufacturer's instructions for devices that they use
Appropriate relevant training is provided if required
Sufficient stocks of single-use device are available
All staff are aware of the need to report all incidents relating to single-use in accordance with the Trust's Incident Reporting Policy
Staff are aware of the risks associated with reprocessing single-use devices, i.e. reprocessing may alter the characteristics of the device and therefore its performance and that decontamination may not be effective. Thus, reprocessing may lead to safety and infection control risks to both staff and patients

All Staff: All staff adhere to this policy and any related instructions issued by their line Managers.
The symbol below, which indicates 'Do Not Re-use' appears on the packaging for single-use medical devices.
Under no circumstances devices designated as 'single-use' should be re-used.

The re-use of 'single-use' devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risks.
The re-use of 'single-use' devices has legal implications.
Reprocessing may expose both staff and patients to health and safety and infection control risks and result in civil liability for any injury caused by the device.

6.2 Legal Implications / Issues

Anyone who reprocesses or re-uses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness.
Anyone who reprocesses a 'single-use' device and passes it to a separate legal entity for use has the same legal obligations under the Medical Devices Regulations as the original manufacturer of the device.
Inherent cross infection: infection is a major patient safety concern associated with re-use. If the device is not adequately decontaminated, the risk of patient and user infection increases.

7.0 Condemning, Decommissioning

An item of medical equipment to be condemned generally falls into one of the three categories identified below:

Obsolescence	Equipment Failure	Hazard Warning

but specifically for one or more of the following reasons:

- Worn out beyond economical repair
- Damaged beyond economic repair
- Unreliable
- Clinically or technically obsolete
- Spare parts no longer available
- More cost or clinically effective equipment are now available
- Unable to be cleaned effectively prior to disinfection and/ or sterilisation
- Is the subject of a Hazard Warning resulting in removal from service
- Not economical to maintain
- Surplus to requirements

If any of the above criteria applies then the device/equipment must be considered for replacement. Should the device pass the above criteria then a date should be set for re-testing, preferably in one year's time.

Where an item is still serviceable but no longer required by the user department, consideration should be given to its re-location within the Trust. If re-use is not immediately possible the Medical Equipment Manager should declare the item surplus to requirements in writing to the Finance Department. They will consider, in conjunction with the asset owner whether the item can be scrapped or stored for future use.

Where an item is to be disposed of as scrap, reference should be made to the Trust's safe disposal of waste.

When an item has been condemned the need for a replacement should be critically assessed. The issue of a condemned note does not mean a replacement will automatically be ordered. Before placing an order funding must be agreed with the appropriate fund holder.

Equipment that is damaged or defective should be removed from use immediately, labelled "Do Not Use" and reported to the CE Department. The equipment will be delivered to the CE department by the users. If the damage or defect is severe, it may result in the need for the equipment to be condemned and the user will be notified; the equipment will then be archived within the equipment asset register.
Where a ward or department wishes to condemn or dispose of equipment then they should notify the equipment maintainer (normally CE).
For both senarios above CE will generate a Medical Equipment Disposal Notice (Appendix A) and send it to the ward/department. Once this form has been completed by the ward or department the disposal form should be returned to CE. CE will then send a copy of the disposal form to finance to update computerized the equipment record and the asset database, both managed by finance.

Any medical device/equipment deemed not useable should be decommissioned. This requires the device/equipment to be de-contaminated, made safe and made unusable so that an

inappropriate person does not use the medical device/equipment and expose themselves and others to potential hazards. A decontamination certificate should be made available to the asset owner as a record. The decontamination certificate should be held on record when the equipment has been scrapped, when the equipment is transferred, scrapped or donated the certificate must be transferred to the new asset owner. In the case of transferred, scrapped or donated equipment, a copy of the certificate should be retained by the original asset owner. Any equipment holding patient identifiable info will be destroyed before leaving the Trust as per the guidelines.

8.0 Disposal

The removal and disposal of any device needs to be considered under the Special Waste Regulations. As identified special waste can include:

Wastes containing metal
Oil wastes
Waste from coolants
Batteries
Radioactive waste
Waste from human or animal healthcare and research
Waste from natal care, diagnosis or prevention of disease in humans.

Consideration also needs to be given to the Electronic Equipment (WEE Regulations) and the transport of Medical Equipment prior to disposal (i.e. returning to manufacturer). The Waste Electrical and Electronic Equipment Regulations 2013. (SI 2013/3113)
The medical equipment may be auctioned after removal from clinical areas as per the Disposal Flowchart 2 process in Appendix F.

8.1 Disposal Arrangements

When reporting obsolete equipment for removal, actions are as follows:

The CE Department will liaise with the department and give full details of the obsolete equipment to be removed and the exact location of the same (Where the estates department are leading on equipment changes or replacement, they will liaise directly with the Head of Department to ensure the correct documentation is completed and reporting takes place).

CE will move the equipment to the CE workshop and follow the approved Disposal Flowchart 1 or 2 process in Appendix F.

8.2 Transfer of Old or Obsolete Equipment

Any decision on re-use must be agreed with the Purchasing Manager and Clinical Director in the first instance, taking full account of the risks associated with its re-use within the Trust or re-use outside the Trust (this also includes the transfer of equipment). The Trust must be indemnified against future liability of equipment that is no longer of use to the Trust and is being scrapped or donated, see Appendix G Form of Indemnity. For each device being transferred, scrapped or donated Directorates and/or Departments (the current asset owners) must ensure that:

The Trust's indemnity form is completed

Equipment containing Hard Drives (Patient/Carer/Staff information details) is destroyed where applicable.
Equipment information is provided to the prospective recipient whether for transfer or donation. Where appropriate and depending upon the risk of the device this should include: Documentation of decontamination, user manuals and training requirements, service history and manual and quality assurance test details (if applicable).

Equipment containing Hard Drives (Patient/Carer/Staff information details)
All equipment without exception, that has/holds patient, carer or staff information on hard drives, memory cards, flash drives or PCB main boards and/or any other electronic database MUST be processed correctly using the Appendix F Disposal of Medical Equipment Flow Chart 1 or 2 PRIOR to it leaving the Trust.

For advice contact CE or the Medical Equipment Manager for advice/guidance.

Appendix A- Medical Equipment Disposal notification form

MEDICAL EQUIPMENT DISPOSAL NOTICE

Date:

From: CLINICAL ENGINEERING DEPARTMENT

To: WARD/DEPT MANAGER

Copies to: FINANCE

Disposal Note No:

Job No:

Asset No:

Equipment Description:

Make:

Model:

Serial No

Acceptance Date:

Reason for disposal:

Replacement details for CAPITAL PROJECTS ONLY

Equipment Description:

Make:

Model:

Asset No (if known):

Capital Asset No (finance to advice):

BC No:

Disposal Authorisation

Position: MEDICAL EQUIPMENT LIBRARY MANAGER / MEDICAL EQUIPMENT MANAGER

Date:

Name and Signature:

Appendix B- MIA CALL-OFF AGREEMENT

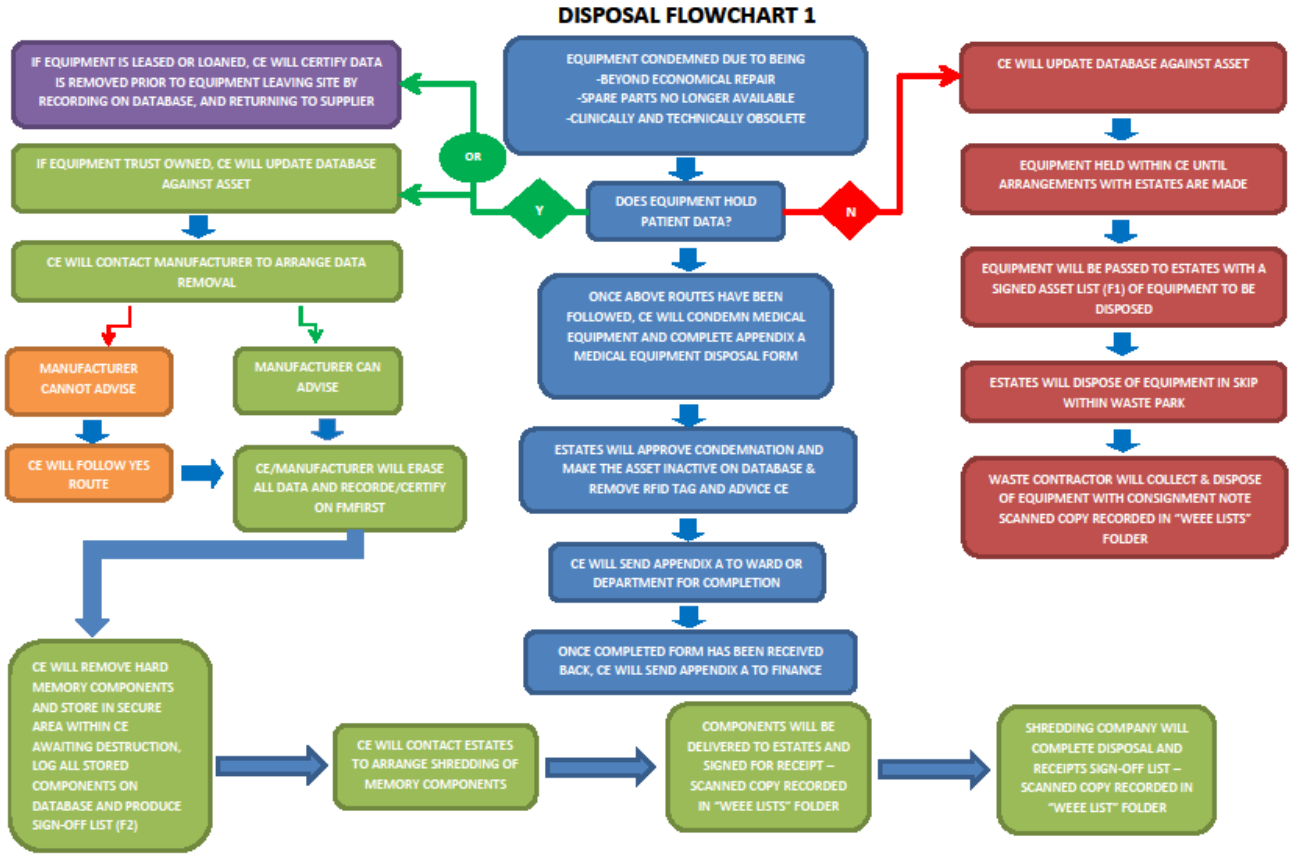
MIA Call-Off Agreement

Note: An Authority should not enter into an MIA Call-Off Agreement unless there is a current Overarching Master Indemnity Agreement with current insurance in place, as evidenced by the fact that the Supplier is on Master Indemnity Agreement Register with current insurance that can be viewed at https://www.supplychain.nhs.uk/mia

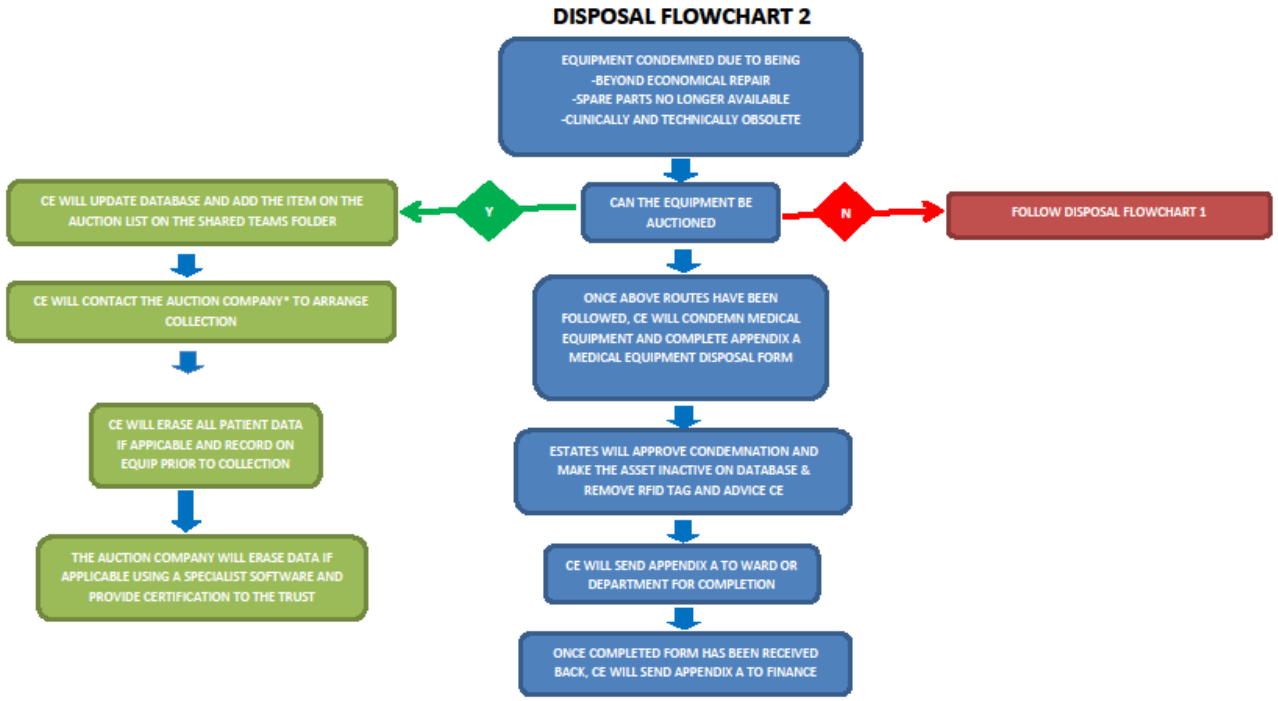
This form is intended for use as a template only and should be **printed on the Authority's letterhead**. The document should not be altered in any other way, except for editing the input boxes in the right-hand columns of the form.

1	Supplier name	
2	Supplier address (including post code)	
3	Contact name	
4	Contact email	
5	Telephone number	
6	Company registration number	
7	Is there an Overarching Master Indemnity Agreement in place with current insurance? If yes, state "Yes" and insert the MIA number here. If not, state "No":	
8	Delivery date	(of the Equipment to the Authority)
9	Authority	
10	Authority address (including post code)	
11	Authority contact name	
12	Authority contact email	
13	Authority telephone number	
14	Type of Equipment and its purpose	
15	Model and make	
16	Serial numbers	
17	Value	
18	Personal Data and Data Subjects	Will the MIA Call-Off Agreement involve the Processing of Personal Data? [Please enter "yes" or "no" as appropriate]

Appendix C – Disposal of Medical Equipment Flowchart 1



Appendix C- Disposal of Medical Equipment Flowchart 2



Appendix D –
Form of Indemnity Agreement for The Donation of Equipment

This Indemnity made the day of 201

Between

Milton Keynes University Hospital NHS Foundation Trust (the Trust)

And (the Recipient)

Whereas

It is the wish to the Trust to donate to the Recipient the equipment (the equipment) identified in Schedule A attached hereto (this schedule to identify the equipment instruction books, maintenance manuals, log books and other relevant information being provided).

It is the wish of the Recipient to receive the equipment hereto for the purposes of

NOW IT IS HEREBY AGREED THAT

1.0 No warranty or liability, express or implied including but not limited to fitness for purpose, safety of the equipment in either use or condition, or suitability shall arise on the part of the Trust either directly or indirectly from the donation of the equipment to the Recipient who shall assume full responsibility and liability for the equipment from the moment of donation.

2.0 In consideration for such donation by the Trust, the Recipient indemnifies and holds harmless the Trust its employees and agents against all claims and proceedings arising from the donation of the equipment (to include any settlements or ex-gratia payments and reasonable legal and expert costs and expenses) made or brought (whether successful or otherwise) against the Trust, its employees or agents.

3.0 The Trust shall keep the recipient fully informed of the progress of any such claim or proceeding and will consult fully with the recipient on the nature of any defence to be advanced and will not settle any such claim or proceeding without first discussing the proposed settlement with the recipient.

4.0 The Recipient further undertakes to use the equipment strictly in accordance with any manufacturer's instructions and will ensure the equipment is regularly checked and maintained as appropriate.

5.0 This indemnity agreement shall be governed by and construed in accordance with English Law.

Signed by the Parties hereto

On behalf of the Trust

Signed: ……

Name: …… Date: ……

On behalf of the Recipient

Signed: ……

Name: …… Date: ……

MKUH-PC-05: MEDICAL EQUIPMENT LIBRARY PROCEDURE (Appendix 5)

1.0 Background

In the past many hours were spent locating essential medical equipment, which, when found, was often unfamiliar, incomplete, not functioning or contaminated. To overcome this shortfall of the supply of essential medical equipment to the hospital, a 'Medical Equipment Library' service has been established. The library provides a speedy, accurate and efficient loan system. The purpose of the library is to ensure that there is a 'free flow' of medical equipment within the Trust. The equipment library will also locate medical equipment when required using the RFiD DISCOVERY Database.
The equipment loan system brings a number of other benefits, these include:
Core equipment standardised and used to their maximum potential
Equipment is speedily, easily and accurately locatable
Departments have access to a variety of commonly used equipment
All items are decontaminated after every use, reducing the risks of cross infection
Equipment is regularly serviced and well maintained
Equipment shortfalls are identified and purchases can be advised

2.0 Duties and Responsibilities

2.1 Medical Equipment Library (MEL)

The medical equipment library will be responsible for supplying 'listed' (see Appendix C – example) medical equipment for wards and departments within Milton Keynes University Hospital. (Each ward department will have a list of medical equipment that the library will have in stock and updated accordingly). The medical equipment library will ensure that all equipment will be clean on arrival to the wards/department, that all equipment is delivered with the required accessories and maintain a comprehensive medical equipment databases so that vital medical equipment can be traced.

The medical equipment library will be responsible for the management of the RFID database – Radio Frequency Identification (RFID). RFID is Radio Frequency Identification technology which allows the equipment library to track medical equipment within the Trust.

Each piece of medical equipment to be tracked is fitted with an active RFID tag (the grey/white tags that are fixed to the side or back of the medical equipment). At pre-set intervals the tag transmits a unique ID, which is registered on a central database. Signals are picked up either by fixed readers or by mobile handheld readers. The wards and departments that do not have fixed readers will be scanned regularly, using handheld readers, by the equipment library technicians and the information uploaded to the central database. The information obtained from the fixed readers is uploaded automatically to the central database throughout the day.

It is the responsibility of the equipment library and the CE department to tag new equipment that arrives in the Trust along with any medical equipment that can hold patient data.

The criteria for tagging is:

As above apart from the following:

All portable equipment that is enclosed in tight casing or can be placed in a docking station

Any equipment under £50 (due to the equipment being less than the price of the RFID tag (unless the patient data holds patient data)

Static and portable X-Ray equipment (unless the equipment holds patient data)

MRI compatible equipment

Therapeutic equipment

Any equipment that goes out to the community (e.g) community midwives, community Neonatal

Any attachments that is part of a main equipment (e.g ultrasound probes, camera heads)

The equipment library technical assistants are employed to carry out deliveries and collections as well as information checking and recording. The responsibilities of the Medical Equipment Library staff include,
Collecting & delivering loan items to and from the clinical areas.
Cleaning loan items.
Performing basic checks and charging batteries.
Storing loan items ready for distribution.
Monitoring loans.
Liaising with the CE engineers, to report faults or log planned maintenance due.

2.2 Ward Managers, Ward Sisters and Users

The Medical equipment Library relies on the positive contribution and support of all its users at all levels which will contribute to its effectiveness.
Ward Managers, Ward Sisters and Users responsibilities are as follows:
Pre-user checks are carried out and settings are properly adjusted
Patient names will be provided when requesting a loan for specific equipment
Loan items must be returned to the equipment library once the patient no longer requires them
Loan items remain the responsibility of the user department for the period of the loan
Cost of damage as a result of neglect or misuse or replacement of lost items will be charged to user departments
Cleaned loan items to be returned and a decontamination status tag filled in before returned to the equipment library store
Loan items are placed in designated areas for collection
Must inform the library staff when a loan item has been transferred with a patient to another Trust (only applicable to T34 SDs)
Must inform the library staff when a loan item has been transferred to a patient's home (only applicable to T34 SDs)

3.0 Medical Equipment Library Function

The 'normal' opening hours for the equipment library is from 9:00 am to 5:00 pm Monday to Friday. During out of hours and Bank holidays, the wards/department will contact the 'Support Team' services who will deliver the required equipment to the requesting ward/ department.

Equipment held in the Equipment Library includes the following:

Bair Huggers
Bladder Scanners
Cardiac Monitors
Defibrillators
ECG Recorders
Feed Pumps
Injectomat Syringe Drivers
Nebulisers
Portable Suctions
Pulse Oximeters
Slings – Bariatric and Amputee
T34 Syringe Drivers
Volumat Infusion pumps
Wound Pumps

Accessories held in the Equipment Library include the following:

All Spacelabs accessories for the cardiac monitors
All Welch Allyn accessories for the obs machines
All GE accessories for the cardiac monitors
Suction liners
Therapeutic Equipment

3.1 Loan Record Systems

A database is used to record and keep track of loans to individual patients and or ward level.

4.0 Medical Equipment Library Protocol

4.1 Equipment Request

When medical equipment is required, the wards/departments will place a request on CAPMAN (Capacity Management) or telephone the equipment library giving details on the type of equipment needed.

Each piece of equipment will be requested by a particular nurse/designated practitioner for a designated patient.

If the equipment is available, the equipment will be delivered to the requesting ward accompanied with a 'Decontamination Tag' (See Appendix A).

However, if the equipment is not in stock, the library technician will consult the library databases to locate the required equipment and then provide the equipment to the requesting ward/department when it becomes available.

4.2 Equipment Returns

When equipment is no longer required by the patient, the user must clean/decontaminate the equipment as described in this policy.
All returned equipment must be accompanied by either filling out the Decontamination tag which is attached to the equipment from the Equipment Library OR filling out 'Equipment Certificate of Decontamination Status Form (see Appendix A on MKUH-PC-03: MEDICAL EQUIPMENT MAINTENANCE AND CALIBRATION PROCEDURE).
Equipment should be placed in a designated area within the ward/department so it can be collected by the library staff.
No equipment will be collected unless it looks clean and is accompanied by either Decontamination tag which is attached to the equipment from the Equipment Library or by an 'Equipment Certificate of Decontamination Status Form' which has been signed by a member of staff from the returning ward.

If the equipment seems to be in a contaminated condition the equipment will NOT be collected. . Senior managers of that ward/ department will be informed of this, and the equipment shall stay on the ward /department until it is appropriately cleaned. If any device is returned in a 'contaminated' state an incident report will be raised.

Any accessories OR equipment not returned to the Equipment Library or found to be damaged on return will incur a replacement cost to the ward/department to which it was collected from.

4.3 Medical Equipment Library Staff Role

The Medical Equipment Library staff will maintain a database of all equipment contained within the library, which will be continually updated throughout the day.
The library staff will visit the wards/departments to collect any unwanted equipment so that it will be made available to other wards/departments. The first visit will begin at 9.30 am and the second visit will begin at 2:00 pm. It is essential therefore that ward /department staff inform the library as soon as the equipment is no longer required by the patient.

4.4 Out of hours cover

The 'normal' opening hours for the equipment library is from 9:00 am to 4.45 pm Monday to Friday ('Out of Hours' will cover weekends and bank holidays). During out of hours, the wards/department will contact the 'Support Team' services who will deliver the required equipment to the requesting ward/ department.

On request the Support Team will collect the required equipment and deliver it to the requesting ward/department. The Support Team will tear off part B (Appendix A) of the decontamination form and update the location of the receiving ward/department on this form. The Support team members of staff will sign the decontamination form. This form will be left in the Equipment Library for the library staff to update the database.

All returned equipment MUST be placed on the 'Goods In' shelf in the equipment library.

4.5 Equipment not available from the library

If any equipment is not available from the library, the library staff will make a record of:

Equipment required.
Accessories required.
Requesting ward.

The equipment library staff will then consult the databases to locate the requested equipment, and will check with the relevant ward/department(s) whether it can be collected. If the equipment is available for collection and has been decontaminated appropriately, accompanied by a decontamination tag it will then be delivered to the requesting ward. The library database will then be updated accordingly.

If the equipment cannot be made available the requesting ward/department will be informed and the request will be logged until the equipment is available.

4.6 Equipment Leaving the Hospital Site

Temporary or permanent loans to patients

A register of loans out to patients will be held by the EO, (see Appendix B). This will include all electronic, electrical or mechanical equipment. The Department loaning will be held responsible for its safe return.

Equipment may not be loaned, donated or otherwise given to patients/clients that live out of the Trust's area.

Should any equipment be necessary for persons returning to their home stations then pre-discharge arrangements must include contacting the Health Authority local to them to enable the supply of necessary equipment prior to discharge.

The equipment library facility is only for the use of Milton Keynes University Hospital. If a patient requires any equipment to be discharged from the hospital then the equipment should be purchased by the ward/department. This does not apply to the T34 SDs.

If any equipment, due to emergency patient transfers leaves the hospital site/campus then the accompanying nurse /designated practitioner must inform the Medical Equipment Library. The Equipment Library staff will complete the 'Equipment Leaving the Hospital form (Appendix B)' with the assistance of the clinical staff. The form will be kept on each ward and the MEO will inform the Medical Equipment Library as soon as the equipment is returned to the hospital.
All staff must check the 'Service Due Date' label on each piece of equipment and ensure that the equipment is 'in date'. Any equipment that is 'out of date' should not be used, and should be sent to the CE department at the earliest opportunity for servicing.
As per this policy it is the responsibility of the MEO in each ward and department to ensure that all equipment is routinely maintained.

4.6 Transfers to Other Trusts and Local Authority

At times it may be necessary for loan item to be transferred to other Trusts (accompanying a patient) in these circumstances the details of the transfer must be provided using the 'Equipment Leaving the Hospital form (Appendix B)' and must inform the equipment library staff and CE. It is the responsibility of the practitioner to organise for the equipment return. Any equipment not returned, a charge will be incurred to the local authority or the ward/department from which transfer was arranged.

5.0 Other Considerations

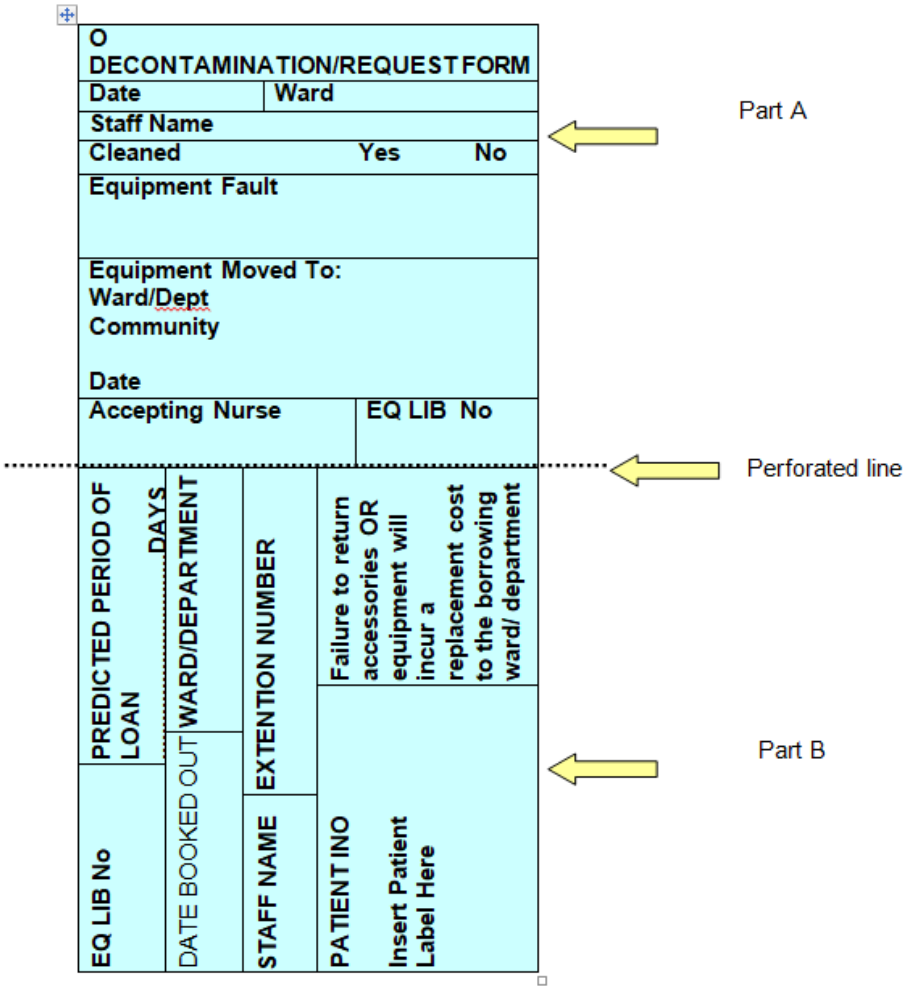
5.1 Consumables

Wards/Departments are responsible for stocking their own consumables, such as, giving sets, syringes, three way taps, etc.

5.2 Accessories

Such as ECG leads, NIBP hoses, cuffs, etc, are supplied with the equipment and are returned with the equipment. Losses and damages are cross charged.

Appendix A: Decontamination Form
Decontamination Tag



Appendix B: Equipment Leaving the Hospital Form
Medical Equipment Leaving the Hospital

Milton Keynes University Hospital NHS
NHS Foundation Trust

Medical Equipment Leaving the Hospital Form

Whether equipment is taken off the premises for loan or transfer purposes a record of equipment leaving the hospital site **must** be recorded. It will be the responsibility of the 'lending' department/ward to ensure that equipment is returned to the hospital, failure to do this may incur a cost to the 'lending' ward/department.

Please return this form and the Lock Box to the Medical Equipment Library on patient discharge LOCK BOX MUST NOT LEAVE THE HOSPITAL

Patient Details			
Date of Loan/Transfer			
Patient Sticker			
Staff Details			
Name of Staff Lending the Equipment.			
Signature of Lending Staff			
Department			
Contact Number			
Equipment Details			
Type of Equipment			
Asset Number			
Make/Model/Serial Number			
Accessories			
Service Due date.			
Loan Details			
Period of Loan			
Destination of Equipment		Home/ Hospice/Other	
Address of Equipment Destination			
EQUIPMENT LIBRARY USE ONLY			
Lock Box Returned	YES/NO	Signature of Library Staff	
Date T34 returned to Eq Library		Signature of Library Staff	

Please return this form to the Medical Equipment Library

Appendix C- Equipment List

EQUIPMENT AVAILABLE FROM THE EQUIPMENT LIBRARY AND WHAT TO ASK FOR WHEN PLACING YOUR REQUEST

VOLUMAT INFUSION PUMP

INJECTOMAT SYRINGE DRIVER

FREEGO FEED PUMP

LAERDAL PORTABLE SUCTION UNIT

Appendix D: Equipment Request/Return Guideline

Equipment Request/Return Guideline

Request

Call X8[illegible]9[illegible]

loaned to the patient, **NOT** the ward

State where equipment is going to. Equipment library staff will deliver the equipment to the requested area and keep a record of it (Decontamination form Part B)

Equipment delivered and in use

Returning equipment

Decontamination

DECONTAMINATION FORM

Date	Ward
Name	
Cleaned	Yes / No
Equipment Fault	
Equipment Movement to	
Ward	
Date	
Accepting Nurse	

The decontamination form (Part B) is to be filled in before the equipment is returned to the equipment library.

Returned cleaned equipment